Dossier zur Nutzenbewertung gemäß § 35a SGB V

Sotorasib (LUMYKRAS®)

Amgen GmbH

Anhang 4-G

Datenschnitt vom 02.08.2022
Data Snapshot: 23.08.2022
zur Studienpopulation

Stand: 01.02.2023

Inhaltsverzeichnis

Seite

1 Mortalität

1.1 Subgruppenanalysen zum Gesamtüberleben

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Overall survival									
Overall	94/174 (54.0)	11.30 (9.00, 14.85)	16.33 (16.07, 17.08)	109/171 (63.7)	10.64 (8.94, 13.96)	17.71 (16.95, 19.15)		1.010 (0.766, 1.331)	0.94
Age - at baseline (years)							0.93		
< 65	57/95 (60.0)	10.87 (6.54, 14.78)	16.66 (16.10, 18.30)	60/91 (65.9)	9.30 (7.39, 12.65)	17.87 (16.79, 19.38)		1.010 (0.706, 1.446)	0.96
≥ 65	37/79 (46.8)	11.93 (9.00, NE)	16.13 (15.64, 16.79)	49/80 (61.3)	12.85 (9.33, 17.58)	17.48 (16.36, 20.01)		1.087 (0.686, 1.723)	0.73

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Sex							0.90		
Male	56/95 (58.9)	11.24 (8.57, 14.82)	16.30 (15.93, 16.79)	68/109 (62.4)	9.63 (7.98, 16.20)	17.31 (16.56, 18.83)		1.007 (0.716, 1.416)	0.97
Female	38/79 (48.1)	12.55 (6.14, NE)	16.36 (15.90, 18.43)	41/62 (66.1)	10.74 (8.08, 15.80)	20.04 (16.79, 21.39)		1.023 (0.642, 1.629)	0.92

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Race category 2							0.78		
Asian	8/22 (36.4)	NE (5.59, NE)	16.16 (9.20, 18.86)	11/21 (52.4)	14.65 (7.52, NE)	18.83 (15.47, 20.50)		0.979 (0.378, 2.535)	0.97
Non-Asian	85/151 (56.3)	11.24 (7.52, 14.82)	16.36 (16.07, 17.18)	97/149 (65.1)	10.64 (8.54, 13.27)	17.71 (16.95, 19.15)		1.027 (0.769, 1.371)	0.86

Page 3 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Region category 1							0.91		
North America	14/22 (63.6)	10.78 (5.59, NE)	16.13 (11.83, 22.11)	12/20 (60.0)	10.05 (4.17, NE)	20.50 (15.70, 21.68)		0.790 (0.356, 1.753)	0.60
Europe	70/126 (55.6)	11.24 (7.29, 14.85)	16.36 (16.07, 17.08)	83/126 (65.9)	10.22 (7.98, 13.27)	17.77 (16.95, 19.15)		1.048 (0.762, 1.441)	0.78
Rest of world	10/26 (38.5)	NE (4.47, NE)	16.16 (10.09, 17.84)	14/25 (56.0)	14.65 (7.52, NE)	16.62 (15.47, 19.38)		0.937 (0.409, 2.148)	0.89

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Region category 2							0.79		
North America and Europe	84/148 (56.8)	11.10 (7.98, 14.78)	16.36 (16.07, 17.18)	95/146 (65.1)	10.22 (8.54, 13.27)	17.77 (16.95, 19.35)		1.034 (0.769, 1.390)	0.83
Rest of world	10/26 (38.5)	NE (4.47, NE)	16.16 (10.09, 17.84)	14/25 (56.0)	14.65 (7.52, NE)	16.62 (15.47, 19.38)		0.937 (0.409, 2.148)	0.89

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Baseline ECOG status (screening)							0.65		
0	25/59 (42.4)	18.17 (11.89, NE)	16.16 (15.70, 16.79)	28/59 (47.5)	18.66 (11.70, NE)	17.87 (16.99, 19.15)		0.900 (0.536, 1.511)	0.71
1	69/115 (60.0)	8.57 (5.42, 11.30)	16.39 (16.10, 18.43)	81/112 (72.3)	8.54 (6.67, 9.63)	17.31 (16.56, 19.38)		1.035 (0.752, 1.426)	0.84

Page 6 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Number of prior lines of therapy in advanced disease							0.99		
1	46/78 (59.0)	11.24 (7.03, 14.78)	16.13 (15.64, 16.66)	50/77 (64.9)	9.30 (6.57, 11.20)	17.77 (16.53, 19.15)		1.050 (0.706, 1.563)	0.81
2	34/69 (49.3)	15.31 (8.84, NE)	17.08 (16.16, 17.84)	38/65 (58.5)	13.08 (8.54, NE)	17.71 (16.62, 20.01)		0.981 (0.623, 1.545)	0.93
> 2	14/27 (51.9)	7.26 (3.48, NE)	16.07 (11.07, 17.77)	21/29 (72.4)	12.65 (7.89, 16.46)	19.38 (15.47, NE)		0.938 (0.462, 1.907)	0.86

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
History of CNS involvement							0.54		
Yes	36/60 (60.0)	8.84 (4.53, 11.93)	16.07 (15.47, 17.77)	42/58 (72.4)	10.74 (7.89, 13.96)	19.15 (16.62, 20.07)		0.888 (0.566, 1.392)	0.61
No	58/114 (50.9)	14.78 (9.92, 18.30)	16.36 (16.13, 17.74)	67/113 (59.3)	10.64 (8.54, 17.58)	17.48 (16.56, 18.46)		1.080 (0.761, 1.532)	0.67

Page 8 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Liver metastasis							0.82		
Yes	22/35 (62.9)	3.94 (2.53, 7.03)	17.77 (11.07, 18.46)	26/30 (86.7)	6.18 (4.47, 8.54)	17.31 (16.53, NE)		0.600 (0.329, 1.096)	0.14
No	72/139 (51.8)	12.55 (10.87, 16.23)	16.30 (15.93, 17.08)	83/141 (58.9)	12.85 (9.66, 17.54)	17.77 (16.79, 19.15)		0.985 (0.717, 1.352)	0.93

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Bone metastasis at baseline							0.85		
Yes	41/69 (59.4)	9.56 (4.47, 16.16)	17.18 (16.16, 18.40)	57/81 (70.4)	7.98 (6.18, 10.22)	17.87 (16.33, 20.01)		1.013 (0.682, 1.503)	0.95
No	53/105 (50.5)	11.93 (9.92, 16.23)	16.13 (15.67, 16.66)	52/90 (57.8)	13.27 (9.66, 17.77)	17.71 (16.79, 18.89)		0.912 (0.612, 1.359)	0.65

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

Table 14-4.2.500. Summary of Overall Survival
(Full Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
PD-L1 protein expression							0.11		
< 1%	22/55 (40.0)	18.30 (9.00, NE)	16.10 (15.47, 17.18)	39/57 (68.4)	9.36 (5.98, 17.58)	18.40 (16.79, 21.39)		1.631 (0.964, 2.759)	0.076
≥ 1% and < 50%	45/70 (64.3)	7.98 (4.47, 11.30)	17.08 (15.70, 18.20)	29/46 (63.0)	10.74 (6.34, 16.20)	17.31 (16.00, 18.83)		0.801 (0.500, 1.285)	0.38
≥ 50%	20/40 (50.0)	12.55 (6.14, NE)	16.36 (16.03, 19.15)	35/60 (58.3)	10.64 (7.46, 17.74)	18.89 (16.56, 20.01)		0.996 (0.561, 1.769)	0.99

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-002-500-eff-os-sub.rtf (Date Generated: 29SEP22:20:43:24) Source: a009pa.adtte, adam.adsl

2 Morbidität

2.1 Progressionsfreies Überleben

2.1.1 Subgruppenanalysen zum progressionsfreien Überleben

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Progression-free survival									
Overall	101/174 (58.0)	4.47 (3.02, 5.68)	6.87 (5.42, 12.52)	122/171 (71.3)	5.62 (4.27, 7.75)	15.24 (14.85, 17.31)		0.663 (0.509, 0.864)	0.003
Age - at baseline (years)							0.95		
< 65	60/95 (63.2)	3.06 (2.73, 5.39)	6.80 (5.42, 17.28)	66/91 (72.5)	4.40 (3.61, 8.34)	15.21 (13.14, 21.29)		0.675 (0.476, 0.957)	0.042
≥ 65	41/79 (51.9)	5.55 (3.52, 6.97)	6.93 (4.17, 13.34)	56/80 (70.0)	5.85 (4.37, 8.57)	15.24 (15.21, 17.38)		0.636 (0.410, 0.988)	0.058

Page 1 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Sex							0.74		
Male	59/95 (62.1)	4.47 (3.02, 5.85)	6.97 (4.24, NE)	77/109 (70.6)	5.68 (4.27, 8.38)	15.21 (13.14, 15.41)		0.560 (0.392, 0.801)	0.003
Female	42/79 (53.2)	4.21 (2.30, 6.97)	6.80 (5.42, 13.34)	45/62 (72.6)	4.60 (4.01, 8.34)	19.19 (11.10, NE)		0.694 (0.446, 1.081)	0.11

Page 2 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Race category 2							0.53		
Asian	13/22 (59.1)	5.55 (1.51, 7.16)	6.93 (4.21, NE)	12/21 (57.1)	8.34 (2.76, 11.07)	15.24 (2.76, NE)		0.332 (0.137, 0.804)	0.023
Non-Asian	87/151 (57.6)	4.21 (3.02, 5.75)	6.80 (4.47, 13.34)	109/149 (73.2)	5.59 (4.24, 7.75)	15.31 (14.78, 17.31)		0.714 (0.540, 0.945)	0.022

Page 3 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Region category 1							0.38		
North America	14/22 (63.6)	6.77 (2.63, 9.72)	13.34 (2.86, NE)	13/20 (65.0)	5.85 (2.76, 13.21)	19.19 (5.82, NE)		0.485 (0.208, 1.134)	0.12
Europe	73/126 (57.9)	3.98 (2.79, 5.68)	5.65 (4.47, 12.52)	94/126 (74.6)	5.59 (4.27, 7.75)	15.31 (13.14, 17.31)		0.675 (0.497, 0.916)	0.015
Rest of world	14/26 (53.8)	5.55 (1.54, 7.16)	6.74 (2.86, NE)	15/25 (60.0)	5.68 (2.76, 11.07)	15.21 (3.02, NE)		0.468 (0.201, 1.090)	0.11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Region category 2							0.20		
North America and Europe	87/148 (58.8)	4.21 (2.86, 5.75)	6.87 (5.42, 13.34)	107/146 (73.3)	5.59 (4.27, 7.75)	15.31 (14.78, 17.31)		0.721 (0.543, 0.957)	0.029
Rest of world	14/26 (53.8)	5.55 (1.54, 7.16)	6.74 (2.86, NE)	15/25 (60.0)	5.68 (2.76, 11.07)	15.21 (3.02, NE)		0.468 (0.201, 1.090)	0.11

Page 5 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Baseline ECOG status (screening)							0.65		
0	31/59 (52.5)	6.74 (4.47, 7.49)	6.97 (5.62, 15.15)	39/59 (66.1)	8.44 (5.72, 11.24)	15.41 (14.78, 21.29)		0.633 (0.382, 1.049)	0.086
1	70/115 (60.9)	2.79 (1.94, 5.39)	5.59 (4.17, 13.34)	83/112 (74.1)	4.37 (3.94, 5.68)	15.21 (13.04, 17.31)		0.606 (0.439, 0.837)	0.004

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Number of prior lines of therapy in advanced disease							0.78		
1	46/78 (59.0)	4.21 (2.73, 5.55)	9.79 (4.21, 13.34)	52/77 (67.5)	4.17 (3.12, 8.38)	15.31 (9.86, 17.38)		0.695 (0.466, 1.036)	0.081
2	40/69 (58.0)	4.83 (2.83, 7.00)	6.80 (4.44, NE)	46/65 (70.8)	5.72 (4.47, 9.53)	15.24 (14.78, 19.19)		0.608 (0.399, 0.924)	0.027
> 2	15/27 (55.6)	4.01 (1.45, 8.97)	5.49 (2.89, NE)	24/29 (82.8)	4.70 (4.07, 8.57)	NE (11.10, NE)		0.740 (0.374, 1.463)	0.38

Page 7 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events[a] /Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI)[b] (Months)	Docetaxel 75 mg/m^2 Q3W Follow-up Time (Months)[c] Median (95% CI)[b]	AMG 510 960 mg QD Events[a] /Subjects (%)	AMG 510 960 mg QD Median (95% CI)[b] (Months)	AMG 510 960 mg QD Follow-up Time (Months)[c] Median (95% CI)[b]	p-value[d] Interaction With Treatment	Hazard Ratio (AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
History of CNS involvement							0.30		
Yes	40/60 (66.7)	2.86 (1.61, 4.50)	9.79 (4.21, NE)	45/58 (77.6)	4.40 (3.94, 8.38)	17.31 (15.21, NE)		0.530 (0.342, 0.821)	0.006
No	61/114 (53.5)	5.68 (3.94, 7.16)	6.74 (4.47, 12.52)	77/113 (68.1)	5.72 (4.34, 8.34)	15.24 (13.04, 17.31)		0.735 (0.528, 1.025)	0.081

Page 8 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Liver metastasis							0.47		
Yes	23/35 (65.7)	1.94 (1.45, 3.02)	6.93 (2.89, NE)	25/30 (83.3)	4.17 (2.66, 6.24)	15.21 (5.82, NE)		0.471 (0.260, 0.853)	0.034
No	78/139 (56.1)	5.55 (4.01, 7.00)	6.87 (4.86, 12.52)	97/141 (68.8)	5.85 (4.37, 8.44)	15.24 (14.78, 17.31)		0.667 (0.493, 0.902)	0.011

Page 9 of 11

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
Bone metastasis at baseline							0.83		
Yes	43/69 (62.3)	3.02 (2.07, 4.50)	5.62 (4.21, NE)	64/81 (79.0)	4.21 (2.99, 5.39)	15.41 (15.21, NE)		0.637 (0.436, 0.931)	0.035
No	58/105 (55.2)	5.55 (3.98, 7.00)	6.80 (4.44, 15.15)	58/90 (64.4)	8.31 (5.62, 9.76)	15.24 (13.04, 17.31)		0.589 (0.399, 0.868)	0.009

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

Table 14-4.1.500. Summary of Progression-Free Survival as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W			AMG 510 960 mg QD			p-value[d]	Hazard Ratio	
	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Events[a] /Subjects (%)	Median (95% CI)[b] (Months)	Follow-up Time (Months)[c] Median (95% CI)[b]	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[e]
PD-L1 protein expression							0.95		
< 1%	32/55 (58.2)	5.85 (3.52, 7.16)	9.79 (4.24, NE)	41/57 (71.9)	8.31 (4.07, 8.57)	15.21 (9.86, NE)		0.657 (0.405, 1.064)	0.12
≥ 1% and < 50%	38/70 (54.3)	3.02 (2.07, 4.47)	4.86 (2.86, 6.74)	36/46 (78.3)	4.60 (3.42, 7.75)	17.31 (13.14, NE)		0.606 (0.385, 0.956)	0.054
≥ 50%	25/40 (62.5)	5.36 (1.97, 10.18)	12.52 (5.65, 15.15)	39/60 (65.0)	5.68 (3.98, 9.99)	15.31 (13.04, 17.31)		0.736 (0.440, 1.230)	0.27

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] Median follow-up time was estimated using the reverse Kaplan-Meier method (Schemper and Smith, 1996).
[d] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[e] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-pfs-os-sub.sas
Output: t14-04-001-500-eff-pfs-sub.rtf (Date Generated: 29SEP22:20:43:17) Source: a009pa.adtte, adam.adsl

2.2 Ansprechen

2.2.1 Subgruppenanalysen zum Gesamtansprechen

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Overall	23/174 (13.2) (8.6, 19.2)	48/171 (28.1) (21.5, 35.4)		14.8 (6.4, 23.1)	2.600 (1.483, 4.557)	2.125 (1.352, 3.340)	< 0.001
Age - at baseline (years)			0.69				
< 65	13/95 (13.7) (7.5, 22.3)	23/91 (25.3) (16.7, 35.5)		12.8 (1.5, 24.1)	2.379 (1.088, 5.203)	1.977 (1.060, 3.688)	0.031
≥ 65	10/79 (12.7) (6.2, 22.0)	25/80 (31.3) (21.3, 42.6)		17.1 (4.3, 29.9)	2.999 (1.251, 7.189)	2.427 (1.139, 5.170)	0.012

Page 1 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Sex			0.66				
Male	11/95 (11.6) (5.9, 19.8)	31/109 (28.4) (20.2, 37.9)		15.8 (5.2, 26.5)	2.918 (1.337, 6.366)	2.332 (1.240, 4.385)	0.005
Female	12/79 (15.2) (8.1, 25.0)	17/62 (27.4) (16.9, 40.2)		13.0 (-0.4, 26.4)	2.383 (0.965, 5.882)	1.881 (0.977, 3.622)	0.060

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Race category 2			0.75				
Asian	3/22 (13.6) (2.9, 34.9)	5/21 (23.8) (8.2, 47.2)		9.1 (-15.1, 33.3)	1.782 (0.359, 8.857)	1.670 (0.399, 6.996)	0.47
Non-Asian	20/151 (13.2) (8.3, 19.7)	42/149 (28.2) (21.1, 36.1)		14.9 (6.0, 23.8)	2.635 (1.448, 4.795)	2.123 (1.318, 3.420)	0.001

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Region category 1			0.55				
North America	6/22 (27.3) (10.7, 50.2)	7/20 (35.0) (15.4, 59.2)		19.5 (-10.2, 49.2)	2.536 (0.571, 11.274)	1.748 (0.748, 4.087)	0.21
Europe	14/126 (11.1) (6.2, 17.9)	34/126 (27.0) (19.5, 35.6)		15.7 (6.2, 25.3)	2.958 (1.490, 5.872)	2.377 (1.355, 4.170)	0.001
Rest of world	3/26 (11.5) (2.4, 30.2)	7/25 (28.0) (12.1, 49.4)		23.7 (1.7, 45.7)	6.607 (0.785, 55.601)	4.738 (0.831, 27.031)	0.057

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Region category 2			0.62				
North America and Europe	20/148 (13.5) (8.5, 20.1)	41/146 (28.1) (21.0, 36.1)		14.6 (5.4, 23.8)	2.518 (1.379, 4.597)	2.046 (1.269, 3.297)	0.002
Rest of world	3/26 (11.5) (2.4, 30.2)	7/25 (28.0) (12.1, 49.4)		23.7 (1.7, 45.7)	6.607 (0.785, 55.601)	4.738 (0.831, 27.031)	0.057

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Baseline ECOG status (screening)			0.38				
0	8/59 (13.6) (6.0, 25.0)	20/59 (33.9) (22.1, 47.4)		21.1 (6.8, 35.4)	4.016 (1.443, 11.173)	2.769 (1.268, 6.047)	0.006
1	15/115 (13.0) (7.5, 20.6)	28/112 (25.0) (17.3, 34.1)		11.5 (1.3, 21.7)	2.155 (1.070, 4.340)	1.869 (1.053, 3.317)	0.029

Page 6 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Number of prior lines of therapy in advanced disease			0.75				
1	9/78 (11.5) (5.4, 20.8)	16/77 (20.8) (12.4, 31.5)		9.3 (-2.2, 20.7)	2.021 (0.830, 4.921)	1.804 (0.850, 3.830)	0.12
2	12/69 (17.4) (9.3, 28.4)	26/65 (40.0) (28.0, 52.9)		22.6 (7.6, 37.6)	3.103 (1.393, 6.915)	2.325 (1.262, 4.283)	0.004

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
> 2	2/27 (7.4) (0.9, 24.3)	6/29 (20.7) (8.0, 39.7)		12.9 (-5.0, 30.8)	3.137 (0.578, 17.033)	2.718 (0.581, 12.719)	0.18

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
History of CNS involvement			0.54				
Yes	6/60 (10.0) (3.8, 20.5)	16/58 (27.6) (16.7, 40.9)		17.2 (3.3, 31.0)	3.331 (1.196, 9.275)	2.679 (1.135, 6.324)	0.019
No	17/114 (14.9) (8.9, 22.8)	32/113 (28.3) (20.2, 37.6)		13.3 (2.9, 23.7)	2.302 (1.174, 4.511)	1.907 (1.117, 3.256)	0.014

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Liver metastasis			0.12				
Yes	5/35 (14.3) (4.8, 30.3)	4/30 (13.3) (3.8, 30.7)		4.2 (-13.5, 22.0)	1.497 (0.277, 8.089)	1.476 (0.252, 8.646)	0.66
No	18/139 (12.9) (7.9, 19.7)	44/141 (31.2) (23.7, 39.5)		18.5 (9.0, 28.0)	3.151 (1.686, 5.890)	2.432 (1.479, 3.998)	< 0.001

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Bone metastasis at baseline			0.82				
Yes	9/69 (13.0) (6.1, 23.3)	20/81 (24.7) (15.8, 35.5)		14.7 (2.4, 27.0)	2.812 (1.105, 7.155)	2.272 (1.056, 4.889)	0.027
No	14/105 (13.3) (7.5, 21.4)	28/90 (31.1) (21.8, 41.7)		18.0 (6.4, 29.6)	3.124 (1.482, 6.589)	2.359 (1.320, 4.217)	0.003

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

Table 14-4.4.500. Summary of Objective Response as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
PD-L1 protein expression			0.28				
< 1%	10/55 (18.2) (9.1, 30.9)	16/57 (28.1) (17.0, 41.5)		10.0 (-4.9, 24.8)	1.891 (0.719, 4.978)	1.567 (0.785, 3.130)	0.20
≥ 1% and < 50%	4/70 (5.7) (1.6, 14.0)	12/46 (26.1) (14.3, 41.1)		19.0 (5.1, 33.0)	5.136 (1.479, 17.835)	3.884 (1.384, 10.904)	0.005
≥ 50%	7/40 (17.5) (7.3, 32.8)	18/60 (30.0) (18.8, 43.2)		11.5 (-6.7, 29.7)	1.779 (0.686, 4.619)	1.629 (0.725, 3.660)	0.21

Page 12 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-004-500-eff-orr-sub.rtf (Date Generated: 29SEP22:20:45:05) Source: a009pa.adresp, adam.adsl

2.2.2 Subgruppenanalysen zur Krankheitskontrollrate

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Overall	105/174 (60.3) (52.7, 67.7)	141/171 (82.5) (75.9, 87.8)		21.8 (12.6, 31.0)	3.077 (1.862, 5.085)	1.359 (1.183, 1.561)	< 0.001
Age - at baseline (years)			0.60				
< 65	55/95 (57.9) (47.3, 68.0)	71/91 (78.0) (68.1, 86.0)		21.0 (7.8, 34.1)	2.720 (1.403, 5.271)	1.369 (1.109, 1.690)	0.003
≥ 65	50/79 (63.3) (51.7, 73.9)	70/80 (87.5) (78.2, 93.8)		21.3 (7.6, 34.9)	3.305 (1.462, 7.473)	1.331 (1.089, 1.627)	0.002

Page 1 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Sex			0.11				
Male	63/95 (66.3) (55.9, 75.7)	88/109 (80.7) (72.1, 87.7)		14.5 (2.2, 26.8)	2.095 (1.109, 3.955)	1.222 (1.022, 1.460)	0.019
Female	42/79 (53.2) (41.6, 64.5)	53/62 (85.5) (74.2, 93.1)		31.3 (17.2, 45.3)	5.725 (2.292, 14.302)	1.588 (1.253, 2.014)	< 0.001

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Race category 2			0.064				
Asian	11/22 (50.0) (28.2, 71.8)	20/21 (95.2) (76.2, 99.9)		43.6 (20.5, 66.8)	20.533 (2.321, 181.639)	1.853 (1.199, 2.864)	0.001
Non-Asian	93/151 (61.6) (53.3, 69.4)	120/149 (80.5) (73.3, 86.6)		18.6 (8.7, 28.5)	2.601 (1.529, 4.424)	1.301 (1.123, 1.506)	< 0.001

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Region category 1			0.46				
North America	13/22 (59.1) (36.4, 79.3)	18/20 (90.0) (68.3, 98.8)		31.7 (8.7, 54.6)	13.500 (1.126, 161.885)	1.545 (1.038, 2.299)	0.022
Europe	77/126 (61.1) (52.0, 69.7)	101/126 (80.2) (72.1, 86.7)		18.2 (7.3, 29.1)	2.549 (1.424, 4.562)	1.293 (1.101, 1.518)	0.001
Rest of world	15/26 (57.7) (36.9, 76.6)	22/25 (88.0) (68.8, 97.5)		25.4 (-1.3, 52.2)	3.727 (0.862, 16.118)	1.442 (0.936, 2.219)	0.055

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Region category 2			0.41				
North America and Europe	90/148 (60.8) (52.5, 68.7)	119/146 (81.5) (74.2, 87.4)		18.7 (8.6, 28.7)	2.641 (1.529, 4.565)	1.298 (1.120, 1.505)	< 0.001
Rest of world	15/26 (57.7) (36.9, 76.6)	22/25 (88.0) (68.8, 97.5)		25.4 (-1.3, 52.2)	3.727 (0.862, 16.118)	1.442 (0.936, 2.219)	0.055

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Baseline ECOG status (screening)			0.72				
0	46/59 (78.0) (65.3, 87.7)	53/59 (89.8) (79.2, 96.2)		12.8 (-1.4, 27.0)	2.387 (0.877, 6.495)	1.168 (0.976, 1.396)	0.071
1	59/115 (51.3) (41.8, 60.7)	88/112 (78.6) (69.8, 85.8)		25.9 (13.9, 37.9)	3.295 (1.836, 5.915)	1.501 (1.223, 1.842)	< 0.001

Page 6 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Number of prior lines of therapy in advanced disease			0.21				
1	45/78 (57.7) (46.0, 68.8)	58/77 (75.3) (64.2, 84.4)		17.6 (3.0, 32.3)	2.224 (1.123, 4.404)	1.306 (1.037, 1.644)	0.021
2	45/69 (65.2) (52.8, 76.3)	56/65 (86.2) (75.3, 93.5)		21.0 (7.2, 34.8)	3.505 (1.448, 8.486)	1.323 (1.088, 1.610)	0.004

Page 7 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
> 2	15/27 (55.6) (35.3, 74.5)	27/29 (93.1) (77.2, 99.2)		36.0 (14.4, 57.6)	8.604 (1.876, 39.450)	1.629 (1.142, 2.324)	0.002

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
History of CNS involvement			0.080				
Yes	29/60 (48.3) (35.2, 61.6)	49/58 (84.5) (72.6, 92.7)		35.8 (19.9, 51.7)	5.502 (2.323, 13.034)	1.744 (1.305, 2.331)	< 0.001
No	76/114 (66.7) (57.2, 75.2)	92/113 (81.4) (73.0, 88.1)		14.6 (3.4, 25.7)	2.210 (1.184, 4.126)	1.218 (1.042, 1.423)	0.012

Page 9 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Liver metastasis			0.44				
Yes	14/35 (40.0) (23.9, 57.9)	22/30 (73.3) (54.1, 87.7)		35.4 (9.2, 61.5)	3.874 (1.276, 11.761)	1.909 (1.109, 3.289)	0.015
No	91/139 (65.5) (56.9, 73.3)	119/141 (84.4) (77.3, 90.0)		18.0 (8.0, 28.0)	2.731 (1.530, 4.875)	1.274 (1.106, 1.469)	< 0.001

Page 10 of 12

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
Bone metastasis at baseline			0.93				
Yes	40/69 (58.0) (45.5, 69.8)	64/81 (79.0) (68.5, 87.3)		21.4 (6.7, 36.2)	2.916 (1.360, 6.253)	1.363 (1.088, 1.707)	0.006
No	65/105 (61.9) (51.9, 71.2)	77/90 (85.6) (76.6, 92.1)		20.8 (8.8, 32.9)	3.206 (1.562, 6.581)	1.331 (1.119, 1.582)	0.001

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

Table 14-4.5.500. Summary of Disease Control Rate as Assessed by the Blinded Independent Central Review Committee (Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W	AMG 510 960 mg QD	p-value[c]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
	Events[a] /Subjects (%) (95% CI)[b]	Events[a] /Subjects (%) (95% CI)[b]	Interaction With Treatment	(AMG 510- Docetaxel)	(AMG 510/ Docetaxel)	AMG 510/ Docetaxel)	p-value (2-sided)[d]
PD-L1 protein expression			0.48				
< 1%	37/55 (67.3) (53.3, 79.3)	46/57 (80.7) (68.1, 90.0)		14.7 (-1.9, 31.4)	2.115 (0.895, 5.000)	1.221 (0.970, 1.537)	0.085
≥ 1% and < 50%	38/70 (54.3) (41.9, 66.3)	38/46 (82.6) (68.6, 92.2)		25.3 (9.4, 41.3)	3.880 (1.483, 10.152)	1.450 (1.134, 1.854)	0.004
≥ 50%	23/40 (57.5) (40.9, 73.0)	50/60 (83.3) (71.5, 91.7)		24.3 (4.8, 43.8)	2.942 (1.186, 7.295)	1.423 (1.045, 1.938)	0.012

CI = Confidence Interval.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Events are Confirmed Responder (PR/CR) or Stable Disease (SD).
[b] Exact 95% confidence interval was calculated using the Clopper Pearson method.
[c] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'Overall' and for subgroups.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-orr-dcr.sas
Output: t14-04-005-500-eff-dcr-sub.rtf (Date Generated: 29SEP22:20:45:13) Source: a009pa.adresp, adam.adsl

2.2.3 Subgruppenanalysen zur Dauer des Ansprechens

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events[a] /Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI)[b] (months)	AMG 510 960 mg QD Events[a] /Subjects (%)	AMG 510 960 mg QD Median (95% CI)[b] (months)	p-value[c] Interaction With Treatment	Hazard Ratio (AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Duration of response							
Overall	14/23 (60.9)	6.80 (4.27, 8.28)	27/48 (56.3)	8.64 (7.06, 17.97)		0.422 (0.219, 0.815)	0.022
Age - at baseline (years)					0.83		
< 65	9/13 (69.2)	7.00 (2.79, 9.86)	14/23 (60.9)	8.87 (7.06, 18.04)		0.310 (0.125, 0.770)	0.024
≥ 65	5/10 (50.0)	6.80 (4.21, NE)	13/25 (52.0)	8.64 (4.47, NE)		0.665 (0.236, 1.874)	0.54

Page 1 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Sex					0.60		
Male	8/11 (72.7)	5.68 (2.07, NE)	17/31 (54.8)	8.64 (6.93, NE)		0.278 (0.107, 0.720)	0.018
Female	6/12 (50.0)	7.00 (2.79, NE)	10/17 (58.8)	8.87 (4.21, NE)		0.796 (0.276, 2.294)	0.71

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Race category 2					-		
Asian	1/3 (33.3)	-	3/5 (60.0)	- - -	- -	-	-
Non-Asian	13/20 (65.0)	-	23/42 (54.8)	- - -	- -	-	-

Page 3 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Region category 1					-		
North America	3/6 (50.0)	-	4/7 (57.1)	-		-	-
Europe	10/14 (71.4)	-	20/34 (58.8)	-		-	-
Rest of world	1/3 (33.3)	-	3/7 (42.9)	-		-	-

Page 4 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Region category 2					-		
North America and Europe	13/20 (65.0)	-	24/41 (58.5)	-	-	-	-
Rest of world	1/3 (33.3)	-	3/7 (42.9)	-		-	-
Baseline ECOG status (screening)					-		
0	5/8 (62.5)	-	13/20 (65.0)	-		-	-
1	9/15 (60.0)	5.68 (4.07, 8.28)	14/28 (50.0)	-		-	-

Page 5 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Number of prior lines of therapy in advanced disease					-		
1	6/9 (66.7)	-	7/16 (43.8)	-		-	-
2	8/12 (66.7)	-	15/26 (57.7)	-		-	-
> 2	0/2 (0.0)	-	5/6 (83.3)	-		-	-

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
History of CNS involvement					-		
Yes	4/6 (66.7)	-	12/16 (75.0)	-		-	-
No	10/17 (58.8)	-	15/32 (46.9)	-		-	-
Liver metastasis					-		
Yes	2/5 (40.0)	-	2/4 (50.0)	-		-	-
No	12/18 (66.7)	-	25/44 (56.8)	-		-	-

Page 7 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
Bone metastasis at baseline					-		
Yes	4/9 (44.4)	-	16/20 (80.0)	7.00 (2.89, 8.87)		-	-
No	10/14 (71.4)	-	11/28 (39.3)	18.04 (7.85, NE)		-	-

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

Table 14-4.3.500. Summary of Duration of Response as Assessed by the Blinded Independent Central Review Committee (Responders in Full Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[c]	Hazard Ratio	
Endpoint	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Events[a] /Subjects (%)	Median (95% CI)[b] (months)	Interaction With Treatment	(AMG 510/ Docetaxel) (95% CI)	p-value (2-sided)[d]
PD-L1 protein expression					-		
< 1%	7/10 (70.0)	-	10/16 (62.5)	-	-	-	-
≥ 1% and < 50%	2/4 (50.0)	-	8/12 (66.7)	-	-	-	-
≥ 50%	4/7 (57.1)	-	9/18 (50.0)	-	-	-	-

Page 9 of 9

CI = Confidence Interval; KM = Kaplan-Meier; NE = Not Estimable.
Stratified analysis was conducted overall and for subgroups.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
For subgroup analyses, a stratification factor is not used for the stratified analysis if the stratification factor is the subgroup of interest.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] Duration of response ending events are disease progression and death.
[b] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[c] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[d] 2-sided p-values were calculated using the stratified log-rank test as specified.
Subject(s) with unknown or missing subgroup value are not included.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/t-eff-dor.sas
Output: t14-04-003-500-eff-dor-sub.rtf (Date Generated: 29SEP22:20:44:35) Source: a009pa.adtte, adam.adsl

2.3 Symptomatik

2.3.1 EORTC QLQ-C30

2.3.1.1 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-C30 Fatigue								
160	104 (65,0)	3,0 [2,1; 4,3]	130	105 (80,8)	1,4 [0,8; 1,4]	0,47 [0,35; 0,63]	<,0001	<,0001
QLQ-C30 Übelkeit und Erbrechen								
160	69 (43,1)	9,1 [5,5; 16,6]	130	56 (43,1)	5,6 [3,9; 9,9]	0,76 [0,53; 1,11]	0,1594	0,1583
QLQ-C30 Schmerz								
160	106 (66,2)	2,8 [2,1; 4,2]	130	91 (70,0)	2,1 [1,4; 2,3]	0,77 [0,57; 1,03]	0,0817	0,0809
QLQ-C30 Atemnot								
160	72 (45,0)	8,3 [5,6; 13,7]	130	68 (52,3)	3,5 [2,3; 5,0]	0,64 [0,45; 0,91]	0,0119	0,0113
QLQ-C30 Insomnie								
160	78 (48,8)	5,9 [4,2; 10,4]	130	66 (50,8)	3,7 [3,0; 5,6]	0,79 [0,56; 1,11]	0,1748	0,1739
QLQ-C30 Appetitverlust								
160	84 (52,5)	5,9 [3,5; 9,2]	130	67 (51,5)	3,5 [2,1; 4,2]	0,68 [0,49; 0,96]	0,0288	0,0279
QLQ-C30 Obstipation								
160	63 (39,4)	12,8 [6,2; n.b.]	130	73 (56,2)	2,8 [1,5; 4,9]	0,52 [0,36; 0,74]	0,0003	0,0002
QLQ-C30 Diarrhoe								
160	94 (58,8)	2,7 [2,1; 3,5]	130	64 (49,2)	4,4 [2,1; 9,9]	1,13 [0,81; 1,56]	0,4684	0,4681

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

2.3.1.2 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30

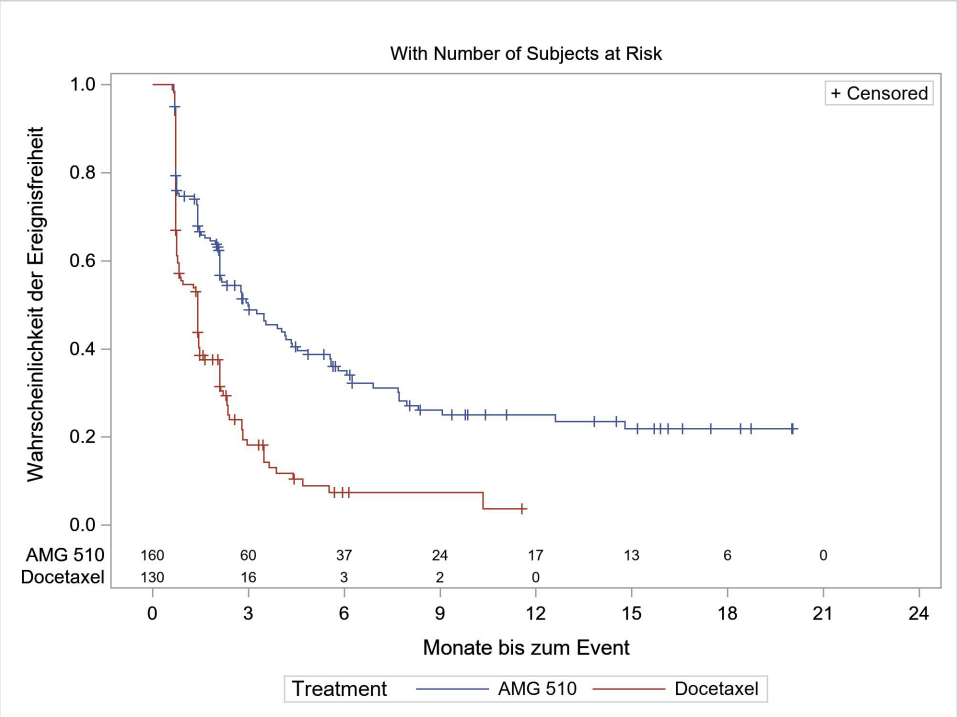

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Fatigue, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

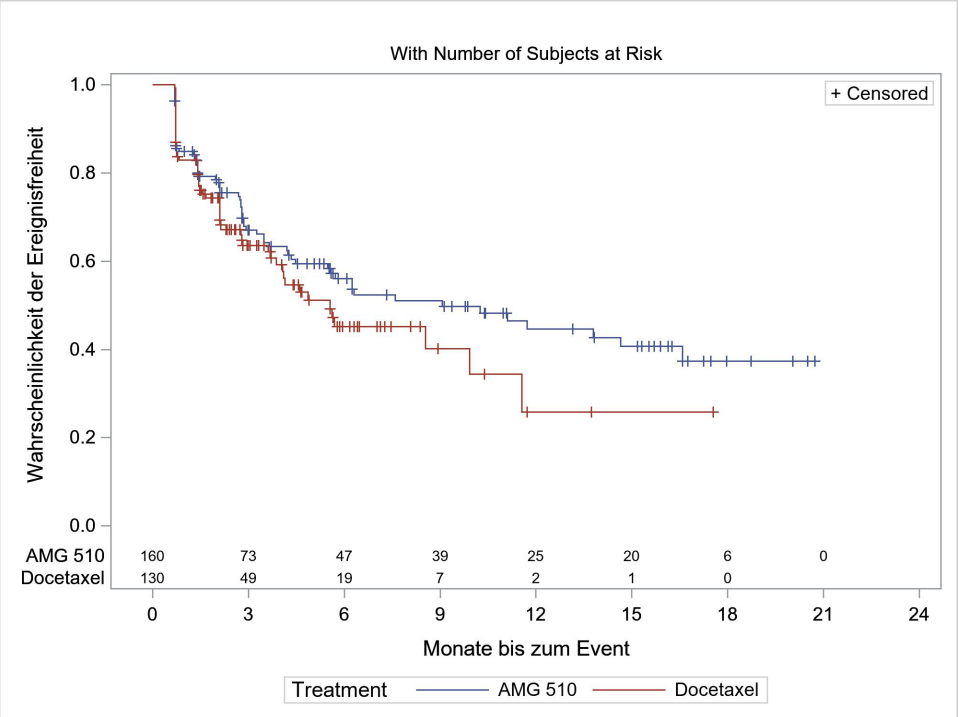

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Übelkeit und Erbrechen, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

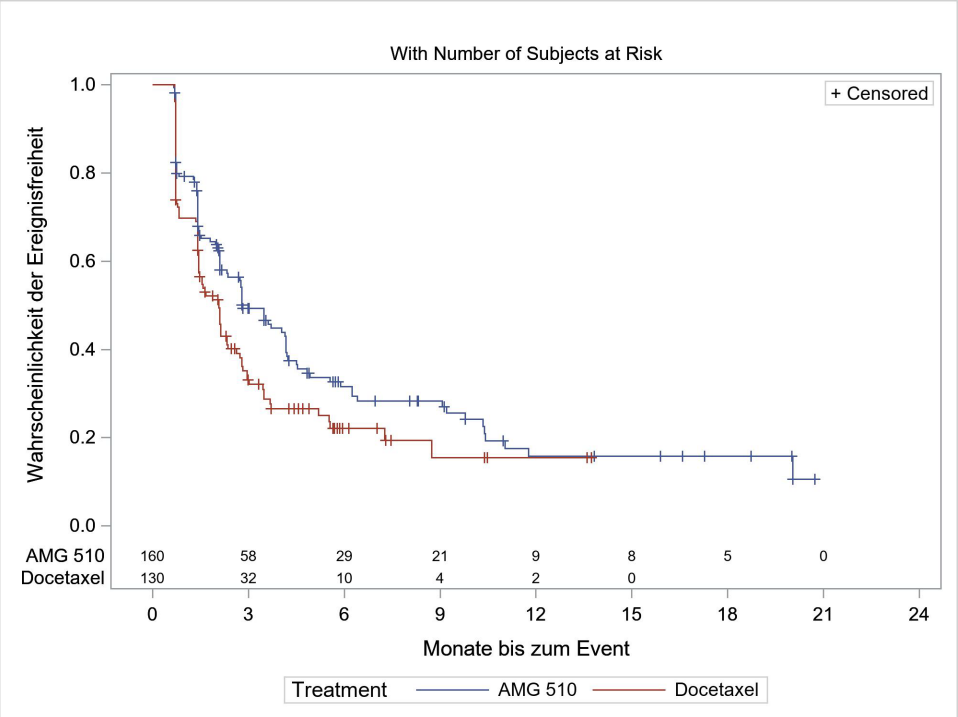

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Schmerz, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

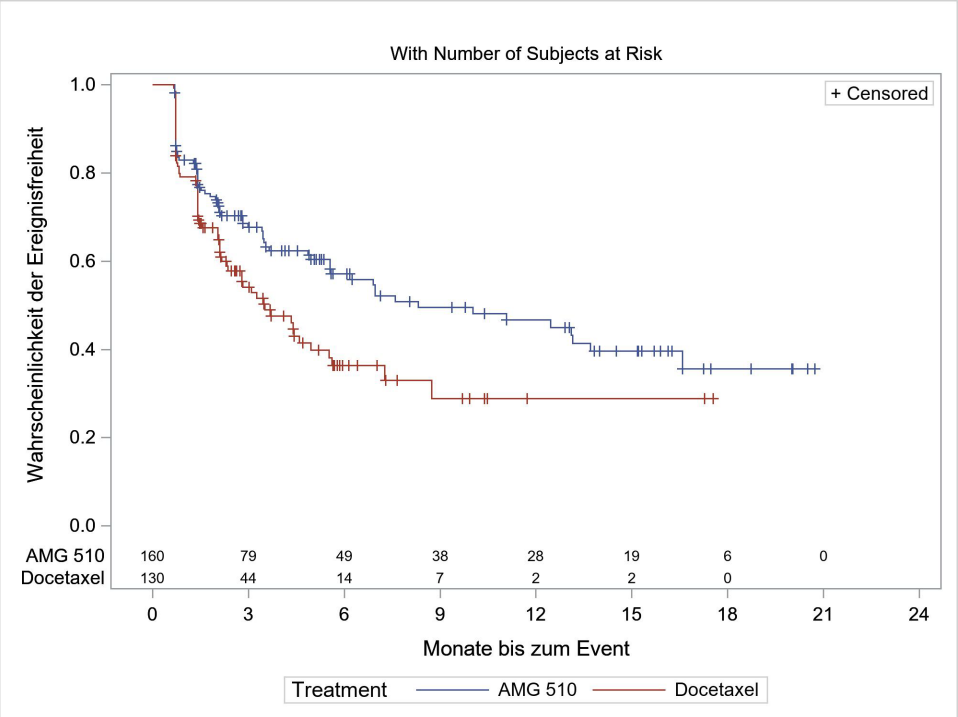

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Atemnot, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

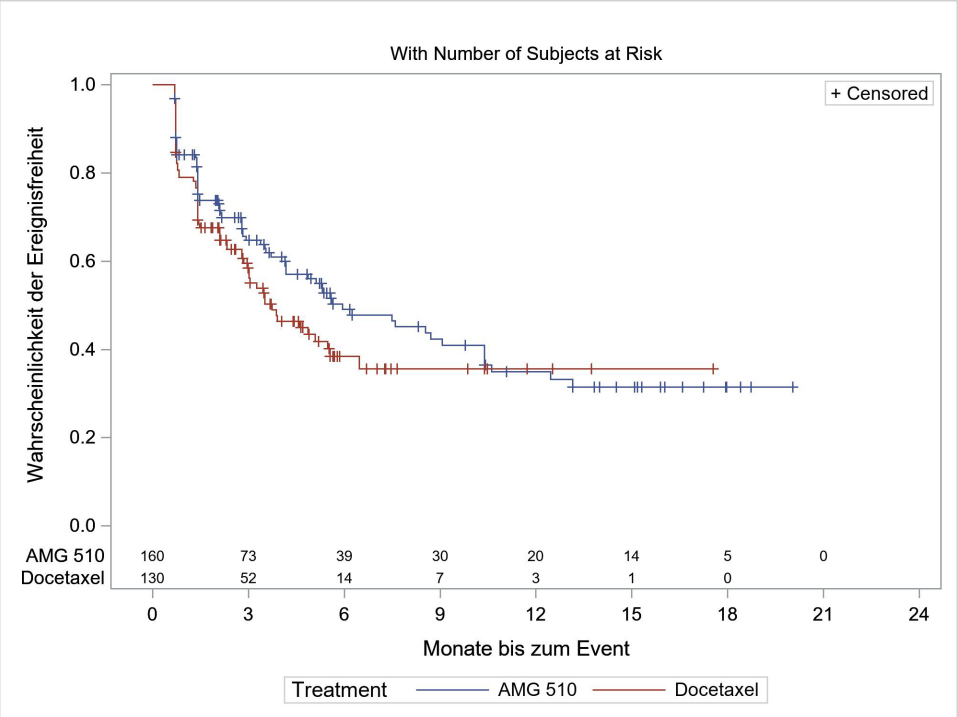

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Insomnie, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

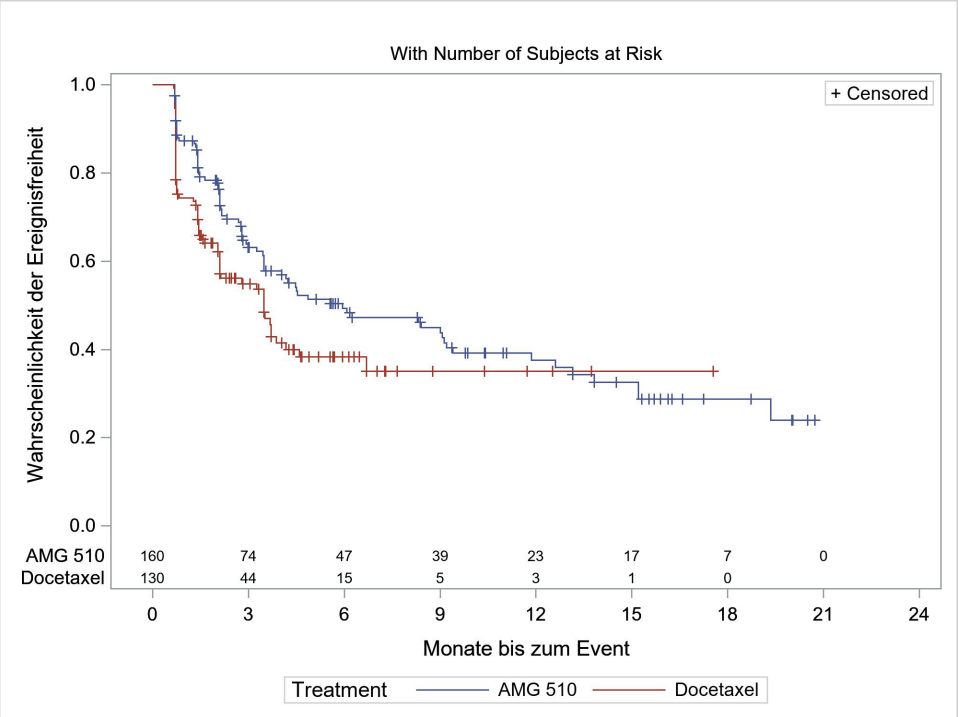

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Appetitverlust, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

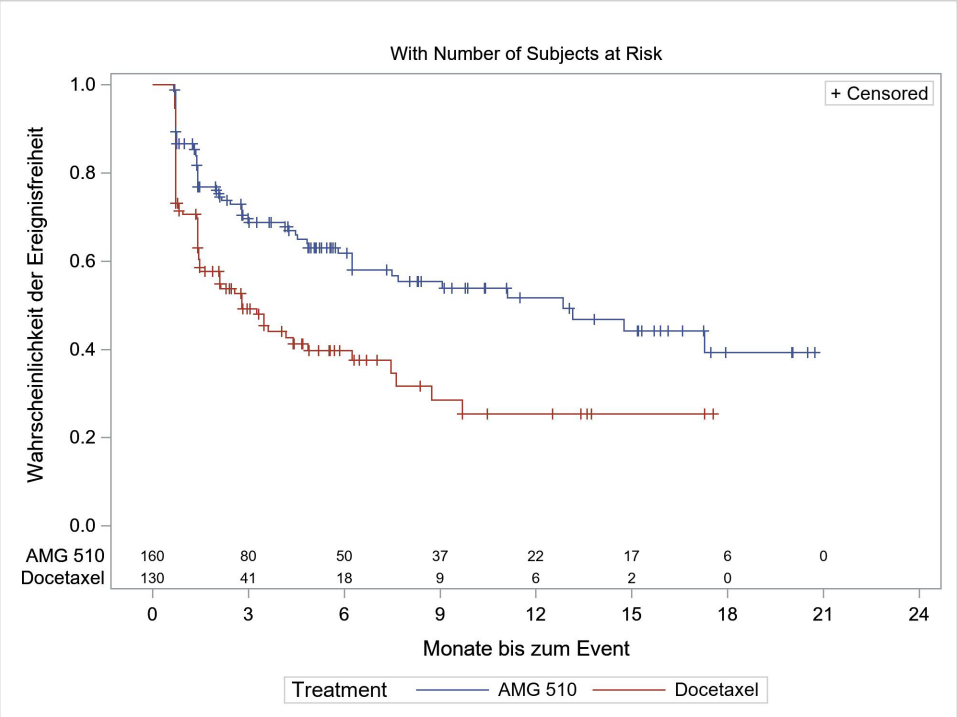

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Obstipation, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

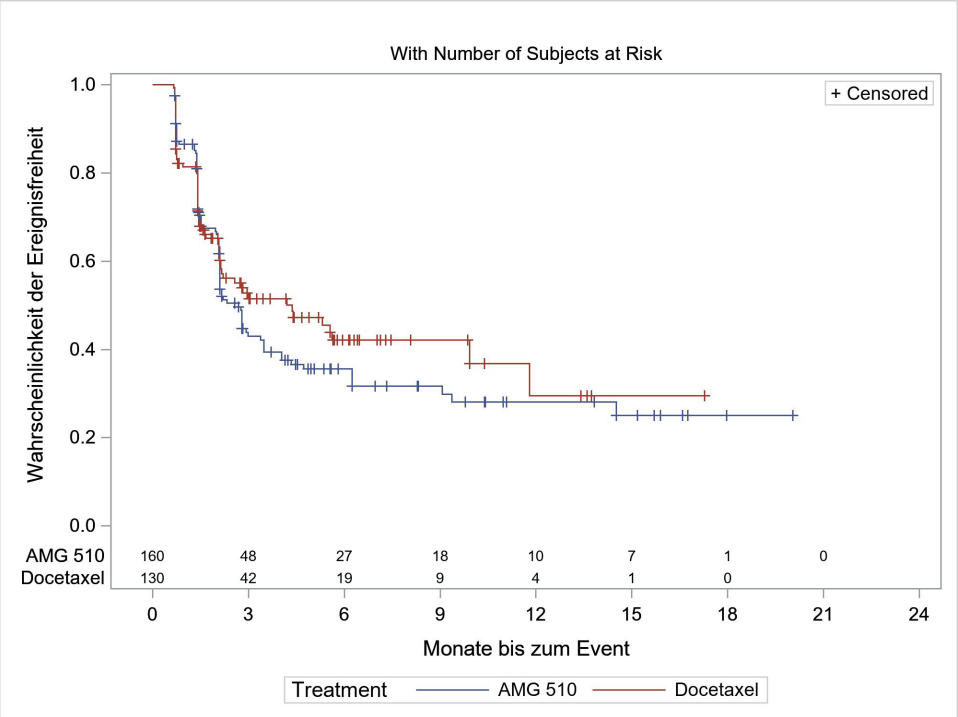

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Diarrhoe, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.1.3 Verlaufskurven für den Endpunkt EORTC QLQ-C30

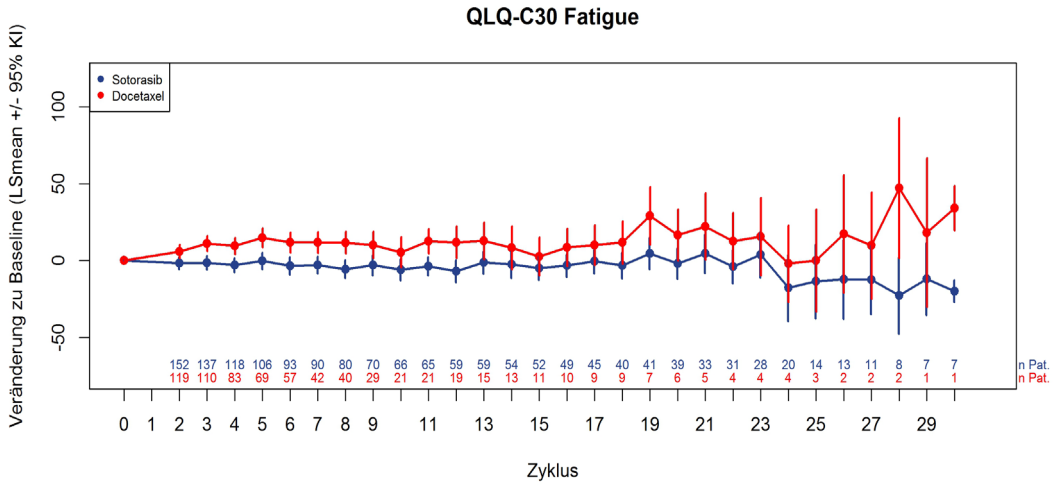

Abbildung 2: Verlaufskurve für den Endpunkt QLQ-C30 Fatigue, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

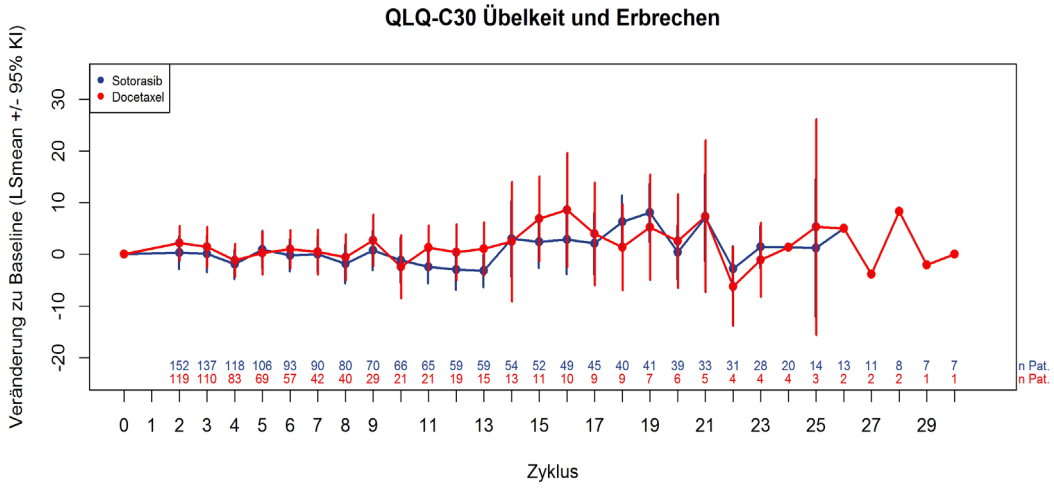

Abbildung 3: Verlaufskurve für den Endpunkt QLQ-C30 Übelkeit und Erbrechen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

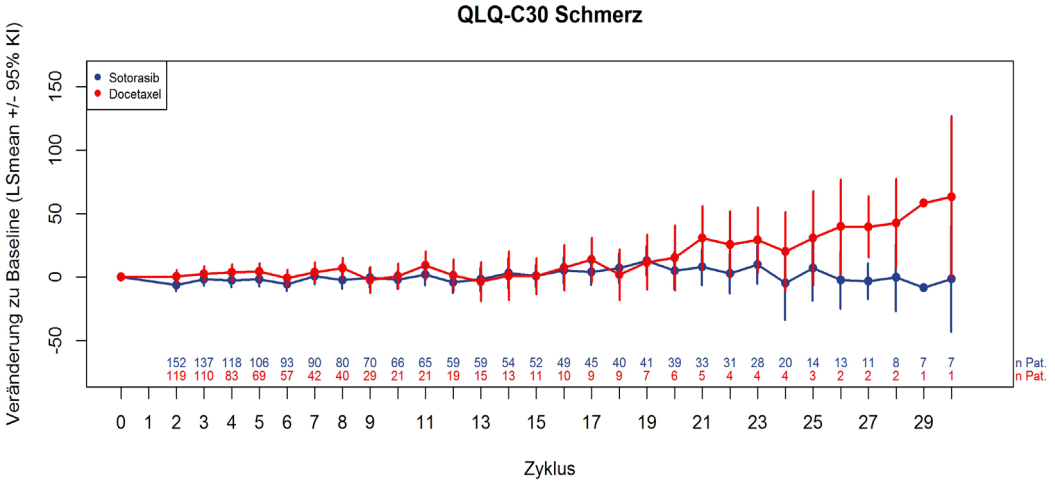

Abbildung 4: Verlaufskurve für den Endpunkt QLQ-C30 Schmerz, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

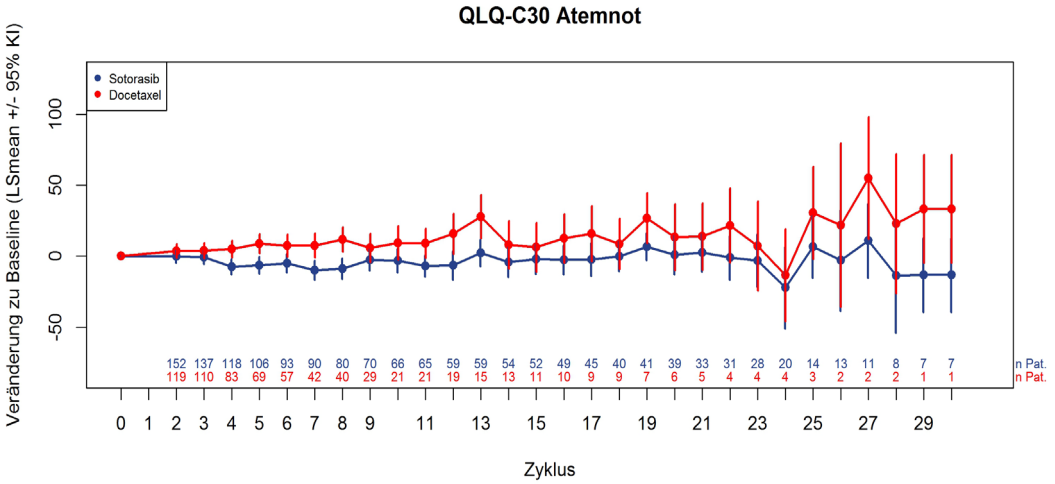

Abbildung 5: Verlaufskurve für den Endpunkt QLQ-C30 Atemnot, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

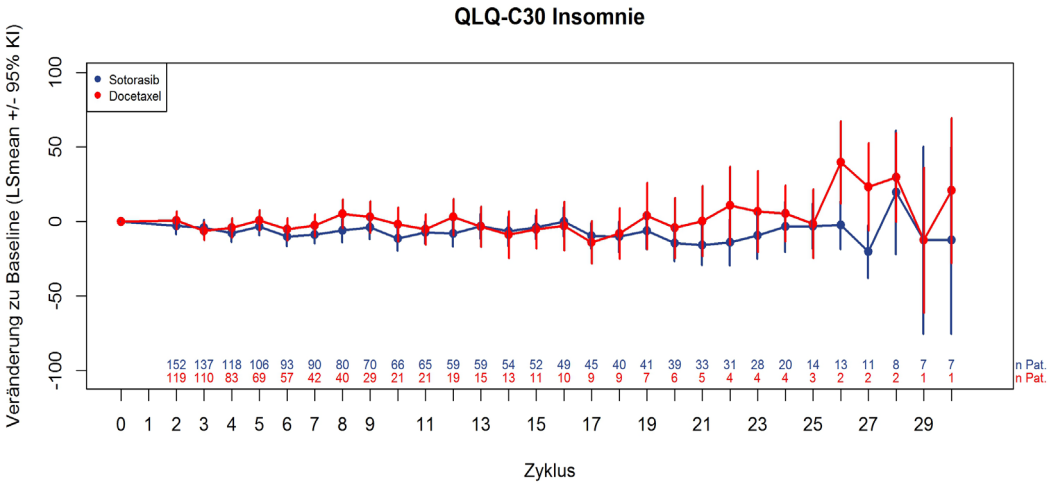

Abbildung 6: Verlaufskurve für den Endpunkt QLQ-C30 Insomnie, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

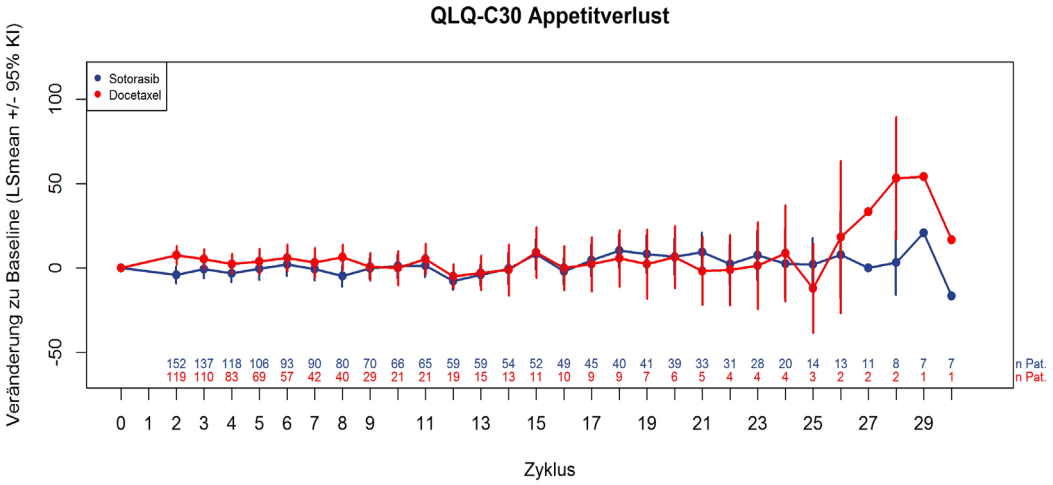

Abbildung 7: Verlaufskurve für den Endpunkt QLQ-C30 Appetitverlust, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

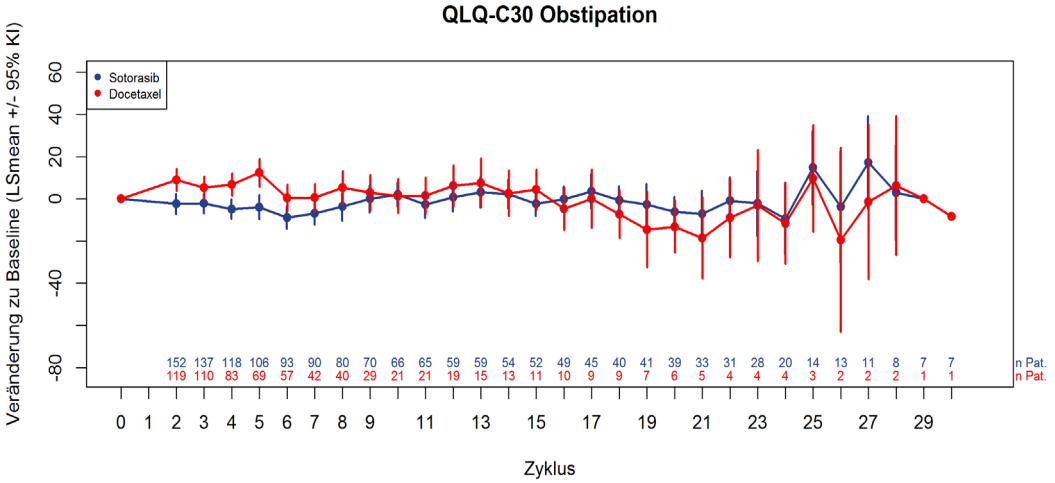

Abbildung 8: Verlaufskurve für den Endpunkt QLQ-C30 Obstipation, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

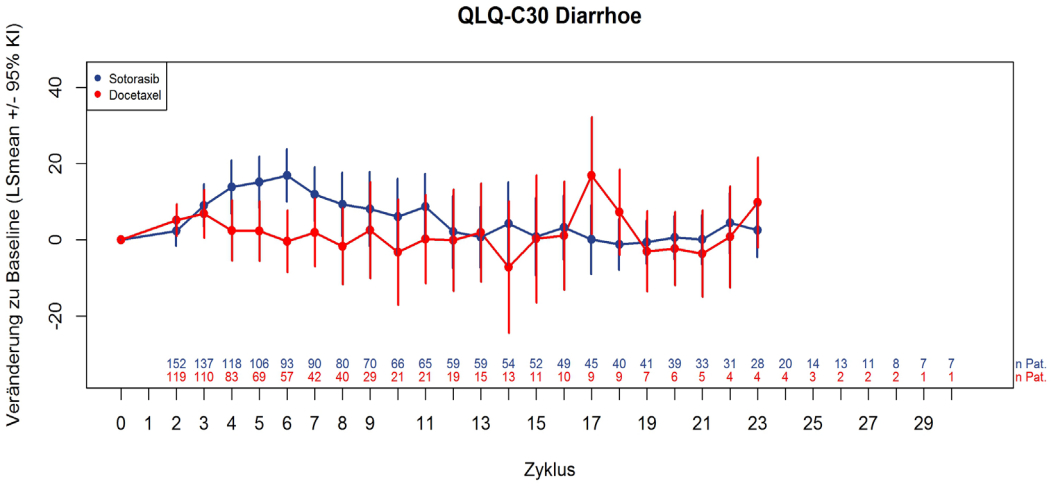

Abbildung 9: Verlaufskurve für den Endpunkt QLQ-C30 Diarrhoe, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.1.4 Subgruppenanalysen für den Endpunkt EORTC QLQ-C30 (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Fatigue; Alter bei Studienbeginn							
<65 Jahre	44/84 (52,4)	7,7 [3,5; 11,1]	45/70 (64,3)	2,1 [1,4; 2,8]	0,5 [0,3; 0,8]	0,0036	0,3134
≥65 Jahre	35/76 (46,1)	9,7 [4,8; 16,0]	38/60 (63,3)	2,8 [1,4; 3,5]	0,4 [0,2; 0,7]	0,0007	
QLQ-C30 Fatigue; Geschlecht							
Weiblich	28/58 (48,3)	7,6 [2,8; 16,0]	33/53 (62,3)	1,9 [1,4; 3,0]	0,4 [0,2; 0,8]	0,0031	0,8350
Männlich	51/102 (50,0)	7,7 [4,8; 12,5]	50/77 (64,9)	2,4 [1,4; 4,4]	0,4 [0,3; 0,7]	0,0002	
QLQ-C30 Fatigue; Region 2							
Nordamerika und Europa	63/135 (46,7)	8,7 [5,2; 12,6]	71/111 (64,0)	2,3 [1,4; 3,0]	0,4 [0,3; 0,6]	<,0001	0,4055
Rest der Welt	16/25 (64,0)	4,1 [2,4; 6,8]	12/19 (63,2)	1,4 [0,8; 4,4]	0,7 [0,3; 1,7]	0,4413	
QLQ-C30 Fatigue; Region 1							
Nordamerika	8/17 (47,1)	10,6 [1,4; n.b.]	9/16 (56,2)	3,0 [0,8; n.b.]	0,7 [0,2; 2,5]	0,5915	0,4396
Europa	55/118 (46,6)	8,7 [5,2; 13,1]	62/95 (65,3)	2,1 [1,4; 2,8]	0,4 [0,3; 0,6]	<,0001	
Rest der Welt	16/25 (64,0)	4,1 [2,4; 6,8]	12/19 (63,2)	1,4 [0,8; 4,4]	0,7 [0,3; 1,7]	0,4413	
QLQ-C30 Fatigue; ECOG Performance-Status							
0	30/56 (53,6)	8,7 [4,5; 12,5]	39/52 (75,0)	2,1 [1,4; 3,5]	0,4 [0,2; 0,7]	0,0003	0,7488
1	49/104 (47,1)	6,1 [4,1; 12,6]	44/78 (56,4)	2,3 [1,4; 3,0]	0,5 [0,3; 0,7]	0,0005	
QLQ-C30 Fatigue; Lebermetastasen bei Studienbeginn							
Nein	65/133 (48,9)	8,3 [5,2; 12,5]	68/108 (63,0)	2,8 [1,6; 3,5]	0,4 [0,3; 0,6]	<,0001	0,8222
Ja	14/27 (51,9)	4,2 [2,8; n.b.]	15/22 (68,2)	1,4 [0,7; 2,3]	0,5 [0,2; 1,4]	0,1642	
QLQ-C30 Fatigue; Knochenmetastasen bei Studienbeginn							
Nein	49/86 (57,0)	7,0 [3,7; 11,1]	49/78 (62,8)	2,4 [1,5; 4,4]	0,5 [0,3; 0,8]	0,0023	0,1147
Ja	30/74 (40,5)	9,1 [4,5; n.b.]	34/52 (65,4)	1,4 [1,4; 2,8]	0,3 [0,2; 0,5]	<,0001	
QLQ-C30 Fatigue; PD-L1-Proteinexpression							
<1%	26/53 (49,1)	8,7 [3,7; 12,6]	27/43 (62,8)	1,5 [1,4; 5,6]	0,4 [0,2; 0,7]	0,0027	0,5436
≥1% und <50%	20/43 (46,5)	7,7 [2,8; n.b.]	25/50 (50,0)	2,8 [2,1; 5,5]	0,5 [0,2; 0,9]	0,0236	
≥50%	29/57 (50,9)	6,1 [3,5; 12,5]	24/29 (82,8)	1,4 [1,4; 3,0]	0,4 [0,2; 0,7]	0,0019	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Fatigue; Ethnie-2							
Asiatisch	13/21 (61,9)	4,1 [2,4; 6,8]	13/18 (72,2)	1,4 [0,7; 4,4]	0,5 [0,2; 1,3]	0,1511	0,5401
Nicht asiatisch	66/138 (47,8)	8,7 [4,8; 12,6]	69/111 (62,2)	2,4 [1,5; 3,0]	0,4 [0,3; 0,6]	<,0001	
QLQ-C30 Fatigue; Vorgeschichte einer Beteiligung des ZNS							
Nein	48/106 (45,3)	8,7 [4,5; 13,1]	56/91 (61,5)	2,4 [1,4; 4,4]	0,5 [0,3; 0,7]	<,0001	0,6556
Ja	31/54 (57,4)	6,8 [3,5; 12,5]	27/39 (69,2)	2,1 [1,4; 3,0]	0,3 [0,2; 0,7]	0,0006	
QLQ-C30 Fatigue; Anzahl an vorherigen Therapielinien							
1	27/70 (38,6)	9,1 [4,8; n.b.]	33/60 (55,0)	2,8 [1,4; 4,4]	0,5 [0,3; 0,9]	0,0107	0,6806
2	33/62 (53,2)	7,6 [4,5; 12,5]	37/50 (74,0)	1,5 [1,4; 2,8]	0,4 [0,2; 0,6]	<,0001	
>2	19/28 (67,9)	4,2 [2,8; 12,5]	13/20 (65,0)	2,3 [1,4; 5,0]	0,5 [0,2; 1,2]	0,1159	
QLQ-C30 Übelkeit und Erbrechen; Alter bei Studienbeginn							
<65 Jahre	36/84 (42,9)	11,1 [2,9; n.b.]	27/70 (38,6)	8,5 [3,9; n.b.]	1,0 [0,6; 1,8]	0,8951	0,4429
≥65 Jahre	33/76 (43,4)	6,3 [4,3; n.b.]	29/60 (48,3)	4,1 [2,8; 11,6]	0,7 [0,4; 1,2]	0,2175	
QLQ-C30 Übelkeit und Erbrechen; Geschlecht							
Weiblich	34/58 (58,6)	2,9 [2,1; 7,6]	22/53 (41,5)	5,6 [3,7; n.b.]	1,3 [0,7; 2,4]	0,3818	0,0202
Männlich	35/102 (34,3)	11,7 [6,2; n.b.]	34/77 (44,2)	5,6 [2,8; 11,6]	0,5 [0,3; 0,9]	0,0104	
QLQ-C30 Übelkeit und Erbrechen; Region 2							
Nordamerika und Europa	55/135 (40,7)	11,1 [5,7; n.b.]	50/111 (45,0)	4,9 [3,7; 9,9]	0,8 [0,5; 1,1]	0,1831	0,3778
Rest der Welt	14/25 (56,0)	3,6 [1,4; 13,8]	6/19 (31,6)	n.b. [1,5; n.b.]	1,3 [0,4; 4,6]	0,6498	
QLQ-C30 Übelkeit und Erbrechen; Region 1							
Nordamerika	5/17 (29,4)	n.b. [3,3; n.b.]	8/16 (50,0)	5,6 [3,7; 11,6]	0,4 [0,1; 2,2]	0,2890	0,5132
Europa	50/118 (42,4)	11,1 [4,5; n.b.]	42/95 (44,2)	4,6 [2,8; n.b.]	0,8 [0,5; 1,2]	0,2498	
Rest der Welt	14/25 (56,0)	3,6 [1,4; 13,8]	6/19 (31,6)	n.b. [1,5; n.b.]	1,3 [0,4; 4,6]	0,6498	
QLQ-C30 Übelkeit und Erbrechen; ECOG Performance-Status							
0	21/56 (37,5)	16,6 [10,3; n.b.]	22/52 (42,3)	5,6 [3,9; n.b.]	0,6 [0,3; 1,2]	0,1244	0,3573
1	48/104 (46,2)	5,5 [3,3; 14,7]	34/78 (43,6)	4,1 [2,1; 11,6]	0,9 [0,5; 1,4]	0,5048	
QLQ-C30 Übelkeit und Erbrechen; Lebermetastasen bei Studienbeginn							
Nein	52/133 (39,1)	13,8 [6,2; n.b.]	47/108 (43,5)	5,6 [3,9; 11,6]	0,6 [0,4; 1,0]	0,0276	0,0570
Ja	17/27 (63,0)	3,3 [0,8; 5,7]	9/22 (40,9)	8,5 [1,5; 8,5]	1,3 [0,5; 3,6]	0,5999	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Übelkeit und Erbrechen; Knochenmetastasen bei Studienbeginn							
Nein	40/86 (46,5)	7,6 [2,9; n.b.]	32/78 (41,0)	9,9 [4,1; n.b.]	1,0 [0,6; 1,6]	0,8706	0,2268
Ja	29/74 (39,2)	9,1 [4,5; n.b.]	24/52 (46,2)	3,6 [2,1; 8,5]	0,6 [0,3; 1,0]	0,0575	
QLQ-C30 Übelkeit und Erbrechen; PD-L1-Proteinexpression							
<1%	18/53 (34,0)	n.b. [6,3; n.b.]	24/43 (55,8)	4,1 [1,4; 5,7]	0,4 [0,2; 0,9]	0,0139	0,0257
≥1% und <50%	19/43 (44,2)	7,6 [2,1; n.b.]	15/50 (30,0)	8,5 [4,1; n.b.]	1,5 [0,7; 3,1]	0,2471	
≥50%	28/57 (49,1)	5,6 [3,3; 14,7]	13/29 (44,8)	9,9 [2,1; n.b.]	0,9 [0,5; 2,0]	0,8876	
QLQ-C30 Übelkeit und Erbrechen; Ethnie-2							
Asiatisch	13/21 (61,9)	5,5 [1,4; 10,3]	7/18 (38,9)	n.b. [1,5; n.b.]	0,9 [0,3; 2,6]	0,8864	0,2520
Nicht asiatisch	56/138 (40,6)	11,7 [5,7; n.b.]	49/111 (44,1)	4,9 [3,9; 9,9]	0,7 [0,5; 1,1]	0,1422	
QLQ-C30 Übelkeit und Erbrechen; Vorgeschichte einer Beteiligung des ZNS							
Nein	42/106 (39,6)	6,3 [4,2; n.b.]	38/91 (41,8)	5,6 [4,1; n.b.]	0,9 [0,6; 1,4]	0,6465	0,3998
Ja	27/54 (50,0)	10,3 [3,3; 14,7]	18/39 (46,2)	4,9 [1,7; n.b.]	0,6 [0,3; 1,1]	0,0731	
QLQ-C30 Übelkeit und Erbrechen; Anzahl an vorherigen Therapielinien							
1	28/70 (40,0)	9,1 [2,8; n.b.]	28/60 (46,7)	4,1 [2,3; 9,9]	0,8 [0,4; 1,3]	0,3209	0,4497
2	25/62 (40,3)	11,7 [5,7; n.b.]	21/50 (42,0)	5,7 [2,8; n.b.]	0,6 [0,3; 1,2]	0,1529	
>2	16/28 (57,1)	4,5 [1,4; n.b.]	7/20 (35,0)	8,5 [3,9; n.b.]	1,2 [0,5; 3,0]	0,7337	
QLQ-C30 Schmerz; Alter bei Studienbeginn							
<65 Jahre	54/84 (64,3)	2,8 [2,3; 4,2]	46/70 (65,7)	2,1 [1,4; 2,8]	0,8 [0,5; 1,3]	0,3609	0,9429
≥65 Jahre	52/76 (68,4)	2,8 [1,5; 4,5]	45/60 (75,0)	1,7 [1,4; 2,3]	0,8 [0,5; 1,2]	0,2264	
QLQ-C30 Schmerz; Geschlecht							
Weiblich	43/58 (74,1)	2,1 [1,4; 2,8]	37/53 (69,8)	1,5 [1,4; 2,8]	0,9 [0,6; 1,5]	0,6782	0,1599
Männlich	63/102 (61,8)	4,2 [2,8; 5,9]	54/77 (70,1)	2,1 [1,4; 2,7]	0,6 [0,4; 0,9]	0,0225	
QLQ-C30 Schmerz; Region 2							
Nordamerika und Europa	90/135 (66,7)	2,8 [2,1; 4,2]	78/111 (70,3)	2,1 [1,4; 2,6]	0,9 [0,6; 1,2]	0,3341	0,2753
Rest der Welt	16/25 (64,0)	4,1 [1,4; 11,0]	13/19 (68,4)	1,5 [0,8; 3,5]	0,6 [0,2; 1,4]	0,2018	
QLQ-C30 Schmerz; Region 1							
Nordamerika	12/17 (70,6)	4,8 [0,7; 6,2]	13/16 (81,2)	2,2 [0,7; 3,4]	0,9 [0,3; 2,4]	0,8368	0,5487
Europa	78/118 (66,1)	2,8 [2,1; 4,2]	65/95 (68,4)	2,1 [1,4; 2,8]	0,8 [0,6; 1,2]	0,3426	
Rest der Welt	16/25 (64,0)	4,1 [1,4; 11,0]	13/19 (68,4)	1,5 [0,8; 3,5]	0,6 [0,2; 1,4]	0,2018	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Schmerz; ECOG Performance-Status							
0	41/56 (73,2)	3,6 [2,0; 4,9]	40/52 (76,9)	1,7 [1,4; 2,8]	0,7 [0,4; 1,1]	0,1561	0,6217
1	65/104 (62,5)	2,8 [2,1; 4,2]	51/78 (65,4)	2,1 [1,4; 2,7]	0,7 [0,5; 1,1]	0,1466	
QLQ-C30 Schmerz; Lebermetastasen bei Studienbeginn							
Nein	88/133 (66,2)	3,5 [2,1; 4,2]	73/108 (67,6)	2,1 [1,5; 2,8]	0,8 [0,6; 1,1]	0,2100	0,3238
Ja	18/27 (66,7)	2,8 [1,4; 4,8]	18/22 (81,8)	1,4 [0,7; 2,1]	0,4 [0,2; 1,0]	0,0543	
QLQ-C30 Schmerz; Knochenmetastasen bei Studienbeginn							
Nein	58/86 (67,4)	2,8 [1,8; 4,2]	57/78 (73,1)	2,1 [1,4; 2,8]	0,8 [0,5; 1,2]	0,2100	0,7857
Ja	48/74 (64,9)	2,8 [2,1; 4,5]	34/52 (65,4)	2,1 [1,4; 2,6]	0,7 [0,4; 1,1]	0,1117	
QLQ-C30 Schmerz; PD-L1-Proteinexpression							
<1%	36/53 (67,9)	2,8 [2,1; 4,5]	31/43 (72,1)	1,4 [0,8; 3,0]	0,7 [0,4; 1,2]	0,2213	0,8604
≥1% und <50%	28/43 (65,1)	2,8 [1,4; 10,4]	28/50 (56,0)	2,3 [2,0; 2,8]	1,0 [0,5; 1,8]	0,9320	
≥50%	38/57 (66,7)	2,8 [2,0; 4,1]	24/29 (82,8)	1,4 [0,7; 3,0]	0,7 [0,4; 1,3]	0,2642	
QLQ-C30 Schmerz; Ethnie-2							
Asiatisch	12/21 (57,1)	4,1 [2,1; 11,8]	13/18 (72,2)	1,4 [0,7; 2,7]	0,4 [0,2; 1,0]	0,0526	0,0757
Nicht asiatisch	94/138 (68,1)	2,8 [2,1; 4,2]	77/111 (69,4)	2,1 [1,4; 2,6]	0,8 [0,6; 1,2]	0,2842	
QLQ-C30 Schmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	66/106 (62,3)	3,5 [2,1; 4,8]	66/91 (72,5)	2,1 [1,4; 2,4]	0,7 [0,5; 1,0]	0,0498	0,4838
Ja	40/54 (74,1)	2,8 [2,1; 4,2]	25/39 (64,1)	2,1 [1,4; 3,0]	0,8 [0,5; 1,4]	0,5156	
QLQ-C30 Schmerz; Anzahl an vorherigen Therapielinien							
1	45/70 (64,3)	2,3 [1,4; 4,2]	44/60 (73,3)	1,6 [1,4; 2,1]	0,7 [0,5; 1,1]	0,1773	0,7254
2	40/62 (64,5)	4,0 [2,8; 5,6]	34/50 (68,0)	2,1 [1,4; 3,0]	0,7 [0,4; 1,1]	0,1381	
>2	21/28 (75,0)	2,8 [1,4; 4,5]	13/20 (65,0)	2,7 [0,8; 8,7]	1,0 [0,5; 2,2]	0,9264	
QLQ-C30 Atemnot; Alter bei Studienbeginn							
<65 Jahre	37/84 (44,0)	7,6 [4,9; 16,6]	37/70 (52,9)	3,3 [2,1; 7,3]	0,7 [0,4; 1,1]	0,1265	0,4636
≥65 Jahre	35/76 (46,1)	11,1 [3,5; n.b.]	31/60 (51,7)	3,5 [2,2; 5,0]	0,6 [0,3; 1,0]	0,0435	
QLQ-C30 Atemnot; Geschlecht							
Weiblich	32/58 (55,2)	3,5 [2,1; 11,1]	25/53 (47,2)	5,0 [2,1; n.b.]	1,1 [0,6; 2,0]	0,6510	0,0402
Männlich	40/102 (39,2)	13,1 [6,9; n.b.]	43/77 (55,8)	2,8 [2,1; 4,6]	0,5 [0,3; 0,8]	0,0022	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Atemnot; Region 2							
Nordamerika und Europa	60/135 (44,4)	8,3 [5,6; n.b.]	59/111 (53,2)	3,5 [2,3; 5,0]	0,6 [0,4; 0,9]	0,0111	0,5156
Rest der Welt	12/25 (48,0)	5,6 [2,0; n.b.]	9/19 (47,4)	4,4 [0,8; n.b.]	0,7 [0,3; 2,0]	0,5476	
QLQ-C30 Atemnot; Region 1							
Nordamerika	4/17 (23,5)	n.b. [2,1; n.b.]	8/16 (50,0)	3,7 [1,5; n.b.]	0,4 [0,1; 1,9]	0,2587	0,6756
Europa	56/118 (47,5)	7,0 [4,9; 13,1]	51/95 (53,7)	2,8 [2,1; 5,0]	0,6 [0,4; 0,9]	0,0183	
Rest der Welt	12/25 (48,0)	5,6 [2,0; n.b.]	9/19 (47,4)	4,4 [0,8; n.b.]	0,7 [0,3; 2,0]	0,5476	
QLQ-C30 Atemnot; ECOG Performance-Status							
0	27/56 (48,2)	13,1 [5,6; n.b.]	32/52 (61,5)	3,5 [2,0; 5,5]	0,5 [0,3; 0,8]	0,0091	0,3142
1	45/104 (43,3)	6,2 [3,5; n.b.]	36/78 (46,2)	3,5 [2,1; n.b.]	0,8 [0,5; 1,3]	0,4474	
QLQ-C30 Atemnot; Lebermetastasen bei Studienbeginn							
Nein	55/133 (41,4)	12,5 [6,9; n.b.]	58/108 (53,7)	3,5 [2,2; 5,0]	0,5 [0,3; 0,8]	0,0012	0,1885
Ja	17/27 (63,0)	3,4 [0,8; 5,0]	10/22 (45,5)	n.b. [0,7; n.b.]	0,7 [0,3; 2,0]	0,5144	
QLQ-C30 Atemnot; Knochenmetastasen bei Studienbeginn							
Nein	38/86 (44,2)	12,5 [5,6; n.b.]	38/78 (48,7)	4,3 [2,4; n.b.]	0,6 [0,3; 0,9]	0,0197	0,7784
Ja	34/74 (45,9)	6,9 [3,5; n.b.]	30/52 (57,7)	2,8 [2,0; 5,5]	0,6 [0,3; 1,0]	0,0533	
QLQ-C30 Atemnot; PD-L1-Proteinexpression							
<1%	23/53 (43,4)	10,0 [3,4; n.b.]	25/43 (58,1)	2,1 [1,4; 4,4]	0,5 [0,3; 0,9]	0,0264	0,4090
≥1% und <50%	21/43 (48,8)	7,0 [2,0; n.b.]	21/50 (42,0)	4,6 [2,8; n.b.]	0,8 [0,4; 1,5]	0,4333	
≥50%	25/57 (43,9)	12,5 [3,6; n.b.]	17/29 (58,6)	3,5 [1,4; n.b.]	0,6 [0,3; 1,1]	0,1023	
QLQ-C30 Atemnot; Ethnie-2							
Asiatisch	10/21 (47,6)	12,5 [1,4; n.b.]	9/18 (50,0)	4,4 [0,8; n.b.]	0,8 [0,3; 2,1]	0,6192	0,5569
Nicht asiatisch	61/138 (44,2)	8,3 [5,6; 16,6]	58/111 (52,3)	3,5 [2,2; 5,5]	0,6 [0,4; 0,9]	0,0109	
QLQ-C30 Atemnot; Vorgeschichte einer Beteiligung des ZNS							
Nein	50/106 (47,2)	7,0 [3,4; n.b.]	48/91 (52,7)	4,3 [2,2; 5,6]	0,7 [0,5; 1,1]	0,0994	0,3393
Ja	22/54 (40,7)	13,1 [6,2; n.b.]	20/39 (51,3)	2,8 [1,4; n.b.]	0,4 [0,2; 0,9]	0,0144	
QLQ-C30 Atemnot; Anzahl an vorherigen Therapielinien							
1	26/70 (37,1)	n.b. [5,0; n.b.]	28/60 (46,7)	3,7 [2,1; n.b.]	0,7 [0,4; 1,3]	0,2820	0,8213
2	31/62 (50,0)	7,6 [4,9; 16,6]	30/50 (60,0)	2,8 [2,0; 5,6]	0,5 [0,3; 0,9]	0,0116	
>2	15/28 (53,6)	5,6 [2,1; n.b.]	10/20 (50,0)	5,5 [0,8; n.b.]	0,7 [0,3; 1,7]	0,4783	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Insomnie; Alter bei Studienbeginn							
<65 Jahre	43/84 (51,2)	4,9 [2,8; 9,1]	33/70 (47,1)	4,6 [2,8; n.b.]	1,0 [0,6; 1,6]	0,9393	0,1741
≥65 Jahre	35/76 (46,1)	7,6 [4,2; n.b.]	33/60 (55,0)	3,5 [2,1; 5,5]	0,6 [0,4; 1,1]	0,1142	
QLQ-C30 Insomnie; Geschlecht							
Weiblich	28/58 (48,3)	5,3 [2,8; 13,1]	25/53 (47,2)	3,9 [3,0; n.b.]	1,1 [0,6; 1,9]	0,8228	0,2252
Männlich	50/102 (49,0)	5,9 [4,2; 10,4]	41/77 (53,2)	3,5 [2,1; 5,5]	0,6 [0,4; 1,0]	0,0543	
QLQ-C30 Insomnie; Region 2							
Nordamerika und Europa	67/135 (49,6)	5,6 [4,2; 10,4]	55/111 (49,5)	3,9 [3,0; 6,5]	0,9 [0,6; 1,3]	0,5833	0,3530
Rest der Welt	11/25 (44,0)	7,6 [2,1; n.b.]	11/19 (57,9)	2,8 [1,3; n.b.]	0,5 [0,2; 1,4]	0,1809	
QLQ-C30 Insomnie; Region 1							
Nordamerika	8/17 (47,1)	4,9 [2,8; 13,1]	9/16 (56,2)	5,1 [1,3; n.b.]	1,4 [0,4; 5,0]	0,5994	0,6898
Europa	59/118 (50,0)	5,6 [4,1; 10,4]	46/95 (48,4)	3,9 [2,9; n.b.]	0,8 [0,6; 1,2]	0,3789	
Rest der Welt	11/25 (44,0)	7,6 [2,1; n.b.]	11/19 (57,9)	2,8 [1,3; n.b.]	0,5 [0,2; 1,4]	0,1809	
QLQ-C30 Insomnie; ECOG Performance-Status							
0	30/56 (53,6)	6,2 [2,8; 12,5]	28/52 (53,8)	3,9 [2,1; n.b.]	0,8 [0,5; 1,4]	0,4436	0,9039
1	48/104 (46,2)	5,6 [4,1; 10,4]	38/78 (48,7)	3,5 [2,9; 5,5]	0,8 [0,5; 1,2]	0,3160	
QLQ-C30 Insomnie; Lebermetastasen bei Studienbeginn							
Nein	66/133 (49,6)	5,9 [3,7; 10,4]	53/108 (49,1)	3,9 [3,1; 6,5]	0,9 [0,6; 1,3]	0,6117	0,1562
Ja	12/27 (44,4)	5,6 [3,5; 10,4]	13/22 (59,1)	2,1 [0,8; n.b.]	0,5 [0,2; 1,6]	0,2337	
QLQ-C30 Insomnie; Knochenmetastasen bei Studienbeginn							
Nein	46/86 (53,5)	5,6 [3,7; 10,4]	39/78 (50,0)	4,9 [3,0; n.b.]	1,0 [0,6; 1,5]	0,8500	0,1887
Ja	32/74 (43,2)	8,7 [3,5; n.b.]	27/52 (51,9)	3,3 [2,1; 6,5]	0,5 [0,3; 0,9]	0,0188	
QLQ-C30 Insomnie; PD-L1-Proteinexpression							
<1%	29/53 (54,7)	5,6 [3,4; 9,1]	20/43 (46,5)	5,1 [3,3; n.b.]	1,1 [0,6; 1,9]	0,8566	0,4268
≥1% und <50%	19/43 (44,2)	8,5 [2,8; 13,1]	24/50 (48,0)	2,3 [1,4; n.b.]	0,6 [0,3; 1,1]	0,1145	
≥50%	27/57 (47,4)	4,2 [2,8; n.b.]	14/29 (48,3)	3,5 [3,0; n.b.]	1,1 [0,6; 2,3]	0,6995	
QLQ-C30 Insomnie; Ethnie-2							
Asiatisch	11/21 (52,4)	3,5 [0,8; 10,4]	13/18 (72,2)	1,4 [0,8; 3,7]	0,5 [0,2; 1,2]	0,0970	0,3785
Nicht asiatisch	66/138 (47,8)	6,2 [4,2; 10,4]	52/111 (46,8)	4,6 [3,0; n.b.]	0,9 [0,6; 1,3]	0,5054	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Insomnie; Vorgeschichte einer Beteiligung des ZNS							
Nein	55/106 (51,9)	5,6 [3,5; 8,5]	44/91 (48,4)	4,6 [3,0; n.b.]	0,9 [0,6; 1,3]	0,5335	0,1568
Ja	23/54 (42,6)	9,1 [3,5; n.b.]	22/39 (56,4)	3,0 [1,4; 4,9]	0,6 [0,3; 1,1]	0,0777	
QLQ-C30 Insomnie; Anzahl an vorherigen Therapielinien							
1	36/70 (51,4)	4,9 [2,1; 8,7]	36/60 (60,0)	3,0 [1,4; 3,9]	0,7 [0,5; 1,2]	0,2213	0,6744
2	30/62 (48,4)	7,5 [4,2; n.b.]	21/50 (42,0)	5,1 [2,9; n.b.]	0,9 [0,5; 1,6]	0,7226	
>2	12/28 (42,9)	5,9 [2,8; n.b.]	9/20 (45,0)	3,9 [0,8; n.b.]	0,7 [0,3; 1,6]	0,3594	
QLQ-C30 Appetitverlust; Alter bei Studienbeginn							
<65 Jahre	39/84 (46,4)	8,4 [3,5; 15,2]	35/70 (50,0)	3,5 [2,1; 6,7]	0,7 [0,4; 1,2]	0,1651	0,9306
≥65 Jahre	45/76 (59,2)	4,5 [3,3; 9,2]	32/60 (53,3)	3,5 [1,4; n.b.]	0,8 [0,5; 1,3]	0,3018	
QLQ-C30 Appetitverlust; Geschlecht							
Weiblich	35/58 (60,3)	4,2 [2,7; 9,0]	27/53 (50,9)	3,5 [2,1; n.b.]	0,9 [0,5; 1,6]	0,6694	0,1309
Männlich	49/102 (48,0)	6,2 [3,5; 15,2]	40/77 (51,9)	3,5 [1,6; 6,7]	0,5 [0,3; 0,8]	0,0063	
QLQ-C30 Appetitverlust; Region 2							
Nordamerika und Europa	68/135 (50,4)	8,4 [4,2; 12,6]	56/111 (50,5)	3,5 [2,1; 4,6]	0,7 [0,5; 1,0]	0,0484	0,6544
Rest der Welt	16/25 (64,0)	3,4 [2,1; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,7]	0,4319	
QLQ-C30 Appetitverlust; Region 1							
Nordamerika	8/17 (47,1)	3,5 [2,1; n.b.]	8/16 (50,0)	3,7 [0,7; n.b.]	1,3 [0,3; 6,0]	0,7400	0,6182
Europa	60/118 (50,8)	8,4 [4,5; 13,1]	48/95 (50,5)	3,5 [2,1; 6,7]	0,6 [0,4; 0,9]	0,0253	
Rest der Welt	16/25 (64,0)	3,4 [2,1; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,7]	0,4319	
QLQ-C30 Appetitverlust; ECOG Performance-Status							
0	24/56 (42,9)	13,8 [4,9; n.b.]	31/52 (59,6)	2,8 [1,4; 4,6]	0,4 [0,2; 0,8]	0,0041	0,0526
1	60/104 (57,7)	3,5 [2,8; 8,4]	36/78 (46,2)	3,7 [2,1; n.b.]	0,8 [0,5; 1,3]	0,4156	
QLQ-C30 Appetitverlust; Lebermetastasen bei Studienbeginn							
Nein	67/133 (50,4)	6,1 [4,0; 13,1]	54/108 (50,0)	3,5 [2,1; n.b.]	0,7 [0,5; 1,0]	0,0827	0,8612
Ja	17/27 (63,0)	3,3 [2,1; 9,1]	13/22 (59,1)	3,5 [0,7; 4,2]	0,3 [0,1; 1,0]	0,0360	
QLQ-C30 Appetitverlust; Knochenmetastasen bei Studienbeginn							
Nein	48/86 (55,8)	4,9 [2,9; 9,4]	37/78 (47,4)	3,5 [2,1; n.b.]	0,9 [0,5; 1,4]	0,5514	0,0660
Ja	36/74 (48,6)	6,1 [4,2; 13,1]	30/52 (57,7)	2,8 [1,6; 3,7]	0,4 [0,2; 0,7]	0,0008	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Appetitverlust; PD-L1-Proteinexpression							
<1%	26/53 (49,1)	9,4 [4,2; 13,8]	24/43 (55,8)	2,1 [1,4; n.b.]	0,5 [0,3; 1,0]	0,0334	0,2774
≥1% und <50%	22/43 (51,2)	6,2 [2,8; 9,1]	20/50 (40,0)	3,7 [3,5; n.b.]	0,8 [0,4; 1,6]	0,6030	
≥50%	34/57 (59,6)	3,5 [2,8; 6,1]	17/29 (58,6)	3,5 [2,0; 6,7]	0,8 [0,4; 1,5]	0,5168	
QLQ-C30 Appetitverlust; Ethnie-2							
Asiatisch	13/21 (61,9)	3,4 [1,4; 6,1]	12/18 (66,7)	1,5 [0,7; n.b.]	0,7 [0,3; 1,6]	0,3549	0,9632
Nicht asiatisch	71/138 (51,4)	8,3 [4,2; 11,9]	54/111 (48,6)	3,7 [2,1; 6,7]	0,7 [0,5; 1,0]	0,0675	
QLQ-C30 Appetitverlust; Vorgeschichte einer Beteiligung des ZNS							
Nein	54/106 (50,9)	6,2 [3,5; 11,9]	44/91 (48,4)	3,5 [2,1; n.b.]	0,8 [0,5; 1,1]	0,1907	0,2268
Ja	30/54 (55,6)	4,9 [3,0; 12,6]	23/39 (59,0)	2,1 [0,8; 3,7]	0,4 [0,2; 0,8]	0,0073	
QLQ-C30 Appetitverlust; Anzahl an vorherigen Therapielinien							
1	30/70 (42,9)	8,4 [2,8; n.b.]	31/60 (51,7)	3,5 [2,0; 3,7]	0,6 [0,3; 1,0]	0,0468	0,6120
2	34/62 (54,8)	6,2 [3,3; 15,2]	26/50 (52,0)	4,6 [1,4; n.b.]	0,8 [0,5; 1,3]	0,3759	
>2	20/28 (71,4)	4,2 [2,8; 9,0]	10/20 (50,0)	3,7 [1,4; n.b.]	0,7 [0,3; 1,7]	0,4972	
QLQ-C30 Obstipation; Alter bei Studienbeginn							
<65 Jahre	34/84 (40,5)	14,8 [4,1; n.b.]	40/70 (57,1)	2,6 [1,4; 7,6]	0,6 [0,4; 1,1]	0,0850	0,4220
≥65 Jahre	29/76 (38,2)	12,8 [6,2; n.b.]	33/60 (55,0)	3,5 [1,5; 4,9]	0,4 [0,2; 0,7]	0,0009	
QLQ-C30 Obstipation; Geschlecht							
Weiblich	24/58 (41,4)	13,1 [4,1; n.b.]	27/53 (50,9)	2,8 [1,4; n.b.]	0,7 [0,4; 1,3]	0,3128	0,3707
Männlich	39/102 (38,2)	12,8 [5,8; n.b.]	46/77 (59,7)	2,8 [1,4; 4,9]	0,4 [0,3; 0,7]	0,0006	
QLQ-C30 Obstipation; Region 2							
Nordamerika und Europa	54/135 (40,0)	12,8 [6,2; n.b.]	62/111 (55,9)	3,3 [1,5; 6,2]	0,5 [0,4; 0,8]	0,0007	0,8854
Rest der Welt	9/25 (36,0)	6,2 [2,4; n.b.]	11/19 (57,9)	2,1 [1,0; n.b.]	0,7 [0,3; 2,1]	0,5513	
QLQ-C30 Obstipation; Region 1							
Nordamerika	6/17 (35,3)	n.b. [1,4; n.b.]	8/16 (50,0)	6,2 [0,7; n.b.]	0,7 [0,2; 2,3]	0,5285	0,9091
Europa	48/118 (40,7)	12,8 [6,2; n.b.]	54/95 (56,8)	2,8 [1,4; 4,9]	0,5 [0,3; 0,7]	0,0005	
Rest der Welt	9/25 (36,0)	6,2 [2,4; n.b.]	11/19 (57,9)	2,1 [1,0; n.b.]	0,7 [0,3; 2,1]	0,5513	
QLQ-C30 Obstipation; ECOG Performance-Status							
0	26/56 (46,4)	12,8 [6,2; n.b.]	30/52 (57,7)	3,5 [1,4; 9,7]	0,5 [0,3; 0,9]	0,0288	0,8029
1	37/104 (35,6)	13,1 [5,8; n.b.]	43/78 (55,1)	2,8 [1,4; 6,2]	0,5 [0,3; 0,8]	0,0063	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Obstipation; Lebermetastasen bei Studienbeginn							
Nein	54/133 (40,6)	12,8 [6,2; n.b.]	59/108 (54,6)	3,5 [2,1; 7,5]	0,5 [0,4; 0,8]	0,0011	0,5899
Ja	9/27 (33,3)	n.b. [3,0; n.b.]	14/22 (63,6)	1,5 [0,7; 2,8]	0,3 [0,1; 0,9]	0,0279	
QLQ-C30 Obstipation; Knochenmetastasen bei Studienbeginn							
Nein	38/86 (44,2)	11,1 [4,3; n.b.]	47/78 (60,3)	2,8 [1,4; 6,2]	0,5 [0,3; 0,8]	0,0071	0,9851
Ja	25/74 (33,8)	13,1 [5,8; n.b.]	26/52 (50,0)	3,3 [1,4; n.b.]	0,5 [0,3; 0,9]	0,0228	
QLQ-C30 Obstipation; PD-L1-Proteinexpression							
<1%	19/53 (35,8)	17,3 [4,9; n.b.]	26/43 (60,5)	2,8 [1,4; 7,6]	0,5 [0,2; 0,9]	0,0227	0,6175
≥1% und <50%	17/43 (39,5)	14,8 [2,1; n.b.]	23/50 (46,0)	3,5 [1,6; n.b.]	0,8 [0,4; 1,5]	0,4692	
≥50%	24/57 (42,1)	11,1 [4,5; n.b.]	18/29 (62,1)	2,8 [0,7; 7,5]	0,5 [0,2; 0,9]	0,0265	
QLQ-C30 Obstipation; Ethnie-2							
Asiatisch	6/21 (28,6)	6,2 [2,8; n.b.]	12/18 (66,7)	1,4 [0,7; 4,2]	0,3 [0,1; 1,0]	0,0388	0,2075
Nicht asiatisch	56/138 (40,6)	12,8 [6,2; n.b.]	60/111 (54,1)	3,5 [1,5; 7,5]	0,6 [0,4; 0,8]	0,0016	
QLQ-C30 Obstipation; Vorgeschichte einer Beteiligung des ZNS							
Nein	43/106 (40,6)	12,8 [6,2; n.b.]	50/91 (54,9)	3,3 [1,6; 7,5]	0,5 [0,4; 0,8]	0,0037	0,5096
Ja	20/54 (37,0)	13,1 [4,5; n.b.]	23/39 (59,0)	2,1 [1,4; 9,7]	0,4 [0,2; 0,8]	0,0087	
QLQ-C30 Obstipation; Anzahl an vorherigen Therapielinien							
1	24/70 (34,3)	14,8 [6,2; n.b.]	33/60 (55,0)	3,3 [1,5; 4,4]	0,5 [0,3; 0,8]	0,0047	0,7819
2	26/62 (41,9)	11,1 [5,8; n.b.]	30/50 (60,0)	2,1 [1,4; 9,7]	0,5 [0,3; 0,9]	0,0198	
>2	13/28 (46,4)	13,1 [1,4; n.b.]	10/20 (50,0)	2,8 [0,7; n.b.]	0,6 [0,3; 1,5]	0,2963	
QLQ-C30 Diarrhoe; Alter bei Studienbeginn							
<65 Jahre	53/84 (63,1)	2,1 [1,5; 2,9]	34/70 (48,6)	5,3 [2,1; n.b.]	1,3 [0,8; 2,0]	0,3170	0,5770
≥65 Jahre	41/76 (53,9)	3,4 [2,2; 6,2]	30/60 (50,0)	3,0 [2,1; n.b.]	1,0 [0,6; 1,7]	0,9798	
QLQ-C30 Diarrhoe; Geschlecht							
Weiblich	40/58 (69,0)	2,1 [2,1; 2,8]	27/53 (50,9)	5,3 [1,4; 11,8]	1,3 [0,7; 2,2]	0,3797	0,3770
Männlich	54/102 (52,9)	2,9 [2,1; 6,2]	37/77 (48,1)	4,2 [2,1; n.b.]	1,0 [0,7; 1,6]	0,9630	
QLQ-C30 Diarrhoe; Region 2							
Nordamerika und Europa	79/135 (58,5)	2,3 [2,1; 3,5]	55/111 (49,5)	4,4 [2,1; 9,9]	1,1 [0,8; 1,6]	0,5211	0,8508
Rest der Welt	15/25 (60,0)	2,8 [1,4; 6,2]	9/19 (47,4)	2,6 [1,4; n.b.]	1,3 [0,5; 3,4]	0,5773	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Diarrhoe; Region 1							
Nordamerika	9/17 (52,9)	2,7 [1,5; n.b.]	7/16 (43,8)	5,6 [1,4; n.b.]	1,9 [0,5; 6,5]	0,3222	0,9546
Europa	70/118 (59,3)	2,2 [2,1; 3,5]	48/95 (50,5)	4,2 [2,1; 9,9]	1,1 [0,7; 1,5]	0,7771	
Rest der Welt	15/25 (60,0)	2,8 [1,4; 6,2]	9/19 (47,4)	2,6 [1,4; n.b.]	1,3 [0,5; 3,4]	0,5773	
QLQ-C30 Diarrhoe; ECOG Performance-Status							
0	37/56 (66,1)	2,1 [2,0; 3,0]	27/52 (51,9)	5,3 [2,1; 11,8]	1,3 [0,8; 2,3]	0,2979	0,7069
1	57/104 (54,8)	2,8 [2,1; 4,0]	37/78 (47,4)	3,0 [2,1; n.b.]	1,1 [0,7; 1,6]	0,8052	
QLQ-C30 Diarrhoe; Lebermetastasen bei Studienbeginn							
Nein	76/133 (57,1)	2,8 [2,1; 4,0]	57/108 (52,8)	3,0 [2,1; 9,9]	1,1 [0,7; 1,5]	0,7424	0,2820
Ja	18/27 (66,7)	2,1 [1,6; 3,5]	7/22 (31,8)	n.b. [1,4; n.b.]	1,2 [0,4; 3,3]	0,7859	
QLQ-C30 Diarrhoe; Knochenmetastasen bei Studienbeginn							
Nein	54/86 (62,8)	2,3 [2,1; 3,5]	34/78 (43,6)	9,9 [2,8; n.b.]	1,6 [1,0; 2,5]	0,0366	0,0084
Ja	40/74 (54,1)	2,8 [1,5; 9,4]	30/52 (57,7)	2,1 [1,4; 4,4]	0,6 [0,4; 1,1]	0,0807	
QLQ-C30 Diarrhoe; PD-L1-Proteinexpression							
<1%	31/53 (58,5)	2,9 [2,0; 9,1]	20/43 (46,5)	4,4 [2,2; n.b.]	1,0 [0,6; 1,8]	0,9818	0,3128
≥1% und <50%	26/43 (60,5)	2,1 [1,4; 2,8]	28/50 (56,0)	2,1 [1,4; 5,6]	0,9 [0,5; 1,5]	0,6112	
≥50%	33/57 (57,9)	2,8 [2,2; 3,5]	10/29 (34,5)	n.b. [2,1; n.b.]	2,1 [1,0; 4,4]	0,0574	
QLQ-C30 Diarrhoe; Ethnie-2							
Asiatisch	14/21 (66,7)	2,7 [1,4; 4,7]	8/18 (44,4)	n.b. [1,0; n.b.]	1,4 [0,6; 3,6]	0,4372	0,5275
Nicht asiatisch	80/138 (58,0)	2,3 [2,1; 3,5]	55/111 (49,5)	4,4 [2,1; 9,9]	1,1 [0,8; 1,6]	0,5194	
QLQ-C30 Diarrhoe; Vorgeschichte einer Beteiligung des ZNS							
Nein	63/106 (59,4)	2,7 [2,1; 3,5]	49/91 (53,8)	2,8 [2,1; 5,6]	1,0 [0,7; 1,5]	0,8898	0,3072
Ja	31/54 (57,4)	2,8 [2,0; 9,1]	15/39 (38,5)	n.b. [2,1; n.b.]	1,4 [0,8; 2,6]	0,2849	
QLQ-C30 Diarrhoe; Anzahl an vorherigen Therapielinien							
1	41/70 (58,6)	2,1 [1,4; 3,4]	26/60 (43,3)	9,9 [1,4; n.b.]	1,3 [0,8; 2,1]	0,3498	0,5323
2	37/62 (59,7)	2,8 [2,1; 4,0]	28/50 (56,0)	4,4 [2,1; 11,8]	1,2 [0,7; 1,9]	0,5121	
>2	16/28 (57,1)	3,5 [2,1; n.b.]	10/20 (50,0)	2,2 [1,4; n.b.]	0,7 [0,3; 1,7]	0,4749	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein). 2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).							
Die Auswertung erfolgte auf Grundlage der ITT-Population. KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-C30 = Quality of Life Questionnaire Core 30; ZNS = Zentrales Nervensystem							

2.3.1.5 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-C30 Fatigue								
160	116 (72,5)	2,8 [2,1; 3,5]	130	108 (83,1)	1,4 [0,8; 1,4]	0,49 [0,37; 0,65]	<,0001	<,0001
QLQ-C30 Übelkeit und Erbrechen								
160	87 (54,4)	6,1 [3,5; 9,1]	130	61 (46,9)	4,6 [3,0; 9,9]	0,87 [0,61; 1,23]	0,4236	0,4233
QLQ-C30 Schmerz								
160	119 (74,4)	2,8 [2,1; 3,5]	130	94 (72,3)	2,1 [1,4; 2,3]	0,80 [0,60; 1,06]	0,1235	0,1228
QLQ-C30 Atemnot								
160	88 (55,0)	6,3 [3,5; 10,2]	130	75 (57,7)	3,3 [2,2; 4,4]	0,69 [0,50; 0,95]	0,0223	0,0216
QLQ-C30 Insomnie								
160	96 (60,0)	4,9 [3,4; 6,2]	130	69 (53,1)	3,5 [2,8; 5,1]	0,89 [0,65; 1,22]	0,4702	0,4700
QLQ-C30 Appetitverlust								
160	101 (63,1)	4,2 [3,3; 6,2]	130	70 (53,8)	3,5 [2,1; 3,9]	0,75 [0,55; 1,04]	0,0857	0,0848
QLQ-C30 Obstipation								
160	83 (51,9)	6,3 [4,8; 10,2]	130	79 (60,8)	2,7 [1,5; 3,6]	0,60 [0,44; 0,83]	0,0021	0,0019
QLQ-C30 Diarrhoe								
160	109 (68,1)	2,2 [2,1; 2,9]	130	73 (56,2)	2,8 [2,1; 5,3]	1,11 [0,82; 1,50]	0,5034	0,5033

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

2.3.1.6 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

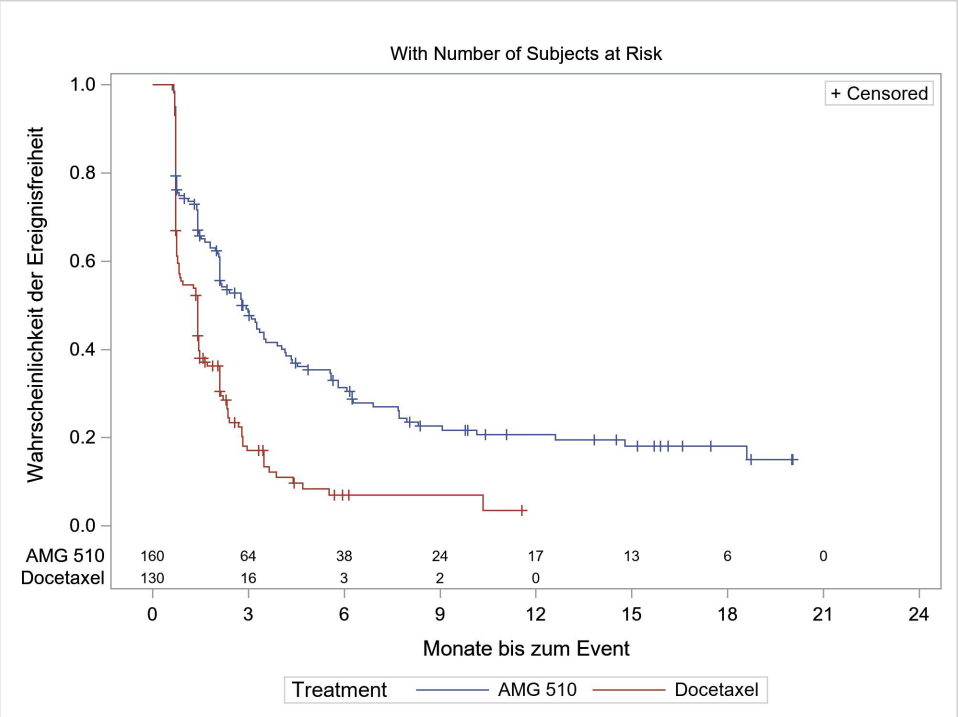

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Fatigue, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

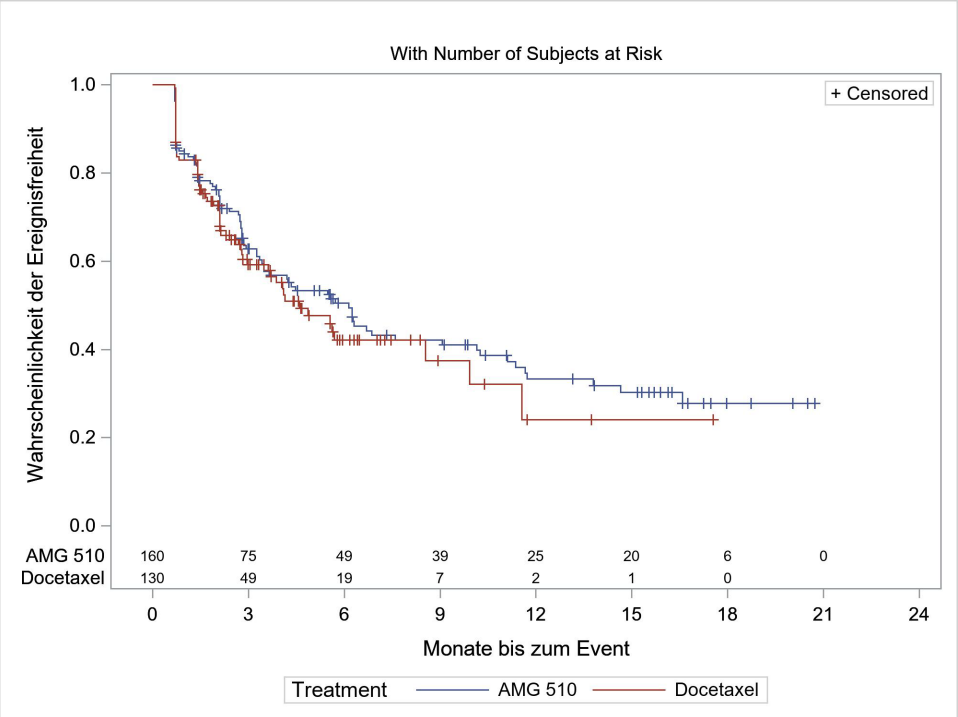

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Übelkeit und Erbrechen, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

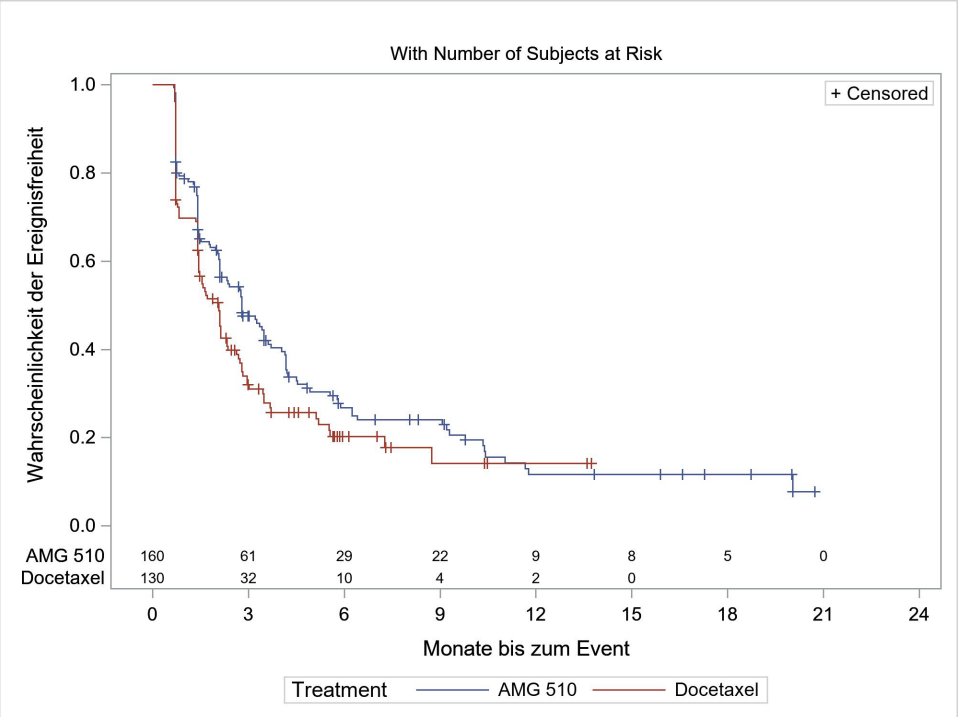

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Schmerz, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

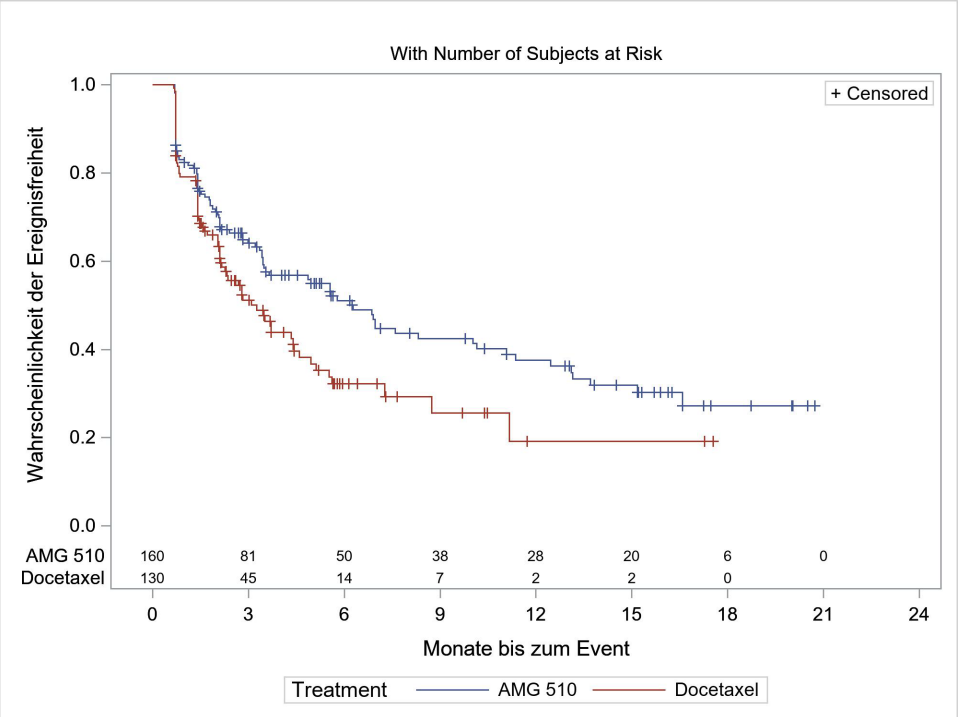

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Atemnot, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

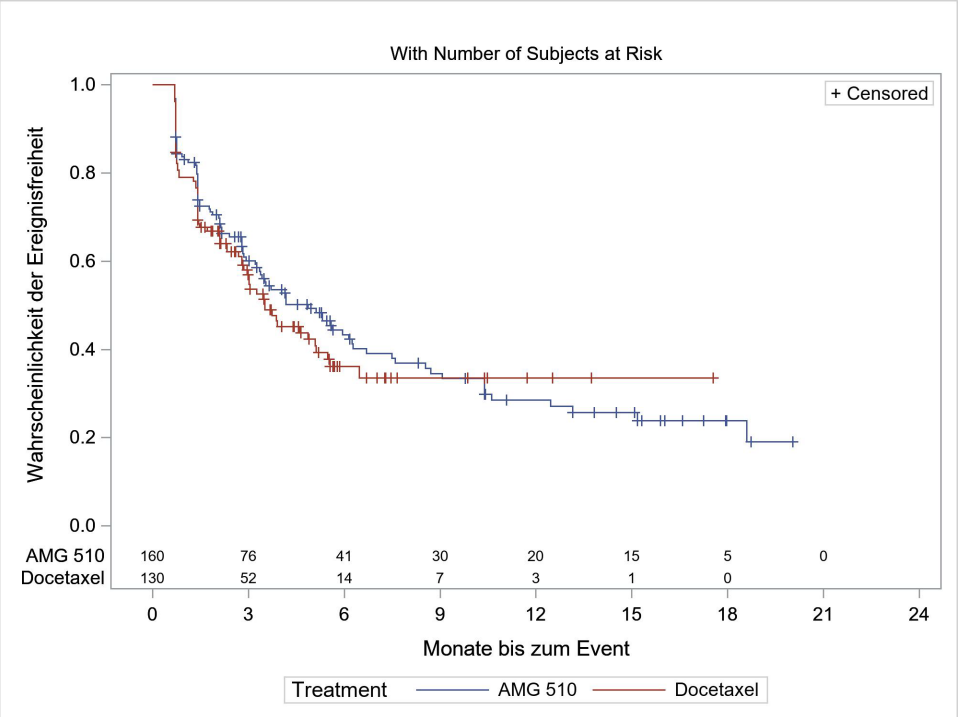

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Insomnie, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

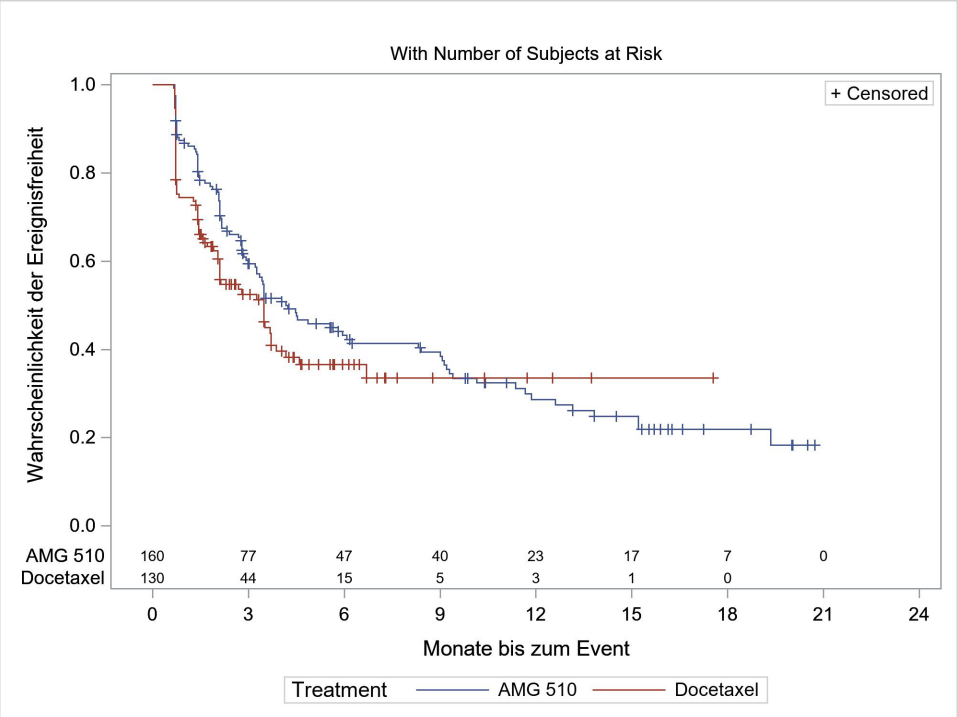

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Appetitverlust, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

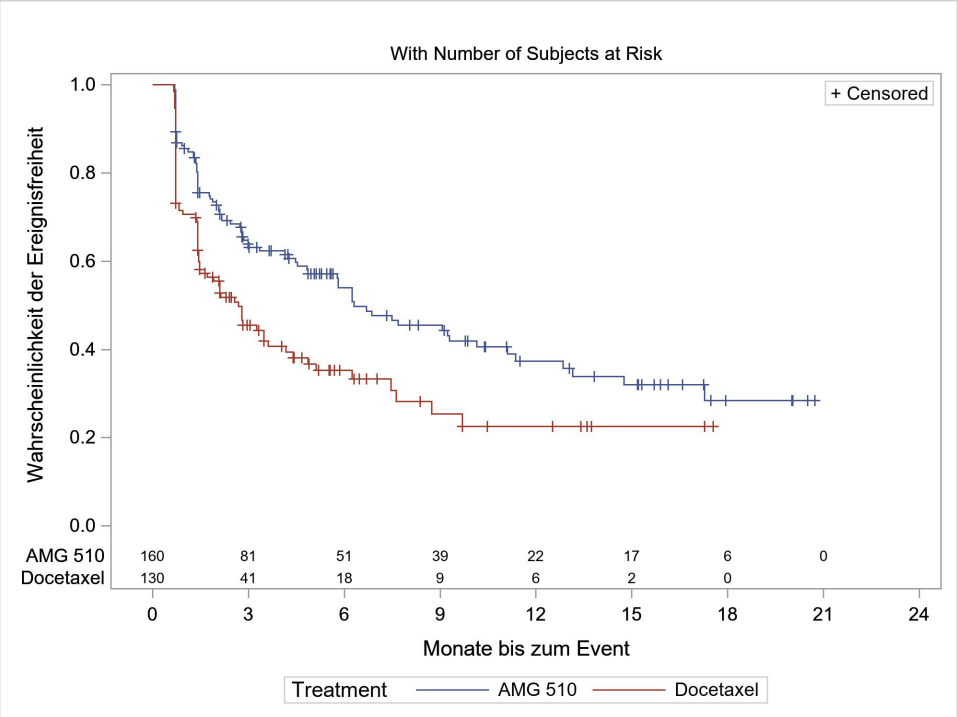

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Obstipation, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

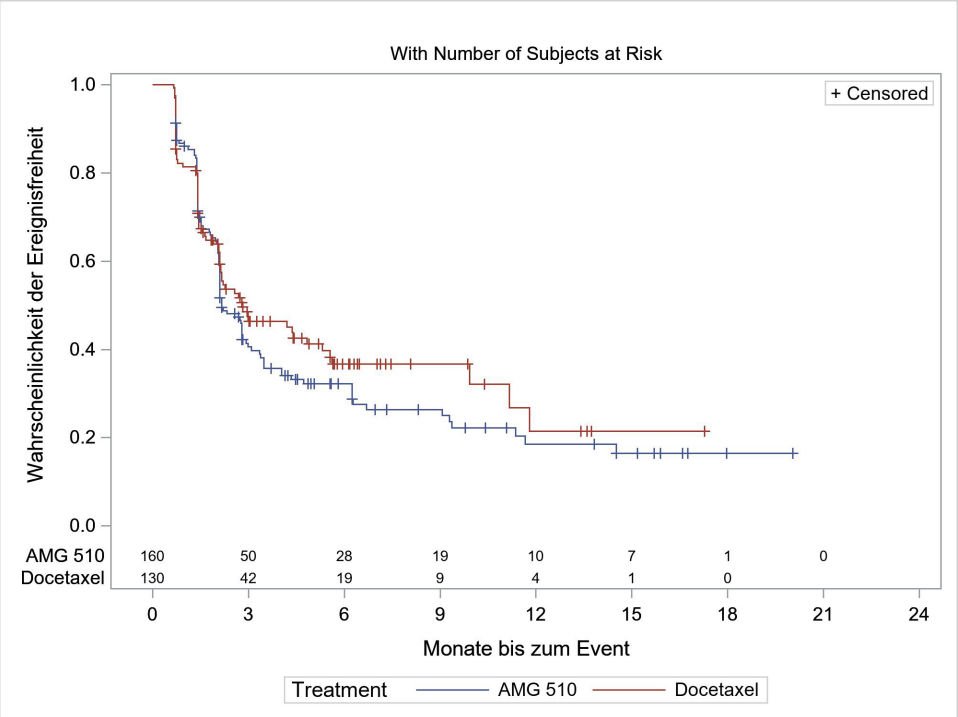

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Diarrhoe, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.1.7 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-C30 Fatigue								
160	96 (60,0)	5,8 [3,7; 8,3]	130	87 (66,9)	2,1 [1,4; 2,8]	0,50 [0,37; 0,68]	<,0001	<,0001
QLQ-C30 Übelkeit und Erbrechen								
160	87 (54,4)	6,1 [3,5; 9,1]	130	61 (46,9)	4,6 [3,0; 9,9]	0,87 [0,61; 1,23]	0,4236	0,4233
QLQ-C30 Schmerz								
160	119 (74,4)	2,8 [2,1; 3,5]	130	94 (72,3)	2,1 [1,4; 2,3]	0,80 [0,60; 1,06]	0,1235	0,1228
QLQ-C30 Atemnot								
160	88 (55,0)	6,3 [3,5; 10,2]	130	75 (57,7)	3,3 [2,2; 4,4]	0,69 [0,50; 0,95]	0,0223	0,0216
QLQ-C30 Insomnie								
160	96 (60,0)	4,9 [3,4; 6,2]	130	69 (53,1)	3,5 [2,8; 5,1]	0,89 [0,65; 1,22]	0,4702	0,4700
QLQ-C30 Appetitverlust								
160	101 (63,1)	4,2 [3,3; 6,2]	130	70 (53,8)	3,5 [2,1; 3,9]	0,75 [0,55; 1,04]	0,0857	0,0848
QLQ-C30 Obstipation								
160	83 (51,9)	6,3 [4,8; 10,2]	130	79 (60,8)	2,7 [1,5; 3,6]	0,60 [0,44; 0,83]	0,0021	0,0019
QLQ-C30 Diarrhoe								
160	109 (68,1)	2,2 [2,1; 2,9]	130	73 (56,2)	2,8 [2,1; 5,3]	1,11 [0,82; 1,50]	0,5034	0,5033

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

2.3.1.8 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

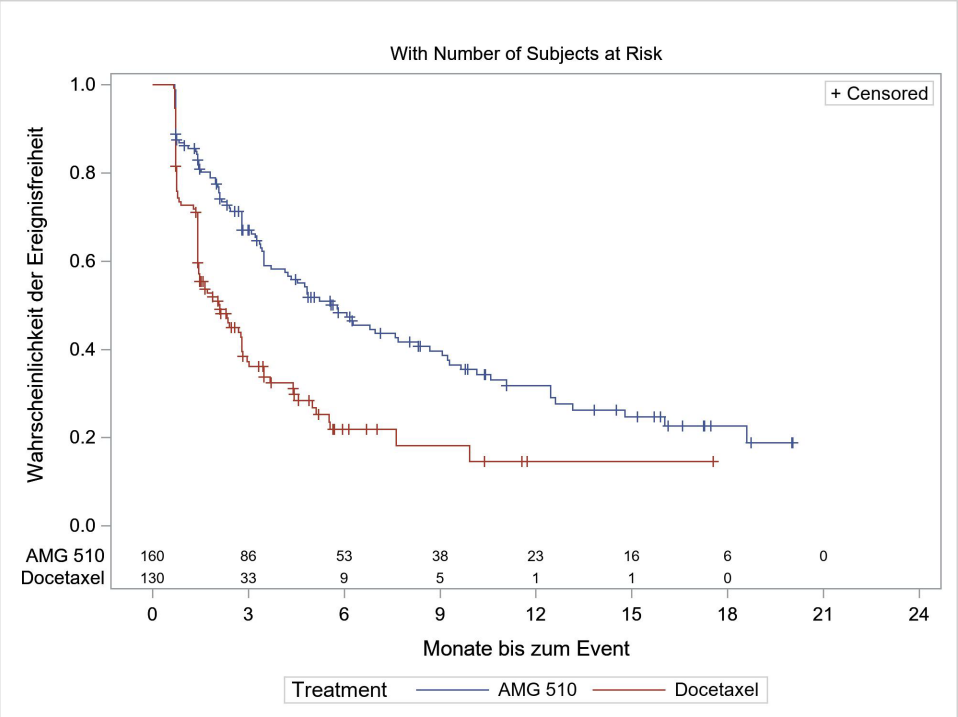

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Fatigue, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

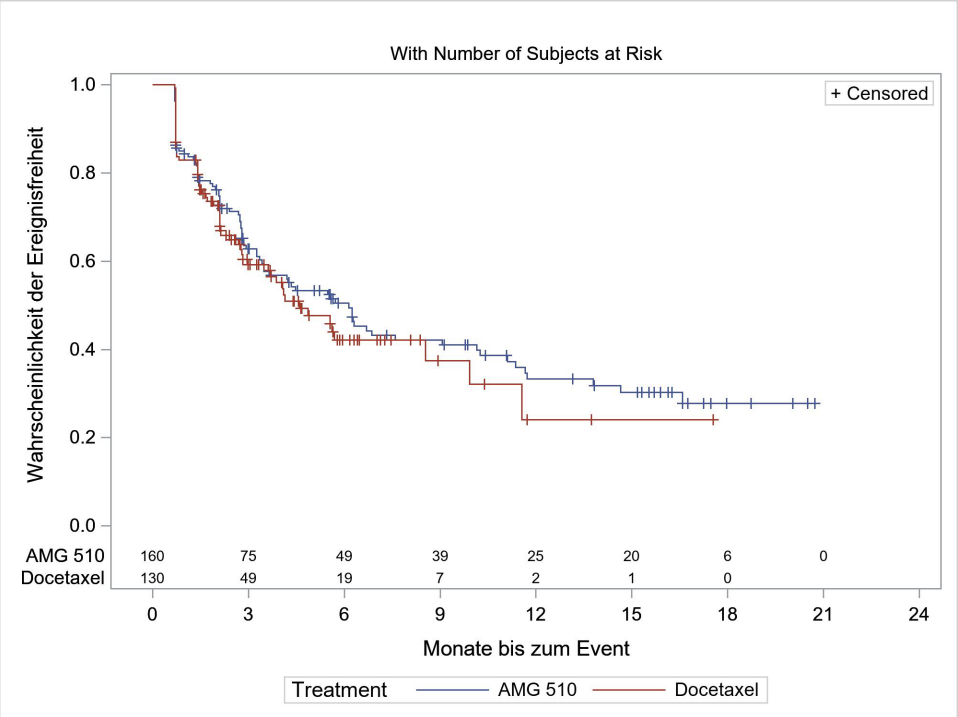

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Übelkeit und Erbrechen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

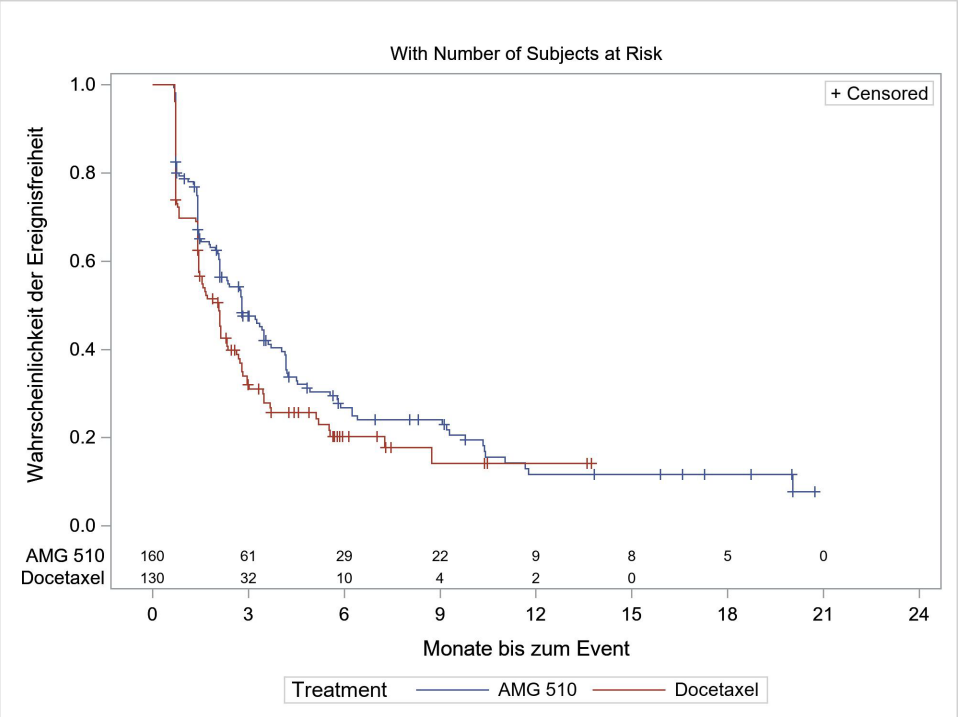

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Schmerz, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

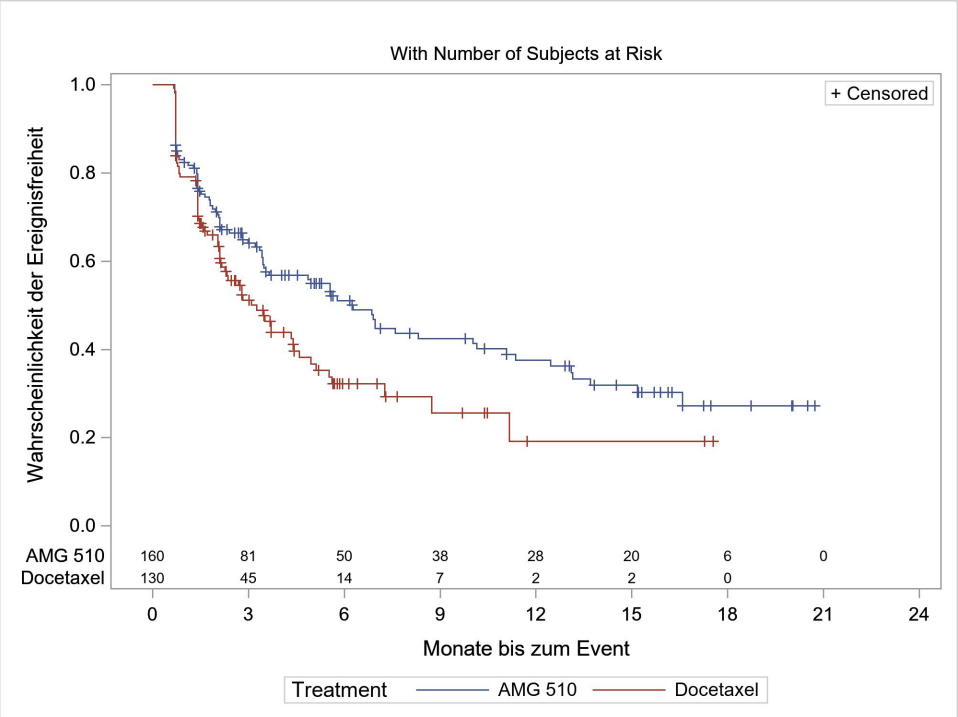

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Atemnot, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

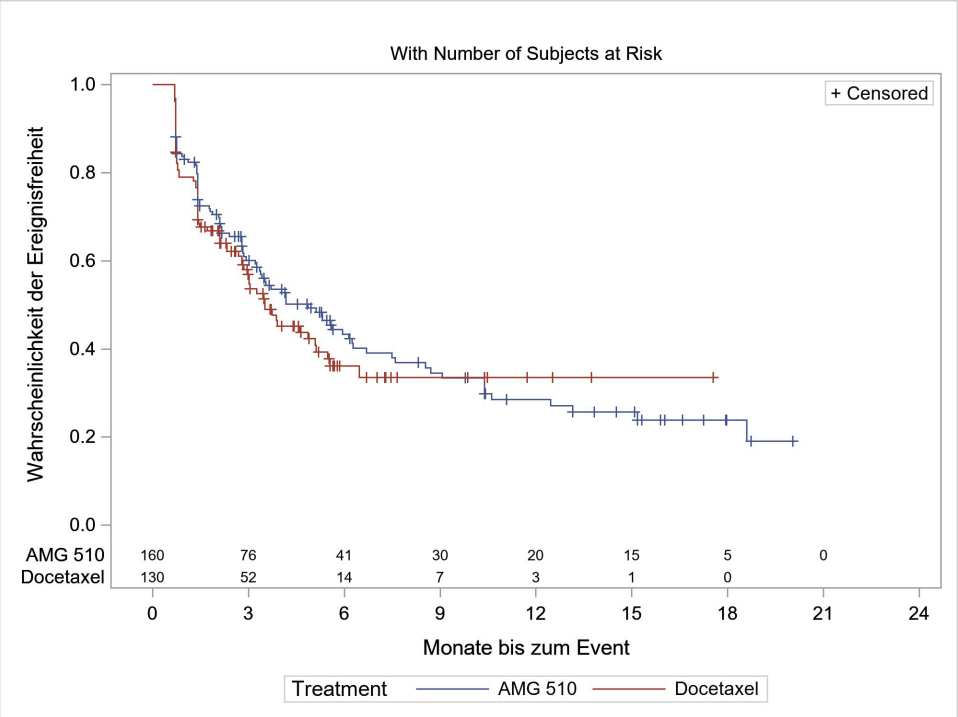

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Insomnie, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

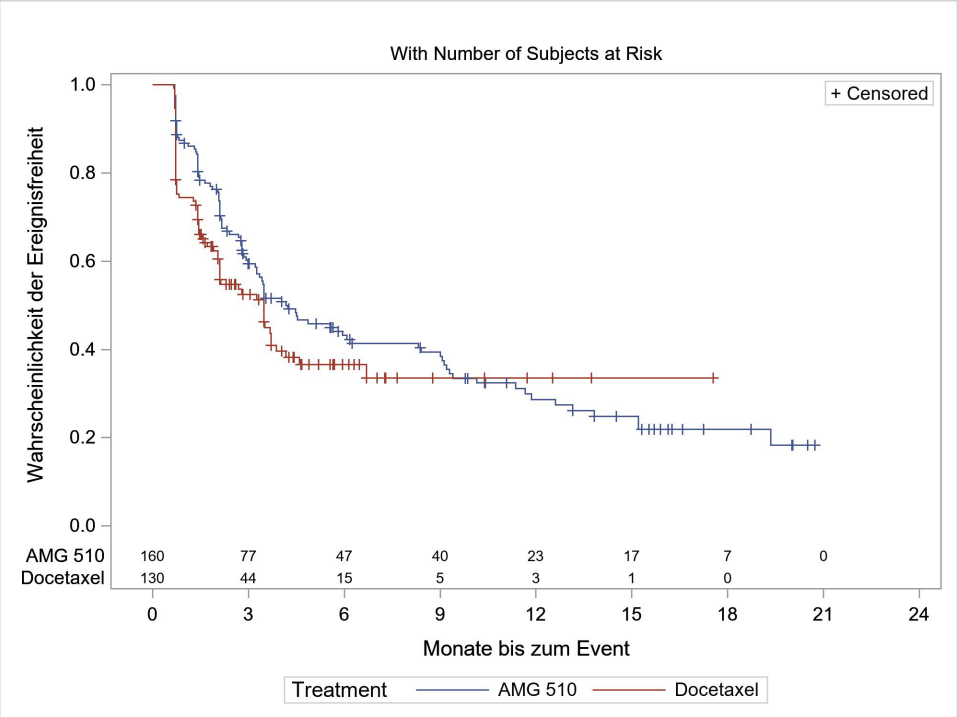

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Appetitverlust, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

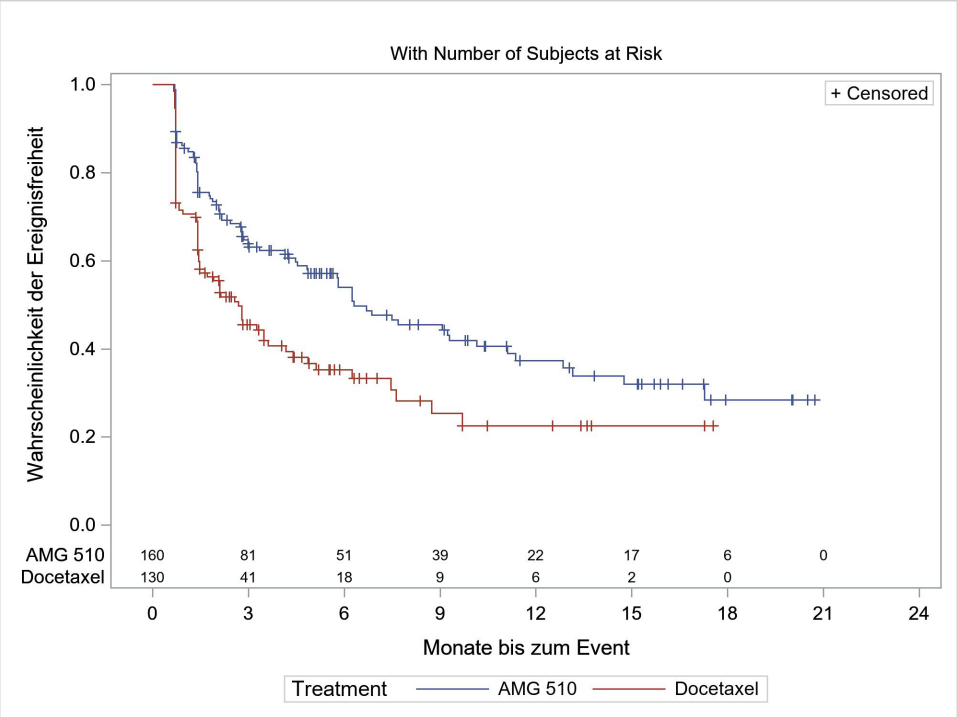

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Obstipation, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

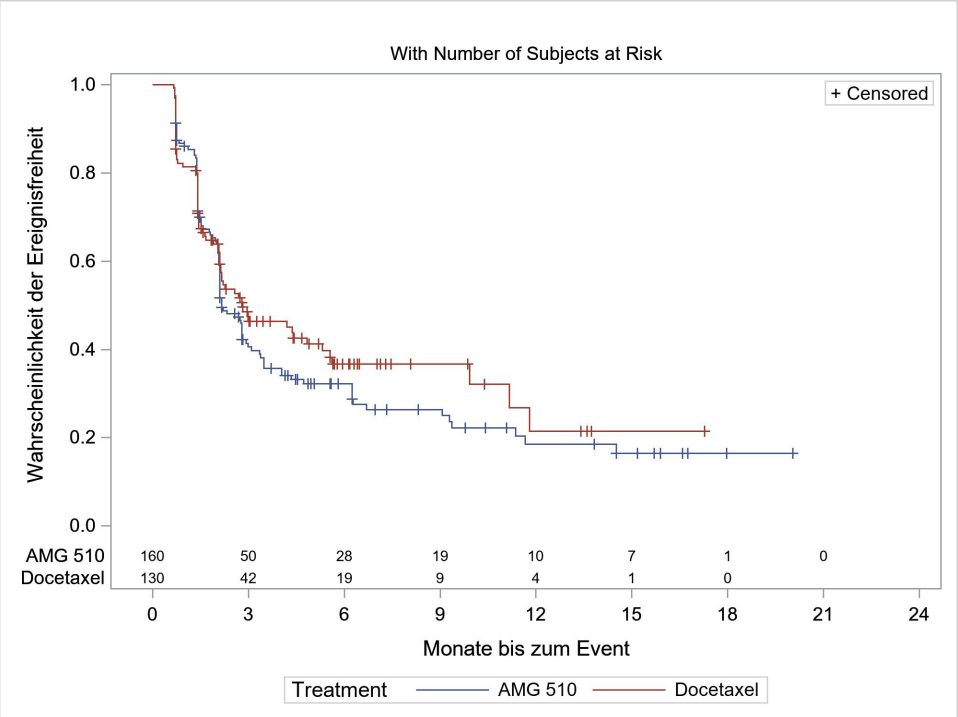

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Diarrhoe, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.1.9 Subgruppenanalysen für den Endpunkt EORTC QLQ-C30 (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Fatigue; Alter bei Studienbeginn							
<65 Jahre	56/84 (66,7)	3,5 [2,8; 8,3]	48/70 (68,6)	2,0 [1,4; 2,8]	0,6 [0,4; 0,9]	0,0159	0,2775
≥65 Jahre	40/76 (52,6)	6,3 [4,3; 12,6]	39/60 (65,0)	2,4 [1,4; 3,5]	0,4 [0,3; 0,8]	0,0019	
QLQ-C30 Fatigue; Geschlecht							
Weiblich	34/58 (58,6)	4,8 [2,8; 11,1]	36/53 (67,9)	1,6 [1,4; 2,8]	0,5 [0,3; 0,8]	0,0035	0,9614
Männlich	62/102 (60,8)	5,8 [4,1; 8,3]	51/77 (66,2)	2,4 [1,4; 4,4]	0,5 [0,3; 0,8]	0,0018	
QLQ-C30 Fatigue; Region 2							
Nordamerika und Europa	79/135 (58,5)	5,8 [3,7; 9,1]	74/111 (66,7)	2,1 [1,4; 2,8]	0,5 [0,4; 0,7]	<,0001	0,5883
Rest der Welt	17/25 (68,0)	4,1 [2,4; 6,8]	13/19 (68,4)	1,4 [0,8; 4,4]	0,7 [0,3; 1,7]	0,4371	
QLQ-C30 Fatigue; Region 1							
Nordamerika	8/17 (47,1)	10,6 [1,4; n.b.]	9/16 (56,3)	3,0 [0,8; n.b.]	0,7 [0,2; 2,5]	0,5915	0,6533
Europa	71/118 (60,2)	5,8 [3,5; 9,1]	65/95 (68,4)	2,1 [1,4; 2,8]	0,5 [0,3; 0,7]	<,0001	
Rest der Welt	17/25 (68,0)	4,1 [2,4; 6,8]	13/19 (68,4)	1,4 [0,8; 4,4]	0,7 [0,3; 1,7]	0,4371	
QLQ-C30 Fatigue; ECOG Performance-Status							
0	35/56 (62,5)	7,6 [3,5; 10,6]	39/52 (75,0)	2,1 [1,4; 3,5]	0,4 [0,2; 0,7]	0,0008	0,5933
1	61/104 (58,7)	4,8 [3,4; 6,2]	48/78 (61,5)	2,1 [1,4; 3,0]	0,5 [0,3; 0,8]	0,0016	
QLQ-C30 Fatigue; Lebermetastasen bei Studienbeginn							
Nein	77/133 (57,9)	6,3 [4,5; 9,7]	72/108 (66,7)	2,4 [1,6; 3,0]	0,5 [0,3; 0,7]	<,0001	0,8599
Ja	19/27 (70,4)	3,5 [2,8; 5,8]	15/22 (68,2)	1,4 [0,7; 2,3]	0,6 [0,2; 1,6]	0,2720	
QLQ-C30 Fatigue; Knochenmetastasen bei Studienbeginn							
Nein	58/86 (67,4)	5,6 [3,5; 8,3]	52/78 (66,7)	2,1 [1,5; 3,7]	0,6 [0,4; 0,9]	0,0073	0,1467
Ja	38/74 (51,4)	5,8 [3,4; 10,2]	35/52 (67,3)	1,4 [1,3; 2,8]	0,3 [0,2; 0,6]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Fatigue; PD-L1-Proteinexpression							
<1%	36/53 (67,9)	4,8 [3,1; 9,1]	28/43 (65,1)	1,5 [1,4; 4,4]	0,5 [0,3; 0,9]	0,0260	0,4265
≥1% und <50%	24/43 (55,8)	7,6 [2,8; 12,5]	27/50 (54,0)	2,8 [2,1; 4,4]	0,5 [0,3; 0,9]	0,0235	
≥50%	32/57 (56,1)	4,9 [3,5; 10,2]	25/29 (86,2)	1,4 [1,4; 3,0]	0,4 [0,2; 0,7]	0,0012	
QLQ-C30 Fatigue; Ethnie-2							
Asiatisch	14/21 (66,7)	4,1 [2,4; 6,8]	14/18 (77,8)	1,4 [0,7; 3,5]	0,6 [0,2; 1,3]	0,1571	0,7710
Nicht asiatisch	82/138 (59,4)	5,8 [3,5; 9,1]	72/111 (64,9)	2,4 [1,5; 2,8]	0,5 [0,4; 0,7]	<,0001	
QLQ-C30 Fatigue; Vorgeschichte einer Beteiligung des ZNS							
Nein	62/106 (58,5)	4,8 [3,5; 8,7]	60/91 (65,9)	2,1 [1,4; 3,5]	0,5 [0,4; 0,8]	0,0005	0,4654
Ja	34/54 (63,0)	6,8 [2,8; 9,7]	27/39 (69,2)	2,1 [1,4; 3,0]	0,4 [0,2; 0,7]	0,0010	
QLQ-C30 Fatigue; Anzahl an vorherigen Therapielinien							
1	38/70 (54,3)	4,9 [3,1; 9,3]	35/60 (58,3)	2,8 [1,4; 4,4]	0,6 [0,4; 1,0]	0,0558	0,5185
2	38/62 (61,3)	6,3 [4,3; 10,6]	38/50 (76,0)	1,5 [1,4; 2,8]	0,4 [0,2; 0,7]	0,0002	
>2	20/28 (71,4)	4,1 [2,8; 12,5]	14/20 (70,0)	2,3 [1,4; 5,0]	0,6 [0,3; 1,2]	0,1168	
QLQ-C30 Übelkeit und Erbrechen; Alter bei Studienbeginn							
<65 Jahre	47/84 (56,0)	4,5 [2,8; 11,4]	30/70 (42,9)	5,6 [2,8; n.b.]	1,2 [0,7; 2,0]	0,4381	0,3170
≥65 Jahre	40/76 (52,6)	6,2 [3,6; 11,7]	31/60 (51,7)	4,1 [2,5; 11,6]	0,7 [0,4; 1,3]	0,3020	
QLQ-C30 Übelkeit und Erbrechen; Geschlecht							
Weiblich	40/58 (69,0)	2,9 [2,1; 5,5]	25/53 (47,2)	4,6 [2,1; n.b.]	1,3 [0,7; 2,2]	0,4155	0,0540
Männlich	47/102 (46,1)	9,1 [5,6; 11,7]	36/77 (46,8)	4,9 [2,8; 11,6]	0,6 [0,4; 1,0]	0,0619	
QLQ-C30 Übelkeit und Erbrechen; Region 2							
Nordamerika und Europa	71/135 (52,6)	6,2 [3,4; 11,4]	55/111 (49,5)	4,1 [2,8; 8,5]	0,8 [0,6; 1,2]	0,3683	0,2230
Rest der Welt	16/25 (64,0)	3,6 [1,4; 6,9]	6/19 (31,6)	n.b. [1,5; n.b.]	1,6 [0,5; 5,3]	0,4657	
QLQ-C30 Übelkeit und Erbrechen; Region 1							
Nordamerika	7/17 (41,2)	6,1 [2,1; n.b.]	8/16 (50,0)	5,6 [3,7; 11,6]	0,6 [0,1; 2,6]	0,4847	0,3903
Europa	64/118 (54,2)	6,2 [3,3; 11,4]	47/95 (49,5)	4,1 [2,5; 5,7]	0,9 [0,6; 1,3]	0,4495	
Rest der Welt	16/25 (64,0)	3,6 [1,4; 6,9]	6/19 (31,6)	n.b. [1,5; n.b.]	1,6 [0,5; 5,3]	0,4657	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Übelkeit und Erbrechen; ECOG Performance-Status							
0	27/56 (48,2)	11,7 [6,3; n.b.]	24/52 (46,2)	5,6 [3,6; n.b.]	0,7 [0,4; 1,2]	0,1876	0,3826
1	60/104 (57,7)	3,5 [2,8; 6,1]	37/78 (47,4)	4,1 [2,1; 11,6]	1,0 [0,6; 1,5]	0,8726	
QLQ-C30 Übelkeit und Erbrechen; Lebermetastasen bei Studienbeginn							
Nein	65/133 (48,9)	6,9 [5,5; 11,7]	49/108 (45,4)	4,9 [3,7; 11,6]	0,7 [0,5; 1,1]	0,1275	0,1303
Ja	22/27 (81,5)	3,3 [0,8; 3,6]	12/22 (54,5)	2,5 [1,5; 8,5]	1,1 [0,5; 2,6]	0,8492	
QLQ-C30 Übelkeit und Erbrechen; Knochenmetastasen bei Studienbeginn							
Nein	48/86 (55,8)	6,2 [2,9; 11,4]	34/78 (43,6)	5,7 [4,1; n.b.]	1,1 [0,7; 1,7]	0,7948	0,1966
Ja	39/74 (52,7)	5,7 [3,4; 9,1]	27/52 (51,9)	2,8 [2,1; 5,6]	0,6 [0,4; 1,1]	0,0780	
QLQ-C30 Übelkeit und Erbrechen; PD-L1-Proteinexpression							
<1%	26/53 (49,1)	11,1 [3,4; n.b.]	24/43 (55,8)	4,1 [1,4; 5,7]	0,6 [0,3; 1,2]	0,1385	0,0778
≥1% und <50%	24/43 (55,8)	6,2 [2,1; 13,8]	19/50 (38,0)	4,6 [2,8; n.b.]	1,5 [0,8; 2,8]	0,2129	
≥50%	32/57 (56,1)	5,5 [3,3; 6,9]	14/29 (48,3)	9,9 [2,1; n.b.]	1,0 [0,5; 2,0]	0,9994	
QLQ-C30 Übelkeit und Erbrechen; Ethnie-2							
Asiatisch	14/21 (66,7)	5,5 [1,4; 6,9]	7/18 (38,9)	n.b. [1,5; n.b.]	1,1 [0,4; 2,9]	0,9039	0,2942
Nicht asiatisch	73/138 (52,9)	6,2 [3,4; 11,1]	53/111 (47,7)	4,6 [3,0; 8,5]	0,8 [0,6; 1,2]	0,3814	
QLQ-C30 Übelkeit und Erbrechen; Vorgeschichte einer Beteiligung des ZNS							
Nein	52/106 (49,1)	5,7 [3,4; 11,7]	42/91 (46,2)	5,6 [2,8; 11,6]	1,0 [0,7; 1,5]	0,9947	0,5874
Ja	35/54 (64,8)	6,9 [2,8; 11,1]	19/39 (48,7)	3,7 [1,7; n.b.]	0,6 [0,4; 1,2]	0,1554	
QLQ-C30 Übelkeit und Erbrechen; Anzahl an vorherigen Therapielinien							
1	37/70 (52,9)	3,6 [2,8; 11,1]	29/60 (48,3)	4,1 [2,3; 9,9]	0,9 [0,6; 1,6]	0,8043	0,6817
2	32/62 (51,6)	6,9 [4,3; 16,6]	23/50 (46,0)	5,6 [2,5; n.b.]	0,7 [0,4; 1,3]	0,2678	
>2	18/28 (64,3)	4,2 [1,4; 14,7]	9/20 (45,0)	4,1 [1,9; n.b.]	1,1 [0,5; 2,4]	0,9017	
QLQ-C30 Schmerz; Alter bei Studienbeginn							
<65 Jahre	63/84 (75,0)	2,8 [2,1; 3,5]	48/70 (68,6)	2,1 [1,4; 2,8]	0,9 [0,6; 1,3]	0,5288	0,6690
≥65 Jahre	56/76 (73,7)	2,8 [1,5; 4,2]	46/60 (76,7)	1,7 [1,4; 2,1]	0,8 [0,5; 1,2]	0,2421	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Schmerz; Geschlecht							
Weiblich	46/58 (79,3)	2,0 [1,4; 2,8]	39/53 (73,6)	1,5 [1,4; 2,7]	0,9 [0,6; 1,4]	0,6377	0,2415
Männlich	73/102 (71,6)	4,1 [2,4; 4,5]	55/77 (71,4)	2,1 [1,4; 2,7]	0,7 [0,4; 1,0]	0,0417	
QLQ-C30 Schmerz; Region 2							
Nordamerika und Europa	101/135 (74,8)	2,8 [2,1; 3,5]	81/111 (73,0)	2,1 [1,4; 2,6]	0,9 [0,7; 1,2]	0,4391	0,2502
Rest der Welt	18/25 (72,0)	4,0 [1,8; 9,3]	13/19 (68,4)	1,5 [0,8; 3,5]	0,6 [0,3; 1,4]	0,2252	
QLQ-C30 Schmerz; Region 1							
Nordamerika	12/17 (70,6)	4,8 [0,7; 6,2]	13/16 (81,3)	2,2 [0,7; 3,4]	0,9 [0,3; 2,4]	0,8368	0,5260
Europa	89/118 (75,4)	2,8 [2,0; 3,5]	68/95 (71,6)	2,1 [1,4; 2,6]	0,9 [0,6; 1,2]	0,4347	
Rest der Welt	18/25 (72,0)	4,0 [1,8; 9,3]	13/19 (68,4)	1,5 [0,8; 3,5]	0,6 [0,3; 1,4]	0,2252	
QLQ-C30 Schmerz; ECOG Performance-Status							
0	43/56 (76,8)	3,5 [2,0; 4,5]	40/52 (76,9)	1,7 [1,4; 2,8]	0,7 [0,5; 1,2]	0,1848	0,5845
1	76/104 (73,1)	2,8 [2,1; 3,5]	54/78 (69,2)	2,1 [1,4; 2,7]	0,8 [0,5; 1,1]	0,1744	
QLQ-C30 Schmerz; Lebermetastasen bei Studienbeginn							
Nein	97/133 (72,9)	2,8 [2,1; 4,1]	76/108 (70,4)	2,1 [1,5; 2,8]	0,8 [0,6; 1,1]	0,2408	0,5000
Ja	22/27 (81,5)	2,8 [1,4; 3,5]	18/22 (81,8)	1,4 [0,7; 2,1]	0,5 [0,2; 1,1]	0,0876	
QLQ-C30 Schmerz; Knochenmetastasen bei Studienbeginn							
Nein	64/86 (74,4)	2,8 [1,5; 4,1]	60/78 (76,9)	2,1 [1,4; 2,7]	0,8 [0,5; 1,1]	0,2118	0,9802
Ja	55/74 (74,3)	2,8 [2,1; 3,6]	34/52 (65,4)	2,1 [1,4; 2,6]	0,7 [0,5; 1,2]	0,1953	
QLQ-C30 Schmerz; PD-L1-Proteinexpression							
<1%	45/53 (84,9)	2,7 [2,1; 4,2]	31/43 (72,1)	1,4 [0,8; 3,0]	0,8 [0,5; 1,4]	0,4594	0,9755
≥1% und <50%	29/43 (67,4)	2,8 [1,4; 9,8]	30/50 (60,0)	2,3 [1,7; 2,8]	0,9 [0,5; 1,7]	0,8117	
≥50%	41/57 (71,9)	2,8 [1,8; 4,0]	25/29 (86,2)	1,4 [0,7; 3,0]	0,8 [0,4; 1,3]	0,3481	
QLQ-C30 Schmerz; Ethnie-2							
Asiatisch	14/21 (66,7)	4,1 [1,8; 11,0]	13/18 (72,2)	1,4 [0,7; 2,7]	0,5 [0,2; 1,1]	0,0618	0,1099
Nicht asiatisch	105/138 (76,1)	2,8 [2,1; 3,5]	80/111 (72,1)	2,1 [1,4; 2,6]	0,9 [0,6; 1,2]	0,3655	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Schmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	76/106 (71,7)	2,8 [2,1; 4,2]	69/91 (75,8)	2,1 [1,4; 2,4]	0,7 [0,5; 1,0]	0,0748	0,5369
Ja	43/54 (79,6)	2,8 [2,1; 4,1]	25/39 (64,1)	2,1 [1,4; 3,0]	0,9 [0,5; 1,4]	0,5529	
QLQ-C30 Schmerz; Anzahl an vorherigen Therapielinien							
1	51/70 (72,9)	2,3 [1,4; 3,4]	45/60 (75,0)	1,6 [1,4; 2,1]	0,8 [0,5; 1,2]	0,2503	0,8067
2	46/62 (74,2)	3,5 [2,1; 4,9]	35/50 (70,0)	2,1 [1,4; 3,0]	0,7 [0,5; 1,2]	0,1800	
>2	22/28 (78,6)	2,8 [1,4; 4,5]	14/20 (70,0)	2,7 [0,8; 5,5]	1,0 [0,5; 2,1]	0,9558	
QLQ-C30 Atemnot; Alter bei Studienbeginn							
<65 Jahre	50/84 (59,5)	5,6 [2,8; 10,0]	40/70 (57,1)	2,8 [2,1; 5,6]	0,8 [0,5; 1,3]	0,3758	0,1021
≥65 Jahre	38/76 (50,0)	7,0 [3,5; 15,2]	35/60 (58,3)	3,5 [1,7; 4,4]	0,5 [0,3; 0,9]	0,0119	
QLQ-C30 Atemnot; Geschlecht							
Weiblich	36/58 (62,1)	3,4 [2,0; 8,3]	28/53 (52,8)	3,7 [2,0; 7,3]	1,1 [0,6; 1,9]	0,7682	0,0494
Männlich	52/102 (51,0)	7,0 [5,0; 13,1]	47/77 (61,0)	2,8 [2,1; 4,4]	0,5 [0,3; 0,8]	0,0025	
QLQ-C30 Atemnot; Region 2							
Nordamerika und Europa	74/135 (54,8)	6,3 [3,4; 10,2]	66/111 (59,5)	3,1 [2,2; 4,4]	0,7 [0,5; 0,9]	0,0187	0,4412
Rest der Welt	14/25 (56,0)	5,6 [1,8; 13,7]	9/19 (47,4)	4,4 [0,8; n.b.]	0,9 [0,3; 2,2]	0,7703	
QLQ-C30 Atemnot; Region 1							
Nordamerika	5/17 (29,4)	n.b. [1,9; n.b.]	8/16 (50,0)	3,7 [1,5; n.b.]	0,6 [0,2; 2,1]	0,4175	0,6793
Europa	69/118 (58,5)	5,8 [3,4; 8,3]	58/95 (61,1)	2,8 [2,1; 4,4]	0,6 [0,4; 0,9]	0,0165	
Rest der Welt	14/25 (56,0)	5,6 [1,8; 13,7]	9/19 (47,4)	4,4 [0,8; n.b.]	0,9 [0,3; 2,2]	0,7703	
QLQ-C30 Atemnot; ECOG Performance-Status							
0	31/56 (55,4)	10,0 [5,6; 13,7]	34/52 (65,4)	3,3 [2,0; 5,5]	0,5 [0,3; 0,8]	0,0057	0,1967
1	57/104 (54,8)	5,0 [3,4; 7,0]	41/78 (52,6)	3,1 [2,1; 5,1]	0,9 [0,6; 1,4]	0,5922	
QLQ-C30 Atemnot; Lebermetastasen bei Studienbeginn							
Nein	69/133 (51,9)	7,0 [5,6; 12,5]	63/108 (58,3)	3,5 [2,2; 4,6]	0,6 [0,4; 0,8]	0,0036	0,3241
Ja	19/27 (70,4)	3,4 [0,8; 3,6]	12/22 (54,5)	2,3 [0,7; n.b.]	0,7 [0,3; 1,7]	0,3985	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Atemnot; Knochenmetastasen bei Studienbeginn							
Nein	46/86 (53,5)	7,0 [3,5; 13,1]	43/78 (55,1)	3,5 [2,3; 5,1]	0,6 [0,4; 0,9]	0,0214	0,8747
Ja	42/74 (56,8)	5,0 [2,8; 10,0]	32/52 (61,5)	2,3 [1,6; 4,6]	0,6 [0,4; 1,0]	0,0590	
QLQ-C30 Atemnot; PD-L1-Proteinexpression							
<1%	32/53 (60,4)	5,0 [2,8; 13,1]	27/43 (62,8)	2,1 [1,4; 3,7]	0,6 [0,3; 1,0]	0,0580	0,4860
≥1% und <50%	24/43 (55,8)	6,3 [1,9; 8,3]	24/50 (48,0)	4,4 [2,4; 5,6]	0,8 [0,4; 1,4]	0,3842	
≥50%	28/57 (49,1)	10,2 [3,6; 16,6]	19/29 (65,5)	3,5 [1,4; 7,3]	0,5 [0,3; 1,0]	0,0557	
QLQ-C30 Atemnot; Ethnie-2							
Asiatisch	12/21 (57,1)	6,9 [1,4; 13,7]	9/18 (50,0)	4,4 [0,8; n.b.]	0,9 [0,4; 2,3]	0,8479	0,3858
Nicht asiatisch	75/138 (54,3)	6,3 [3,5; 10,2]	65/111 (58,6)	3,1 [2,1; 4,4]	0,7 [0,5; 0,9]	0,0158	
QLQ-C30 Atemnot; Vorgeschichte einer Beteiligung des ZNS							
Nein	58/106 (54,7)	5,0 [3,0; 8,3]	55/91 (60,4)	3,5 [2,1; 4,6]	0,7 [0,5; 1,0]	0,0594	0,8361
Ja	30/54 (55,6)	10,2 [5,6; 13,1]	20/39 (51,3)	2,8 [1,4; n.b.]	0,6 [0,3; 1,1]	0,0806	
QLQ-C30 Atemnot; Anzahl an vorherigen Therapielinien							
1	34/70 (48,6)	8,3 [2,8; n.b.]	32/60 (53,3)	3,5 [2,0; 5,0]	0,8 [0,5; 1,3]	0,3207	0,9275
2	37/62 (59,7)	6,3 [3,4; 13,1]	31/50 (62,0)	2,8 [2,0; 5,1]	0,6 [0,3; 0,9]	0,0288	
>2	17/28 (60,7)	3,5 [2,1; 12,5]	12/20 (60,0)	2,7 [0,8; 8,7]	0,7 [0,3; 1,6]	0,4228	
QLQ-C30 Insomnie; Alter bei Studienbeginn							
<65 Jahre	56/84 (66,7)	2,9 [2,1; 4,9]	35/70 (50,0)	3,9 [2,7; n.b.]	1,1 [0,7; 1,8]	0,5487	0,0700
≥65 Jahre	40/76 (52,6)	6,2 [4,2; 10,4]	34/60 (56,7)	3,5 [2,1; 5,5]	0,7 [0,4; 1,1]	0,1430	
QLQ-C30 Insomnie; Geschlecht							
Weiblich	35/58 (60,3)	4,1 [2,2; 8,7]	27/53 (50,9)	3,5 [2,7; n.b.]	1,1 [0,7; 2,0]	0,6497	0,2266
Männlich	61/102 (59,8)	5,3 [3,4; 7,5]	42/77 (54,5)	3,5 [2,1; 5,1]	0,7 [0,5; 1,1]	0,1340	
QLQ-C30 Insomnie; Region 2							
Nordamerika und Europa	82/135 (60,7)	4,9 [3,2; 6,2]	58/111 (52,3)	3,9 [2,9; 5,5]	1,0 [0,7; 1,4]	0,9754	0,4378
Rest der Welt	14/25 (56,0)	6,7 [1,8; 8,5]	11/19 (57,9)	2,8 [1,3; n.b.]	0,6 [0,3; 1,5]	0,2930	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Insomnie; Region 1							
Nordamerika	10/17 (58,8)	4,9 [1,9; 13,1]	9/16 (56,3)	5,1 [1,3; n.b.]	1,6 [0,5; 5,4]	0,4528	0,7723
Europa	72/118 (61,0)	4,2 [2,9; 6,3]	49/95 (51,6)	3,9 [2,7; 5,6]	0,9 [0,6; 1,3]	0,6673	
Rest der Welt	14/25 (56,0)	6,7 [1,8; 8,5]	11/19 (57,9)	2,8 [1,3; n.b.]	0,6 [0,3; 1,5]	0,2930	
QLQ-C30 Insomnie; ECOG Performance-Status							
0	34/56 (60,7)	5,6 [2,4; 8,7]	28/52 (53,8)	3,9 [2,1; n.b.]	0,9 [0,5; 1,5]	0,6775	0,8653
1	62/104 (59,6)	4,2 [3,3; 6,1]	41/78 (52,6)	3,5 [2,8; 5,1]	0,9 [0,6; 1,4]	0,6375	
QLQ-C30 Insomnie; Lebermetastasen bei Studienbeginn							
Nein	77/133 (57,9)	5,3 [2,9; 7,5]	56/108 (51,9)	3,9 [3,0; 5,6]	1,0 [0,7; 1,4]	0,8509	0,3966
Ja	19/27 (70,4)	3,5 [2,2; 6,1]	13/22 (59,1)	2,1 [0,8; n.b.]	0,7 [0,2; 1,9]	0,4354	
QLQ-C30 Insomnie; Knochenmetastasen bei Studienbeginn							
Nein	53/86 (61,6)	5,3 [2,8; 7,6]	42/78 (53,8)	3,7 [2,7; 5,6]	1,0 [0,6; 1,5]	0,9035	0,4767
Ja	43/74 (58,1)	3,5 [2,8; 7,5]	27/52 (51,9)	3,3 [2,3; 6,5]	0,7 [0,4; 1,1]	0,1259	
QLQ-C30 Insomnie; PD-L1-Proteinexpression							
<1%	38/53 (71,7)	3,7 [2,9; 5,9]	20/43 (46,5)	5,1 [3,3; n.b.]	1,3 [0,7; 2,3]	0,3876	0,3384
≥1% und <50%	25/43 (58,1)	6,2 [2,2; 10,6]	26/50 (52,0)	2,3 [1,4; n.b.]	0,7 [0,4; 1,2]	0,1566	
≥50%	30/57 (52,6)	4,2 [2,8; 10,4]	15/29 (51,7)	3,5 [3,0; n.b.]	1,2 [0,6; 2,3]	0,5872	
QLQ-C30 Insomnie; Ethnie-2							
Asiatisch	13/21 (61,9)	3,4 [0,8; 10,4]	13/18 (72,2)	1,4 [0,8; 3,7]	0,6 [0,2; 1,3]	0,1694	0,3805
Nicht asiatisch	82/138 (59,4)	5,3 [3,3; 6,7]	55/111 (49,5)	3,9 [3,0; 5,6]	1,0 [0,7; 1,4]	0,9361	
QLQ-C30 Insomnie; Vorgeschichte einer Beteiligung des ZNS							
Nein	66/106 (62,3)	4,2 [2,9; 6,1]	47/91 (51,6)	3,9 [2,9; 6,5]	1,0 [0,7; 1,4]	0,8354	0,2483
Ja	30/54 (55,6)	6,7 [2,1; 15,2]	22/39 (56,4)	3,0 [1,4; 4,9]	0,7 [0,4; 1,2]	0,1588	
QLQ-C30 Insomnie; Anzahl an vorherigen Therapielinien							
1	46/70 (65,7)	2,9 [2,1; 5,6]	37/60 (61,7)	3,0 [1,4; 3,9]	0,9 [0,6; 1,4]	0,5434	0,6741
2	35/62 (56,5)	5,6 [4,1; 12,5]	22/50 (44,0)	5,1 [3,3; n.b.]	1,0 [0,6; 1,7]	0,9516	
>2	15/28 (53,6)	5,9 [2,8; n.b.]	10/20 (50,0)	3,0 [0,8; n.b.]	0,7 [0,3; 1,6]	0,3754	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Appetitverlust; Alter bei Studienbeginn							
<65 Jahre	52/84 (61,9)	3,5 [2,8; 9,1]	37/70 (52,9)	3,5 [2,1; 4,6]	0,8 [0,5; 1,3]	0,4694	0,5823
≥65 Jahre	49/76 (64,5)	4,2 [3,3; 9,0]	33/60 (55,0)	3,5 [1,4; n.b.]	0,8 [0,5; 1,3]	0,2986	
QLQ-C30 Appetitverlust; Geschlecht							
Weiblich	41/58 (70,7)	3,5 [2,3; 8,3]	30/53 (56,6)	3,5 [1,9; 4,2]	0,9 [0,5; 1,5]	0,6354	0,2434
Männlich	60/102 (58,8)	4,5 [3,4; 9,2]	40/77 (51,9)	3,5 [1,6; 6,7]	0,6 [0,4; 1,0]	0,0337	
QLQ-C30 Appetitverlust; Region 2							
Nordamerika und Europa	83/135 (61,5)	4,5 [3,3; 9,1]	59/111 (53,2)	3,5 [2,1; 4,2]	0,8 [0,5; 1,1]	0,1465	0,8044
Rest der Welt	18/25 (72,0)	3,4 [2,1; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,8]	0,4954	
QLQ-C30 Appetitverlust; Region 1							
Nordamerika	9/17 (52,9)	3,3 [2,1; n.b.]	8/16 (50,0)	3,7 [0,7; n.b.]	1,6 [0,4; 6,7]	0,5487	0,6728
Europa	74/118 (62,7)	4,9 [3,3; 9,1]	51/95 (53,7)	2,8 [2,1; 4,2]	0,7 [0,5; 1,0]	0,0801	
Rest der Welt	18/25 (72,0)	3,4 [2,1; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,8]	0,4954	
QLQ-C30 Appetitverlust; ECOG Performance-Status							
0	29/56 (51,8)	10,2 [4,5; 19,4]	31/52 (59,6)	2,8 [1,4; 4,6]	0,5 [0,3; 0,8]	0,0085	0,0513
1	72/104 (69,2)	3,3 [2,8; 4,2]	39/78 (50,0)	3,5 [2,0; 6,7]	0,9 [0,6; 1,4]	0,6504	
QLQ-C30 Appetitverlust; Lebermetastasen bei Studienbeginn							
Nein	78/133 (58,6)	4,9 [3,5; 9,3]	56/108 (51,9)	3,5 [2,1; 6,7]	0,8 [0,5; 1,1]	0,1594	0,9781
Ja	23/27 (85,2)	3,3 [2,2; 4,2]	14/22 (63,6)	1,9 [0,7; 3,7]	0,4 [0,2; 1,1]	0,0817	
QLQ-C30 Appetitverlust; Knochenmetastasen bei Studienbeginn							
Nein	55/86 (64,0)	3,5 [2,3; 9,2]	39/78 (50,0)	3,5 [2,1; n.b.]	0,9 [0,6; 1,4]	0,7224	0,1089
Ja	46/74 (62,2)	4,5 [3,0; 9,0]	31/52 (59,6)	2,1 [1,6; 3,7]	0,5 [0,3; 0,8]	0,0026	
QLQ-C30 Appetitverlust; PD-L1-Proteinexpression							
<1%	34/53 (64,2)	4,5 [2,2; 11,7]	24/43 (55,8)	2,1 [1,4; n.b.]	0,6 [0,4; 1,1]	0,1283	0,4980
≥1% und <50%	27/43 (62,8)	4,9 [2,2; 8,4]	22/50 (44,0)	3,5 [2,1; n.b.]	0,9 [0,5; 1,6]	0,6595	
≥50%	37/57 (64,9)	3,5 [2,8; 5,8]	18/29 (62,1)	3,5 [1,9; 6,7]	0,8 [0,4; 1,5]	0,5311	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Appetitverlust; Ethnie-2							
Asiatisch	15/21 (71,4)	3,0 [1,4; 6,1]	12/18 (66,7)	1,5 [0,7; n.b.]	0,7 [0,3; 1,6]	0,4086	0,9144
Nicht asiatisch	86/138 (62,3)	4,5 [3,3; 9,0]	57/111 (51,4)	3,5 [2,1; 4,6]	0,8 [0,6; 1,1]	0,1715	
QLQ-C30 Appetitverlust; Vorgeschichte einer Beteiligung des ZNS							
Nein	65/106 (61,3)	3,5 [2,9; 8,4]	47/91 (51,6)	3,5 [2,1; 6,7]	0,8 [0,6; 1,2]	0,3513	0,3137
Ja	36/54 (66,7)	4,5 [2,8; 9,1]	23/39 (59,0)	2,1 [0,8; 3,7]	0,5 [0,3; 0,9]	0,0169	
QLQ-C30 Appetitverlust; Anzahl an vorherigen Therapielinien							
1	41/70 (58,6)	3,4 [2,7; 9,1]	32/60 (53,3)	3,5 [1,7; 3,7]	0,7 [0,4; 1,2]	0,1592	0,9540
2	39/62 (62,9)	4,9 [2,8; 13,8]	26/50 (52,0)	4,6 [1,4; n.b.]	0,9 [0,5; 1,4]	0,5622	
>2	21/28 (75,0)	4,2 [2,8; 5,9]	12/20 (60,0)	3,5 [1,4; 4,2]	0,7 [0,3; 1,5]	0,3678	
QLQ-C30 Obstipation; Alter bei Studienbeginn							
<65 Jahre	49/84 (58,3)	4,5 [2,8; 9,2]	44/70 (62,9)	2,1 [1,4; 5,1]	0,8 [0,5; 1,2]	0,2923	0,1467
≥65 Jahre	34/76 (44,7)	9,1 [5,8; 13,1]	35/60 (58,3)	2,8 [1,5; 4,2]	0,4 [0,2; 0,7]	0,0013	
QLQ-C30 Obstipation; Geschlecht							
Weiblich	33/58 (56,9)	6,7 [2,8; 13,1]	31/53 (58,5)	2,7 [1,4; 7,6]	0,8 [0,5; 1,4]	0,4518	0,2190
Männlich	50/102 (49,0)	6,2 [4,5; 11,4]	48/77 (62,3)	2,8 [1,4; 4,9]	0,5 [0,3; 0,8]	0,0019	
QLQ-C30 Obstipation; Region 2							
Nordamerika und Europa	69/135 (51,1)	7,5 [4,8; 12,8]	67/111 (60,4)	2,8 [1,5; 4,4]	0,6 [0,4; 0,9]	0,0042	0,6983
Rest der Welt	14/25 (56,0)	6,2 [1,8; 6,9]	12/19 (63,2)	2,1 [1,0; n.b.]	0,8 [0,3; 2,1]	0,6797	
QLQ-C30 Obstipation; Region 1							
Nordamerika	7/17 (41,2)	4,9 [1,4; n.b.]	8/16 (50,0)	6,2 [0,7; n.b.]	0,8 [0,3; 2,6]	0,7151	0,7941
Europa	62/118 (52,5)	7,5 [4,5; 12,8]	59/95 (62,1)	2,7 [1,4; 3,6]	0,5 [0,4; 0,8]	0,0016	
Rest der Welt	14/25 (56,0)	6,2 [1,8; 6,9]	12/19 (63,2)	2,1 [1,0; n.b.]	0,8 [0,3; 2,1]	0,6797	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Obstipation; ECOG Performance-Status							
0	30/56 (53,6)	10,2 [4,5; 17,3]	30/52 (57,7)	3,5 [1,4; 9,7]	0,6 [0,3; 1,0]	0,0430	0,9070
1	53/104 (51,0)	5,8 [3,0; 9,2]	49/78 (62,8)	2,6 [1,4; 4,2]	0,6 [0,4; 0,9]	0,0146	
QLQ-C30 Obstipation; Lebermetastasen bei Studienbeginn							
Nein	68/133 (51,1)	6,9 [5,8; 11,4]	64/108 (59,3)	3,3 [1,5; 5,1]	0,6 [0,4; 0,9]	0,0047	0,8756
Ja	15/27 (55,6)	4,8 [2,8; n.b.]	15/22 (68,2)	1,6 [0,7; 2,8]	0,3 [0,1; 1,0]	0,0375	
QLQ-C30 Obstipation; Knochenmetastasen bei Studienbeginn							
Nein	46/86 (53,5)	6,3 [2,8; 11,4]	50/78 (64,1)	2,7 [1,4; 4,9]	0,6 [0,4; 0,9]	0,0114	0,6694
Ja	37/74 (50,0)	6,7 [4,5; 12,8]	29/52 (55,8)	2,8 [1,4; 8,7]	0,6 [0,4; 1,0]	0,0625	
QLQ-C30 Obstipation; PD-L1-Proteinexpression							
<1%	24/53 (45,3)	7,5 [4,3; n.b.]	27/43 (62,8)	2,8 [1,4; 7,6]	0,6 [0,3; 1,0]	0,0583	0,3235
≥1% und <50%	26/43 (60,5)	6,2 [1,8; 9,3]	26/50 (52,0)	2,8 [1,6; n.b.]	0,9 [0,5; 1,7]	0,8370	
≥50%	29/57 (50,9)	6,7 [4,1; 11,1]	20/29 (69,0)	2,1 [0,7; 6,2]	0,5 [0,3; 1,0]	0,0390	
QLQ-C30 Obstipation; Ethnie-2							
Asiatisch	10/21 (47,6)	6,2 [2,4; 9,3]	13/18 (72,2)	1,4 [0,7; 4,2]	0,5 [0,2; 1,1]	0,0781	0,3275
Nicht asiatisch	72/138 (52,2)	6,7 [4,5; 11,4]	65/111 (58,6)	2,8 [1,7; 4,9]	0,6 [0,4; 0,9]	0,0092	
QLQ-C30 Obstipation; Vorgeschichte einer Beteiligung des ZNS							
Nein	54/106 (50,9)	7,5 [4,5; 12,8]	55/91 (60,4)	2,8 [1,5; 4,9]	0,6 [0,4; 0,9]	0,0072	0,8927
Ja	29/54 (53,7)	6,3 [2,8; 11,4]	24/39 (61,5)	2,1 [1,4; 4,2]	0,5 [0,3; 1,0]	0,0400	
QLQ-C30 Obstipation; Anzahl an vorherigen Therapielinien							
1	35/70 (50,0)	9,1 [3,4; 12,8]	36/60 (60,0)	2,8 [1,4; 4,2]	0,6 [0,3; 0,9]	0,0215	0,9730
2	33/62 (53,2)	6,2 [4,1; 17,3]	31/50 (62,0)	2,1 [1,4; 7,5]	0,6 [0,4; 1,0]	0,0678	
>2	15/28 (53,6)	6,3 [1,4; n.b.]	12/20 (60,0)	2,7 [0,7; n.b.]	0,6 [0,3; 1,4]	0,2409	
QLQ-C30 Diarrhoe; Alter bei Studienbeginn							
<65 Jahre	62/84 (73,8)	2,1 [1,6; 2,2]	40/70 (57,1)	4,2 [1,9; 5,6]	1,3 [0,8; 1,9]	0,2911	0,5074
≥65 Jahre	47/76 (61,8)	2,8 [2,2; 6,2]	33/60 (55,0)	2,3 [2,1; n.b.]	1,0 [0,6; 1,6]	0,9992	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Diarrhoe; Geschlecht							
Weiblich	45/58 (77,6)	2,1 [2,1; 2,8]	31/53 (58,5)	2,7 [1,4; 9,9]	1,2 [0,7; 2,0]	0,4853	0,3191
Männlich	64/102 (62,7)	2,8 [2,0; 4,0]	42/77 (54,5)	3,0 [2,1; 4,8]	1,0 [0,6; 1,5]	0,8772	
QLQ-C30 Diarrhoe; Region 2							
Nordamerika und Europa	91/135 (67,4)	2,2 [2,1; 2,9]	63/111 (56,8)	3,0 [2,1; 5,3]	1,1 [0,8; 1,6]	0,5165	0,7458
Rest der Welt	18/25 (72,0)	2,8 [1,4; 6,2]	10/19 (52,6)	2,6 [1,3; n.b.]	1,2 [0,5; 3,1]	0,6363	
QLQ-C30 Diarrhoe; Region 1							
Nordamerika	10/17 (58,8)	2,7 [1,5; n.b.]	7/16 (43,8)	5,6 [1,4; n.b.]	2,1 [0,6; 7,0]	0,2367	0,8698
Europa	81/118 (68,6)	2,2 [2,1; 3,0]	56/95 (58,9)	2,8 [2,1; 4,4]	1,0 [0,7; 1,5]	0,8265	
Rest der Welt	18/25 (72,0)	2,8 [1,4; 6,2]	10/19 (52,6)	2,6 [1,3; n.b.]	1,2 [0,5; 3,1]	0,6363	
QLQ-C30 Diarrhoe; ECOG Performance-Status							
0	42/56 (75,0)	2,2 [2,0; 3,0]	31/52 (59,6)	4,8 [2,1; 9,9]	1,3 [0,8; 2,1]	0,3435	0,6612
1	67/104 (64,4)	2,7 [2,1; 3,5]	42/78 (53,8)	2,7 [1,9; 4,4]	1,1 [0,7; 1,6]	0,7436	
QLQ-C30 Diarrhoe; Lebermetastasen bei Studienbeginn							
Nein	89/133 (66,9)	2,3 [2,1; 3,1]	63/108 (58,3)	2,8 [2,1; 5,3]	1,1 [0,8; 1,5]	0,6508	0,6002
Ja	20/27 (74,1)	2,1 [1,6; 3,4]	10/22 (45,5)	3,0 [1,4; n.b.]	1,0 [0,4; 2,4]	0,9288	
QLQ-C30 Diarrhoe; Knochenmetastasen bei Studienbeginn							
Nein	63/86 (73,3)	2,2 [2,1; 3,0]	39/78 (50,0)	5,3 [2,6; 11,2]	1,5 [1,0; 2,4]	0,0398	0,0060
Ja	46/74 (62,2)	2,2 [1,6; 4,0]	34/52 (65,4)	2,1 [1,4; 2,8]	0,7 [0,4; 1,1]	0,0819	
QLQ-C30 Diarrhoe; PD-L1-Proteinexpression							
<1%	37/53 (69,8)	2,1 [1,6; 4,0]	23/43 (53,5)	4,2 [2,2; 9,9]	1,0 [0,6; 1,8]	0,8903	0,3438
≥1% und <50%	32/43 (74,4)	2,1 [1,4; 2,7]	31/50 (62,0)	2,1 [1,4; 3,0]	0,9 [0,5; 1,6]	0,7289	
≥50%	35/57 (61,4)	2,8 [2,1; 3,5]	12/29 (41,4)	11,2 [2,1; n.b.]	1,9 [0,9; 3,7]	0,0802	
QLQ-C30 Diarrhoe; Ethnie-2							
Asiatisch	16/21 (76,2)	1,8 [1,4; 4,7]	10/18 (55,6)	2,2 [1,0; n.b.]	1,3 [0,5; 3,0]	0,5739	0,5084
Nicht asiatisch	93/138 (67,4)	2,2 [2,1; 3,0]	62/111 (55,9)	3,0 [2,1; 5,3]	1,1 [0,8; 1,6]	0,5009	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Diarrhoe; Vorgeschichte einer Beteiligung des ZNS							
Nein	71/106 (67,0)	2,3 [2,1; 3,0]	54/91 (59,3)	2,6 [1,6; 5,3]	1,0 [0,7; 1,5]	0,9238	0,3379
Ja	38/54 (70,4)	2,2 [1,9; 4,7]	19/39 (48,7)	4,8 [2,1; n.b.]	1,4 [0,8; 2,4]	0,2899	
QLQ-C30 Diarrhoe; Anzahl an vorherigen Therapielinien							
1	49/70 (70,0)	2,0 [1,5; 2,9]	30/60 (50,0)	2,8 [1,4; 11,2]	1,2 [0,8; 2,0]	0,3728	0,4349
2	43/62 (69,4)	2,7 [2,1; 3,5]	31/50 (62,0)	3,0 [2,1; 5,6]	1,2 [0,8; 1,9]	0,4396	
>2	17/28 (60,7)	3,5 [2,1; 6,7]	12/20 (60,0)	2,2 [1,4; n.b.]	0,7 [0,3; 1,5]	0,3121	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-C30 = Quality of Life Questionnaire Core 30; ZNS = Zentrales Nervensystem

2.3.2 EORTC QLQ-LC13

2.3.2.1 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-LC13

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-LC13 Dysphagie								
158	45 (28,5)	n.b. [18,7; n.b.]	124	46 (37,1)	6,9 [4,7; n.b.]	0,61 [0,40; 0,93]	0,0223	0,0210
QLQ-LC13 Dyspnoe								
158	93 (58,9)	3,6 [2,8; 6,2]	124	92 (74,2)	1,5 [1,4; 2,1]	0,55 [0,40; 0,75]	0,0001	0,0001
QLQ-LC13 Haarausfall								
158	32 (20,3)	n.b. [19,4; n.b.]	124	110 (88,7)	0,7 [0,7; 0,8]	0,07 [0,05; 0,12]	<,0001	<,0001
QLQ-LC13 Husten								
158	52 (32,9)	16,6 [11,9; n.b.]	124	52 (41,9)	4,6 [2,8; n.b.]	0,50 [0,33; 0,76]	0,0012	0,0010
QLQ-LC13 Periphere Neuropathie								
158	65 (41,1)	10,3 [5,5; n.b.]	124	66 (53,2)	3,5 [2,8; 5,6]	0,61 [0,42; 0,87]	0,0068	0,0063
QLQ-LC13 Schmerzen (Arm/Schulter)								
158	85 (53,8)	5,2 [4,0; 9,0]	124	49 (39,5)	14,1 [3,7; 14,1]	1,11 [0,77; 1,61]	0,5634	0,5632
QLQ-LC13 Schmerzen (andere)								
158	90 (57,0)	4,2 [2,8; 7,8]	124	68 (54,8)	3,0 [2,3; 4,0]	0,82 [0,59; 1,15]	0,2521	0,2514
QLQ-LC13 Schmerzen (Thorax)								
158	59 (37,3)	13,1 [6,4; n.b.]	124	48 (38,7)	7,3 [5,6; n.b.]	0,80 [0,54; 1,18]	0,2601	0,2592
QLQ-LC13 Wirksamkeit der Schmerzmedikation								
137	48 (35,0)	11,0 [7,6; n.b.]	101	32 (31,7)	n.b. [3,5; n.b.]	0,86 [0,53; 1,39]	0,5326	0,5322
QLQ-LC13 Wunder Mund								
158	42 (26,6)	n.b. [14,5; n.b.]	124	57 (46,0)	4,4 [2,8; n.b.]	0,39 [0,26; 0,60]	<,0001	<,0001
QLQ-LC13 Bluthusten								
158	18 (11,4)	n.b. [n.b.; n.b.]	124	21 (16,9)	n.b. [9,9; n.b.]	0,39 [0,20; 0,78]	0,0074	0,0058

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; n.b. = nicht berechenbar; QLQ-LC13 = Quality of Life Questionnaire Lung Cancer 13

2.3.2.2 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-LC13

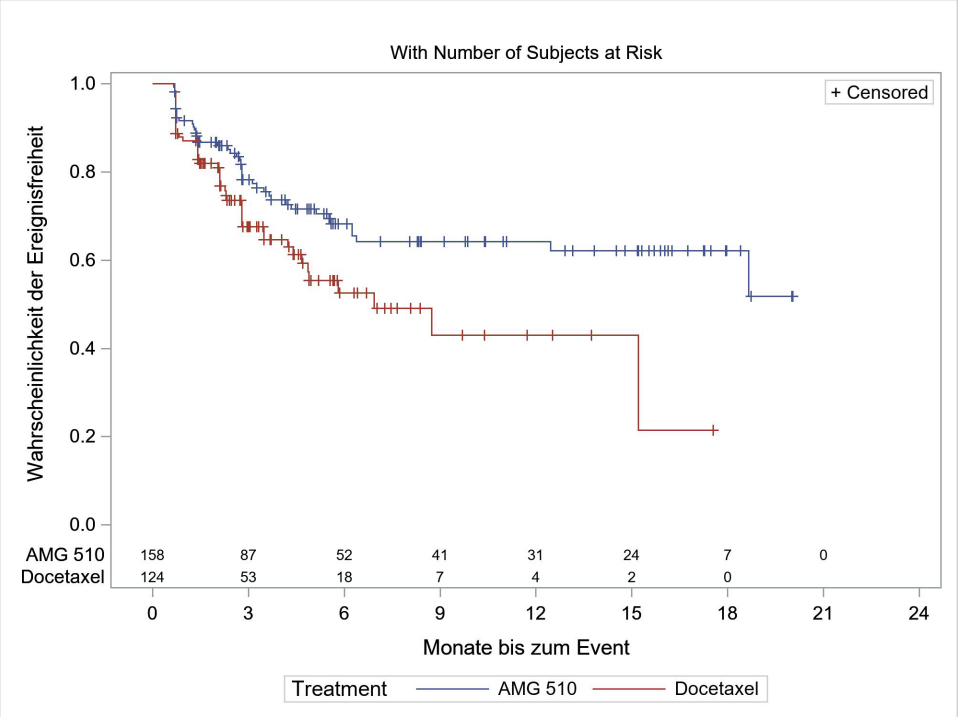

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dysphagie, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

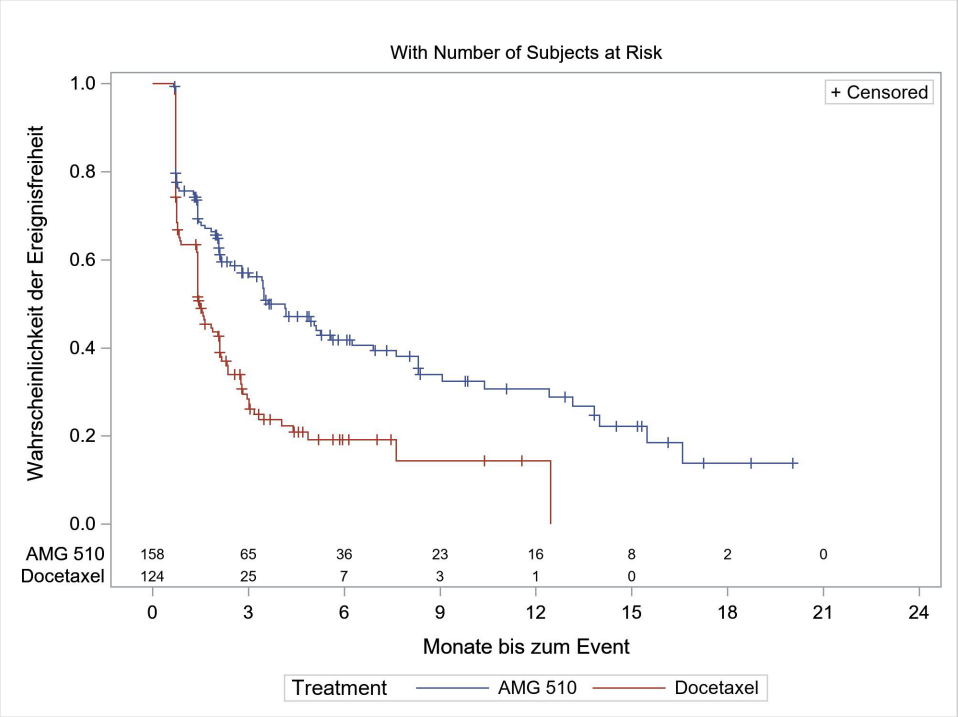

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dyspnoe, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

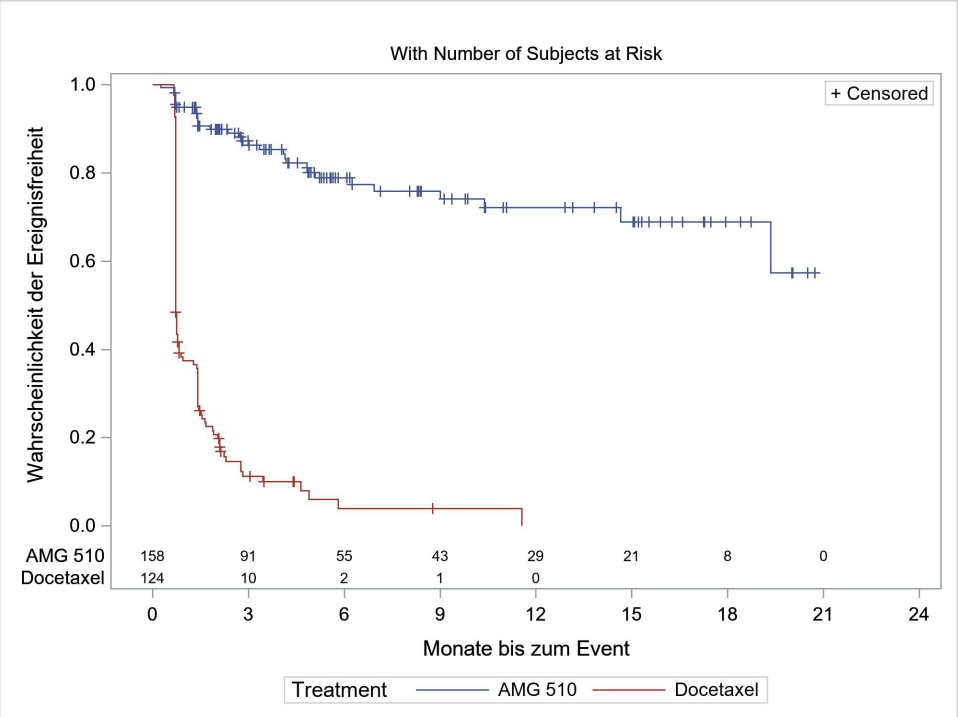

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Haarausfall, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

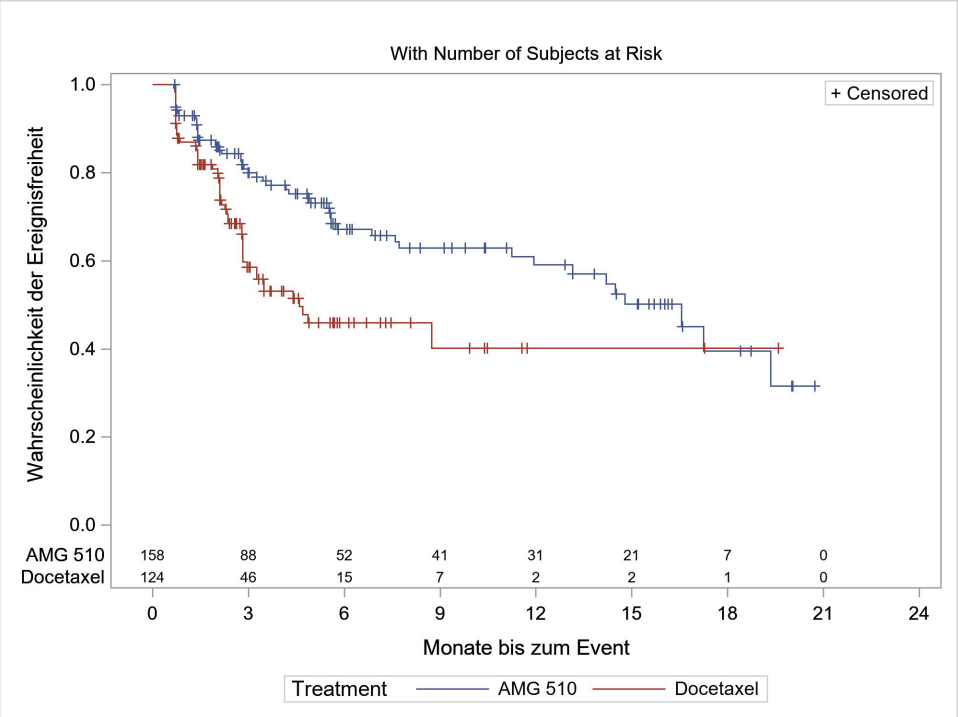

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Husten, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

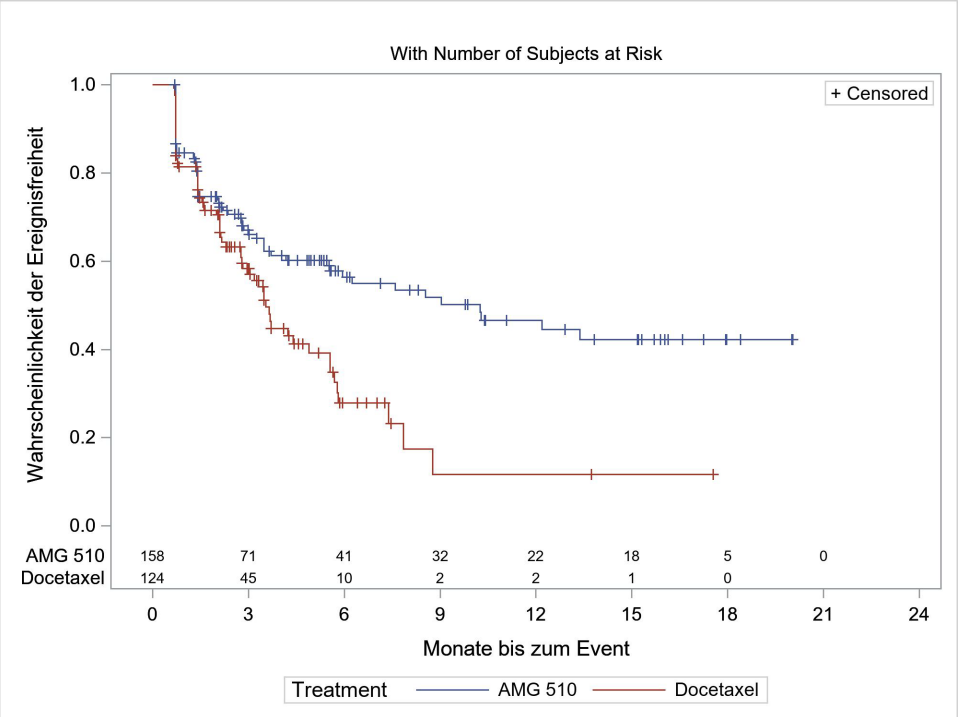

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Periphere Neuropathie, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

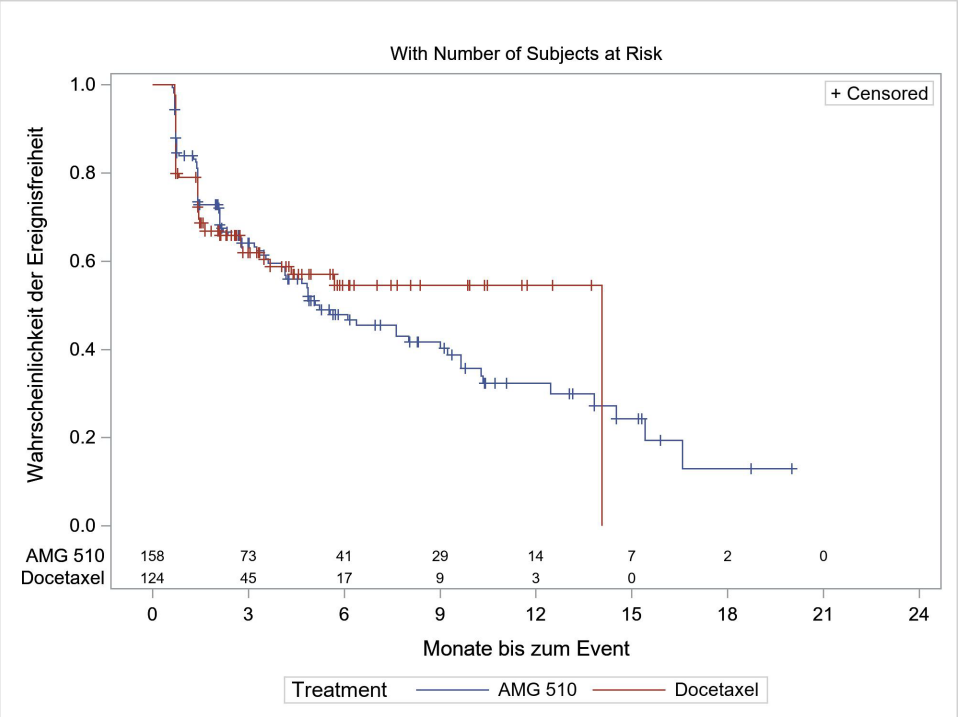

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Arm/Schulter), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

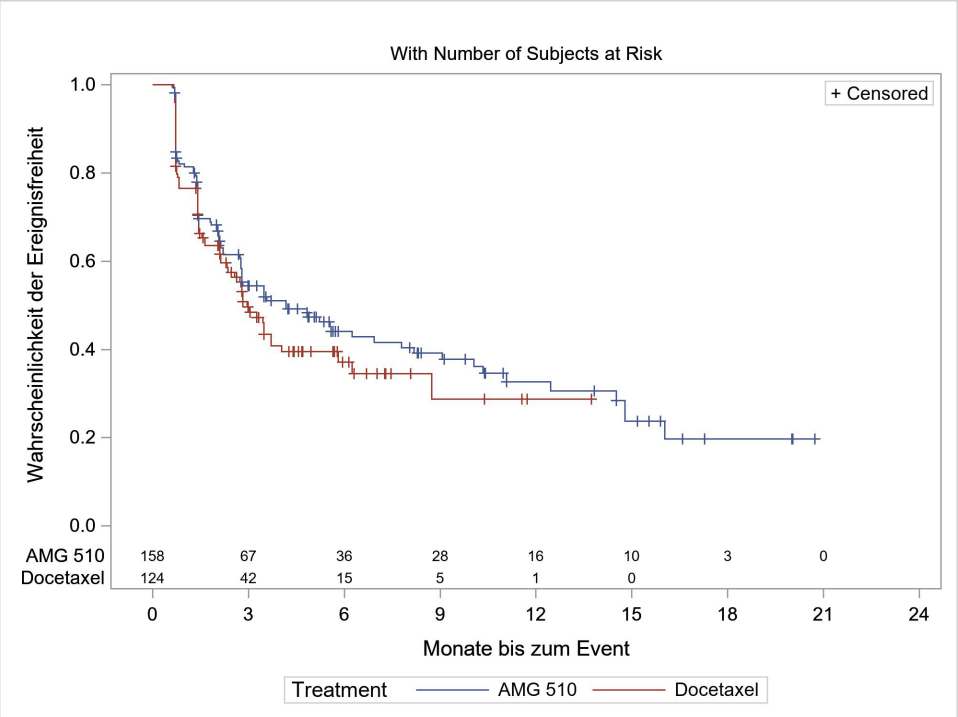

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (andere), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

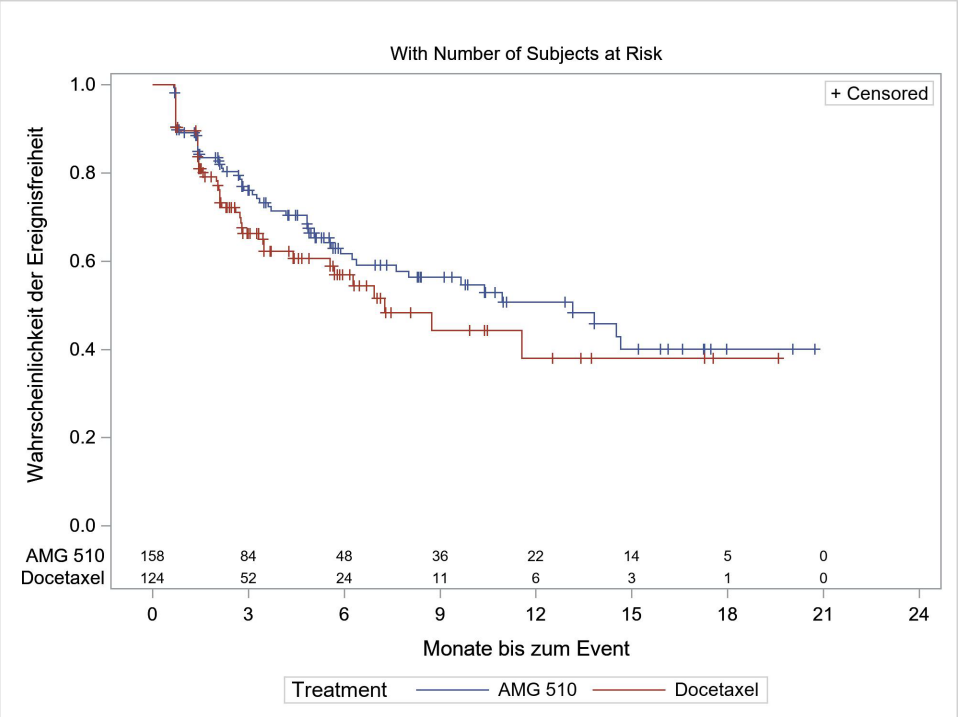

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Thorax), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

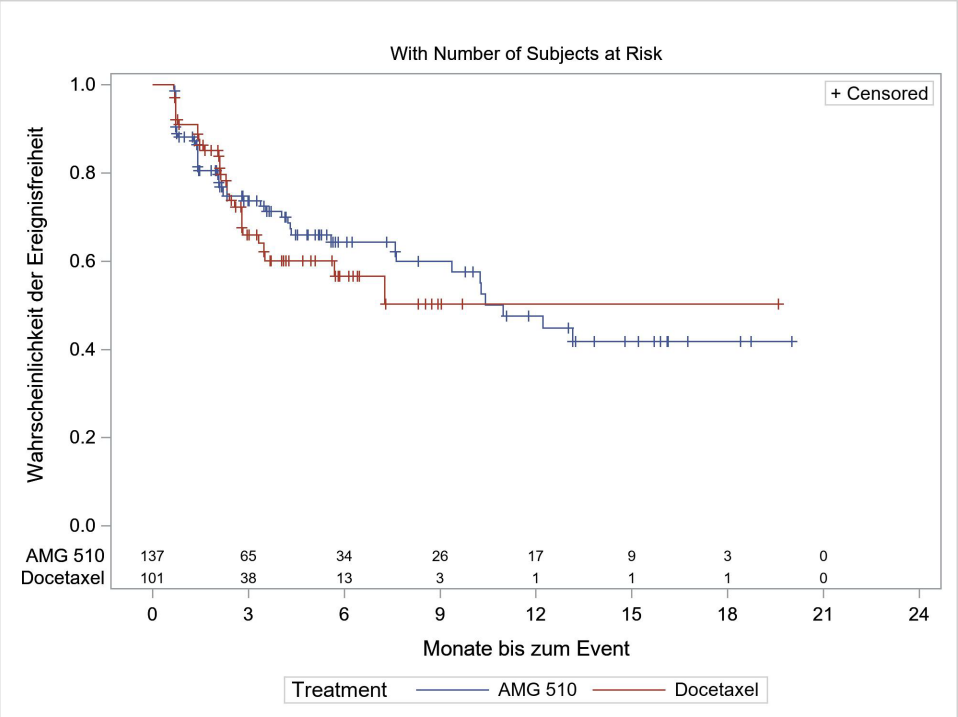

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wirksamkeit der Schmerzmedikation, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

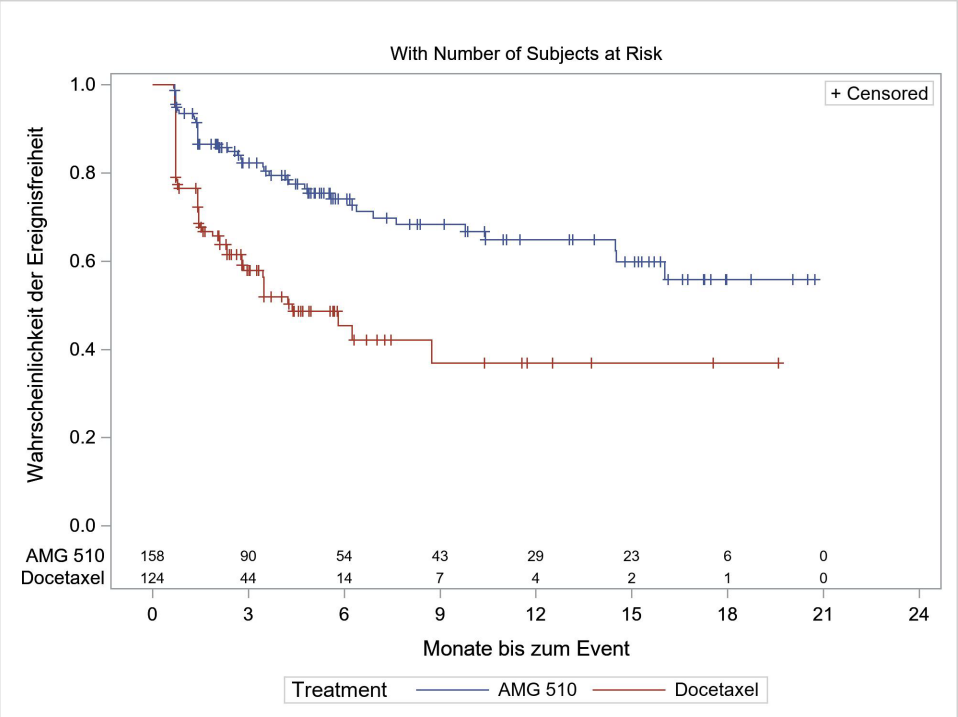

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wunder Mund, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

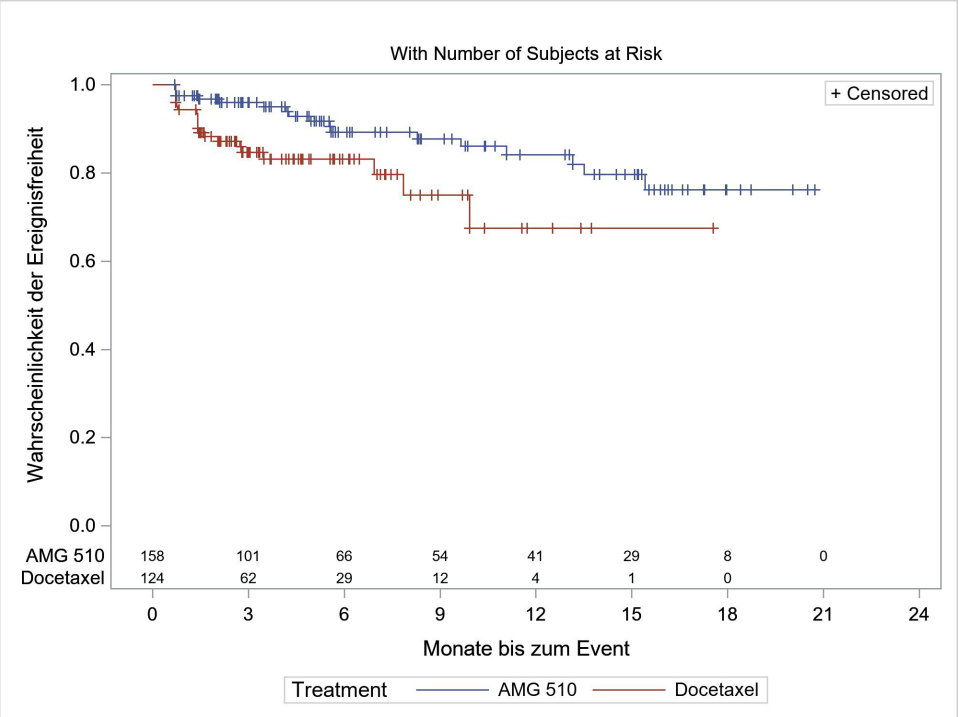

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Bluthusten, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.2.3 Verlaufskurven für den Endpunkt EORTC QLQ-LC13

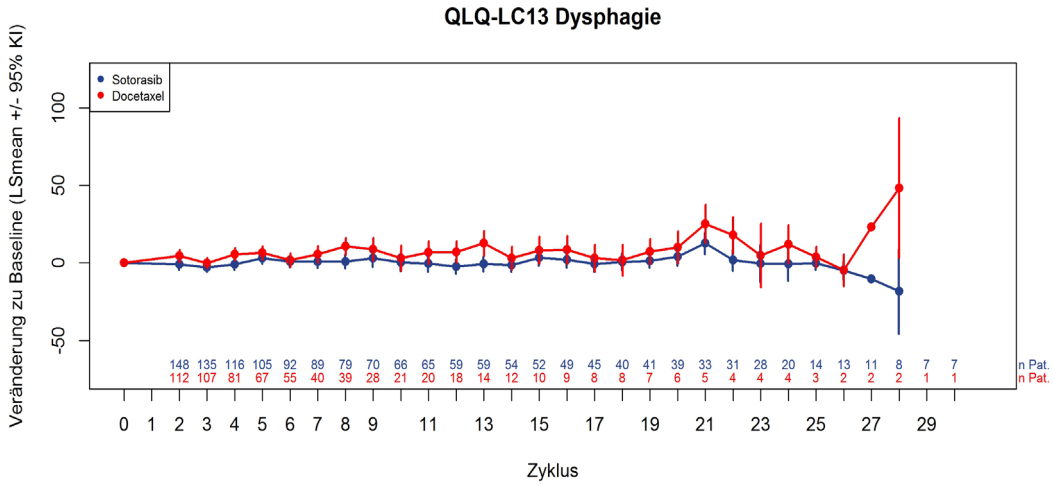

Abbildung 15: Verlaufskurve für den Endpunkt QLQ-LC13 Dysphagie, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

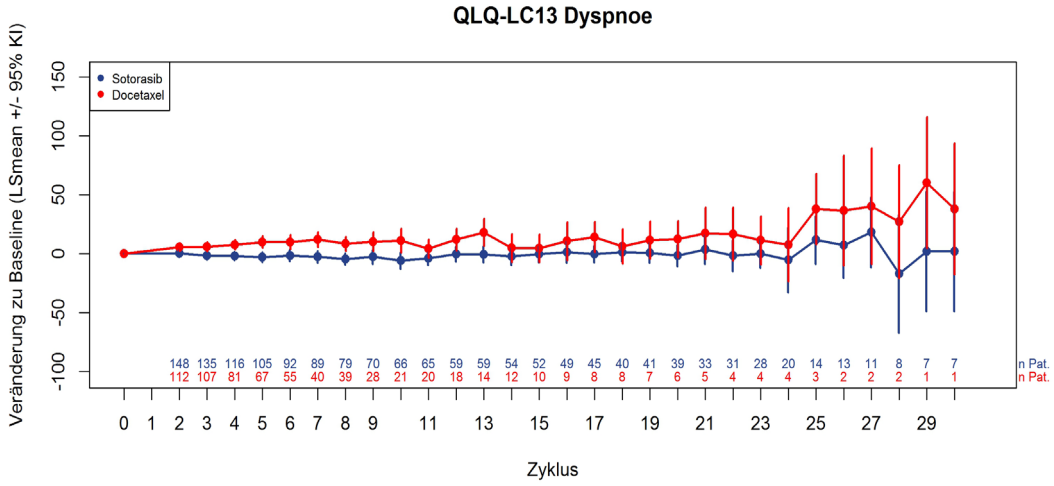

Abbildung 16: Verlaufskurve für den Endpunkt QLQ-LC13 Dyspnoe, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

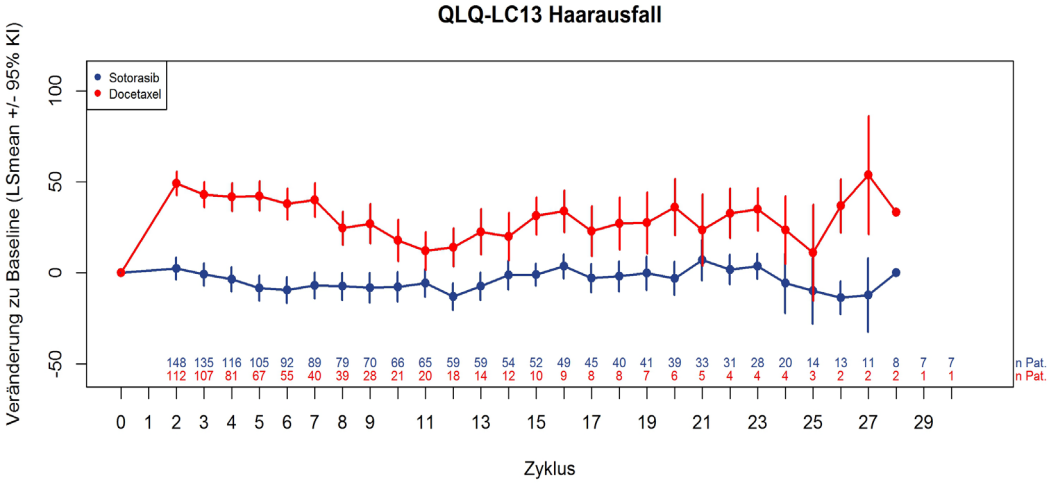

Abbildung 18: Verlaufskurve für den Endpunkt QLQ-LC13 Haarausfall, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

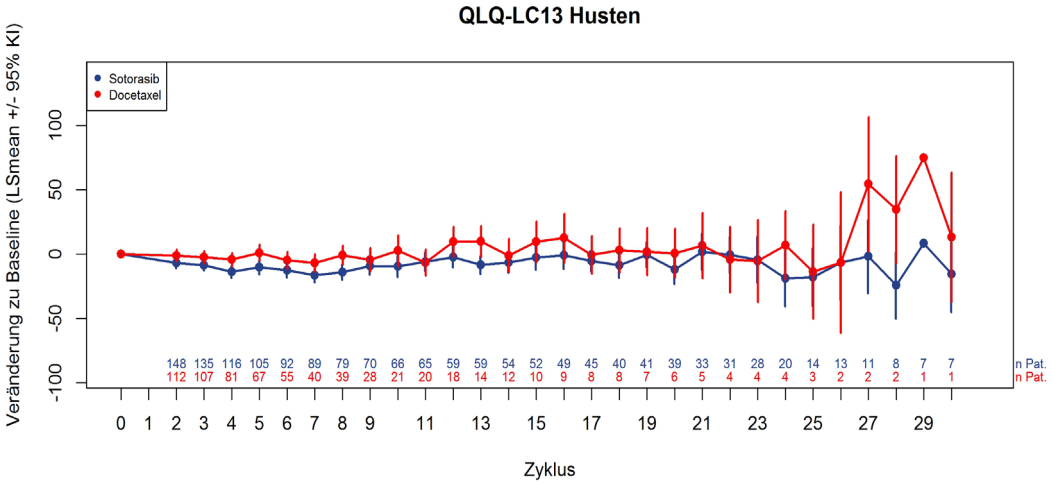

Abbildung 19: Verlaufskurve für den Endpunkt QLQ-LC13 Husten, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

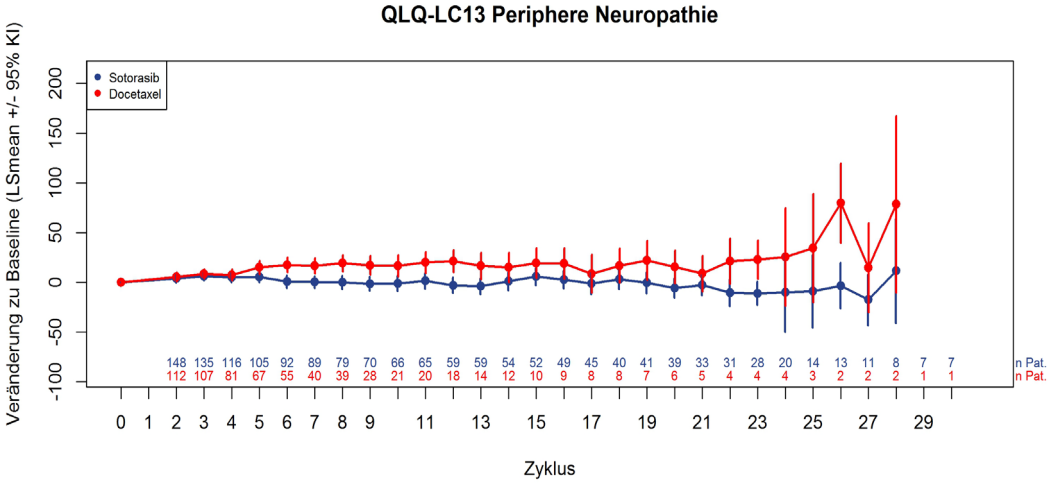

Abbildung 20: Verlaufskurve für den Endpunkt QLQ-LC13 Periphere Neuropathie, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

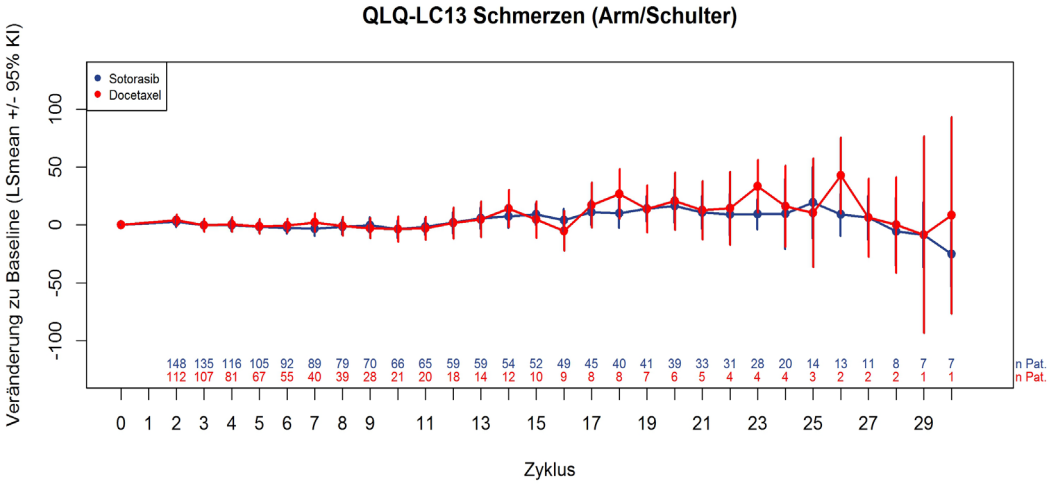

Abbildung 21: Verlaufskurve für den Endpunkt QLQ-LC13 Schmerzen (Arm/Schulter), aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

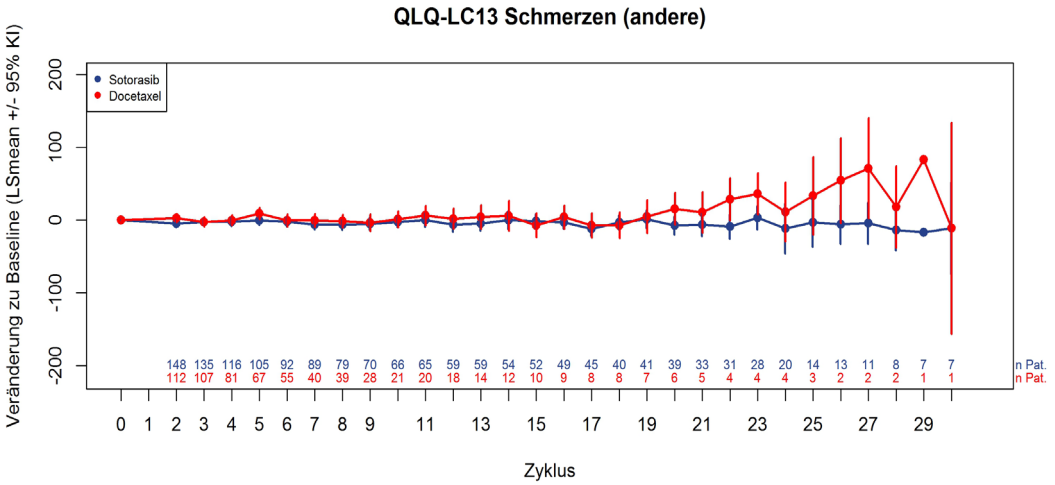

Abbildung 22: Verlaufskurve für den Endpunkt QLQ-LC13 Schmerzen (andere), aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

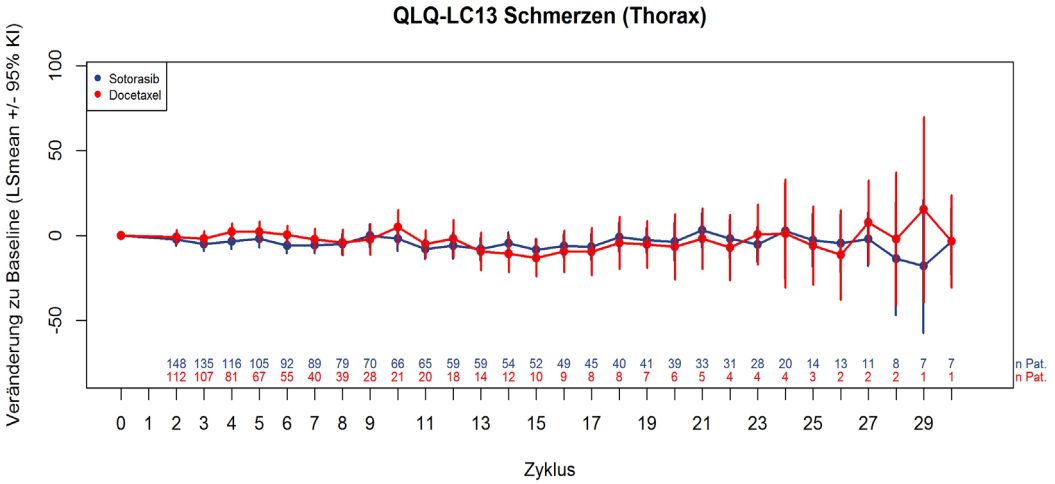

Abbildung 23: Verlaufskurve für den Endpunkt QLQ-LC13 Schmerzen (Thorax), aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

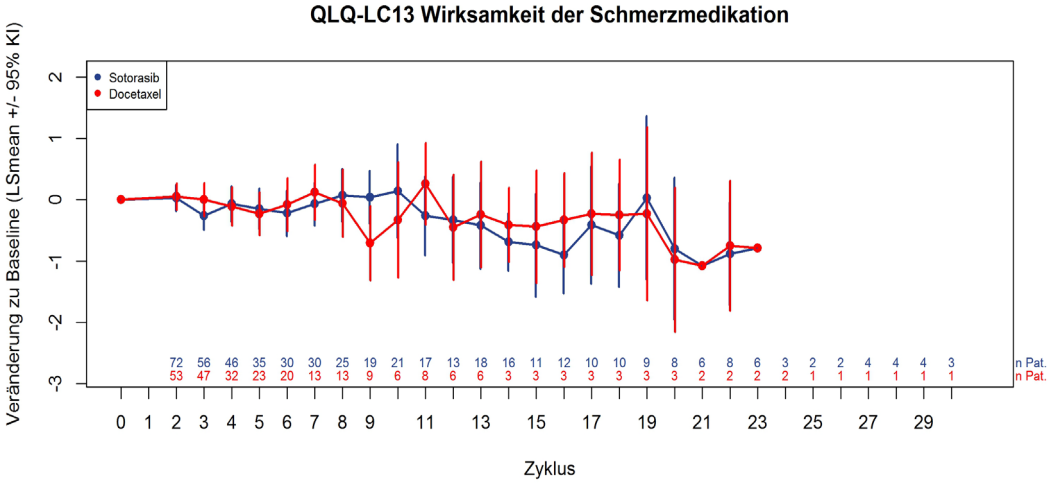

Abbildung 24: Verlaufskurve für den Endpunkt QLQ-LC13 Wirksamkeit der Schmerzmedikation, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

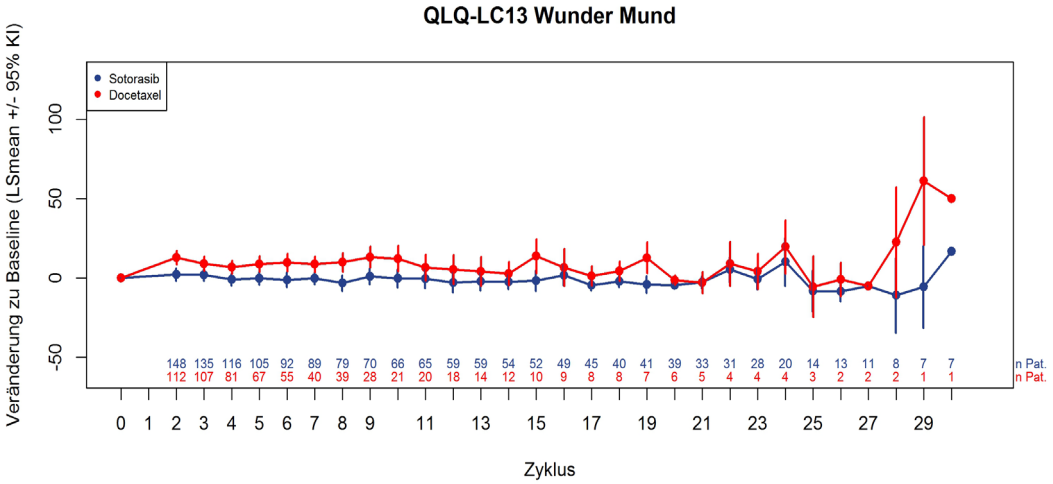

Abbildung 25: Verlaufskurve für den Endpunkt QLQ-LC13 Wunder Mund, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

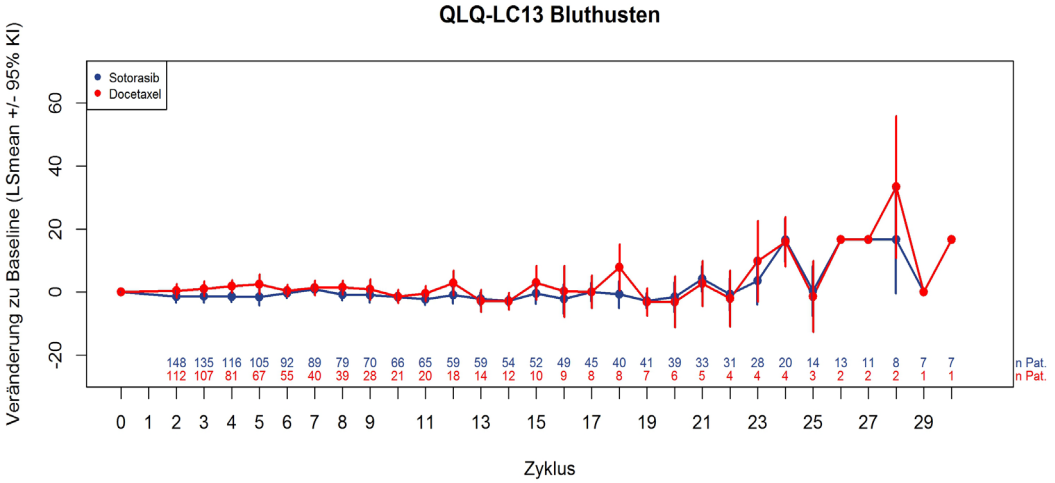

Abbildung 26: Verlaufskurve für den Endpunkt QLQ-LC13 Bluthusten, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.2.4 Subgruppenanalysen für den Endpunkt EORTC QLQ-LC13 (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dysphagie; Alter bei Studienbeginn							
<65 Jahre	25/83 (30,1)	18,7 [12,5; n.b.]	27/67 (40,3)	6,9 [3,5; n.b.]	0,6 [0,3; 1,1]	0,0747	0,8544
≥65 Jahre	20/75 (26,7)	n.b. [6,2; n.b.]	19/57 (33,3)	n.b. [3,5; n.b.]	0,6 [0,3; 1,2]	0,1309	
QLQ-LC13 Dysphagie; Geschlecht							
Weiblich	17/58 (29,3)	18,7 [6,4; n.b.]	20/49 (40,8)	5,8 [2,8; n.b.]	0,5 [0,3; 1,1]	0,0832	0,9284
Männlich	28/100 (28,0)	n.b. [12,5; n.b.]	26/75 (34,7)	8,7 [4,4; n.b.]	0,6 [0,3; 1,0]	0,0678	
QLQ-LC13 Dysphagie; Region 2							
Nordamerika und Europa	35/133 (26,3)	n.b. [18,7; n.b.]	37/105 (35,2)	6,9 [4,7; n.b.]	0,6 [0,3; 0,9]	0,0224	0,5174
Rest der Welt	10/25 (40,0)	4,2 [2,8; n.b.]	9/19 (47,4)	2,8 [1,0; n.b.]	0,6 [0,2; 1,8]	0,3775	
QLQ-LC13 Dysphagie; Region 1							
Nordamerika	2/16 (12,5)	n.b. [n.b.; n.b.]	6/15 (40,0)	15,2 [2,1; 15,2]	0,4 [0,1; 2,2]	0,2588	0,5448
Europa	33/117 (28,2)	18,7 [18,7; n.b.]	31/90 (34,4)	6,9 [4,4; n.b.]	0,6 [0,3; 1,0]	0,0381	
Rest der Welt	10/25 (40,0)	4,2 [2,8; n.b.]	9/19 (47,4)	2,8 [1,0; n.b.]	0,6 [0,2; 1,8]	0,3775	
QLQ-LC13 Dysphagie; ECOG Performance-Status							
0	15/55 (27,3)	n.b. [12,5; n.b.]	19/51 (37,3)	8,7 [4,7; n.b.]	0,4 [0,2; 0,9]	0,0176	0,4933
1	30/103 (29,1)	n.b. [6,2; n.b.]	27/73 (37,0)	15,2 [2,8; 15,2]	0,8 [0,4; 1,3]	0,3225	
QLQ-LC13 Dysphagie; Lebermetastasen bei Studienbeginn							
Nein	39/131 (29,8)	n.b. [12,5; n.b.]	38/103 (36,9)	6,9 [4,7; n.b.]	0,7 [0,4; 1,1]	0,0883	0,2102
Ja	6/27 (22,2)	n.b. [5,6; n.b.]	8/21 (38,1)	15,2 [2,8; 15,2]	0,2 [0,0; 1,2]	0,0562	
QLQ-LC13 Dysphagie; Knochenmetastasen bei Studienbeginn							
Nein	26/86 (30,2)	18,7 [12,5; n.b.]	29/76 (38,2)	5,8 [4,4; n.b.]	0,7 [0,4; 1,2]	0,1449	0,4321
Ja	19/72 (26,4)	n.b. [6,2; n.b.]	17/48 (35,4)	8,7 [2,8; 15,2]	0,5 [0,2; 1,0]	0,0324	
QLQ-LC13 Dysphagie; PD-L1-Proteinexpression							
<1%	12/52 (23,1)	18,7 [n.b.; n.b.]	16/41 (39,0)	6,9 [3,5; n.b.]	0,6 [0,2; 1,2]	0,1408	0,4126
≥1% und <50%	15/42 (35,7)	12,5 [2,8; n.b.]	14/47 (29,8)	15,2 [4,4; n.b.]	0,9 [0,4; 2,0]	0,8212	
≥50%	14/57 (24,6)	n.b. [5,5; n.b.]	11/28 (39,3)	4,9 [4,2; n.b.]	0,5 [0,2; 1,3]	0,1561	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dysphagie; Ethnie-2							
Asiatisch	8/21 (38,1)	5,1 [2,7; n.b.]	9/18 (50,0)	2,8 [1,0; n.b.]	0,6 [0,2; 1,8]	0,3856	0,8465
Nicht asiatisch	37/136 (27,2)	n.b. [18,7; n.b.]	37/105 (35,2)	6,9 [4,7; n.b.]	0,6 [0,4; 1,0]	0,0344	
QLQ-LC13 Dysphagie; Vorgeschichte einer Beteiligung des ZNS							
Nein	26/104 (25,0)	n.b. [18,7; n.b.]	31/86 (36,0)	8,7 [4,2; n.b.]	0,5 [0,3; 0,9]	0,0202	0,5600
Ja	19/54 (35,2)	n.b. [4,2; n.b.]	15/38 (39,5)	6,9 [2,3; 15,2]	0,7 [0,4; 1,5]	0,4113	
QLQ-LC13 Dysphagie; Anzahl an vorherigen Therapielinien							
1	21/68 (30,9)	n.b. [5,6; n.b.]	25/56 (44,6)	4,9 [2,8; n.b.]	0,6 [0,3; 1,0]	0,0644	0,3585
2	14/62 (22,6)	n.b. [18,7; n.b.]	17/50 (34,0)	n.b. [4,2; n.b.]	0,5 [0,2; 1,0]	0,0415	
>2	10/28 (35,7)	n.b. [3,5; n.b.]	4/18 (22,2)	8,7 [4,7; 15,2]	1,3 [0,4; 4,4]	0,6612	
QLQ-LC13 Dyspnoe; Alter bei Studienbeginn							
<65 Jahre	33/83 (39,8)	11,4 [5,9; 16,6]	36/67 (53,7)	3,4 [2,1; 5,8]	0,4 [0,2; 0,7]	0,0019	0,4117
≥65 Jahre	25/75 (33,3)	14,0 [7,6; n.b.]	30/57 (52,6)	2,8 [2,1; 7,6]	0,4 [0,2; 0,7]	0,0009	
QLQ-LC13 Dyspnoe; Geschlecht							
Weiblich	24/58 (41,4)	7,7 [4,2; n.b.]	28/49 (57,1)	3,4 [2,1; 5,6]	0,5 [0,3; 0,9]	0,0197	0,5830
Männlich	34/100 (34,0)	13,1 [9,4; n.b.]	38/75 (50,7)	3,0 [2,1; 7,9]	0,4 [0,2; 0,6]	0,0002	
QLQ-LC13 Dyspnoe; Region 2							
Nordamerika und Europa	51/133 (38,3)	12,5 [7,6; n.b.]	54/105 (51,4)	3,7 [2,8; 5,6]	0,4 [0,3; 0,7]	0,0001	0,3395
Rest der Welt	7/25 (28,0)	13,1 [4,7; n.b.]	12/19 (63,2)	1,6 [0,8; n.b.]	0,3 [0,1; 0,9]	0,0261	
QLQ-LC13 Dyspnoe; Region 1							
Nordamerika	3/16 (18,8)	n.b. [7,1; n.b.]	8/15 (53,3)	3,4 [0,7; n.b.]	0,4 [0,1; 2,0]	0,2523	0,3746
Europa	48/117 (41,0)	11,4 [6,9; 16,6]	46/90 (51,1)	3,7 [2,8; 5,6]	0,4 [0,3; 0,7]	0,0004	
Rest der Welt	7/25 (28,0)	13,1 [4,7; n.b.]	12/19 (63,2)	1,6 [0,8; n.b.]	0,3 [0,1; 0,9]	0,0261	
QLQ-LC13 Dyspnoe; ECOG Performance-Status							
0	26/55 (47,3)	12,5 [5,9; n.b.]	32/51 (62,7)	3,3 [2,1; 5,6]	0,4 [0,2; 0,7]	0,0010	0,8685
1	32/103 (31,1)	13,1 [7,1; n.b.]	34/73 (46,6)	3,0 [2,1; n.b.]	0,4 [0,2; 0,7]	0,0005	
QLQ-LC13 Dyspnoe; Lebermetastasen bei Studienbeginn							
Nein	47/131 (35,9)	13,1 [8,3; n.b.]	56/103 (54,4)	3,3 [2,1; 5,6]	0,3 [0,2; 0,5]	<,0001	0,2854
Ja	11/27 (40,7)	7,1 [3,4; n.b.]	10/21 (47,6)	4,2 [1,4; 6,5]	0,7 [0,2; 2,3]	0,5651	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dyspnoe; Knochenmetastasen bei Studienbeginn							
Nein	38/86 (44,2)	11,1 [6,2; n.b.]	38/76 (50,0)	4,2 [2,8; 7,6]	0,5 [0,3; 0,8]	0,0022	0,1319
Ja	20/72 (27,8)	16,6 [7,1; n.b.]	28/48 (58,3)	2,2 [1,4; 4,6]	0,3 [0,2; 0,6]	0,0001	
QLQ-LC13 Dyspnoe; PD-L1-Proteinexpression							
<1%	20/52 (38,5)	13,1 [5,9; n.b.]	26/41 (63,4)	2,1 [1,4; 5,8]	0,3 [0,1; 0,6]	0,0003	0,4589
≥1% und <50%	17/42 (40,5)	8,3 [7,1; n.b.]	21/47 (44,7)	4,4 [2,8; 6,5]	0,5 [0,2; 1,1]	0,0781	
≥50%	17/57 (29,8)	16,6 [4,7; n.b.]	14/28 (50,0)	3,7 [1,9; n.b.]	0,4 [0,2; 0,9]	0,0245	
QLQ-LC13 Dyspnoe; Ethnie-2							
Asiatisch	6/21 (28,6)	13,1 [4,7; n.b.]	12/18 (66,7)	1,5 [0,7; n.b.]	0,2 [0,1; 0,7]	0,0079	0,1813
Nicht asiatisch	52/136 (38,2)	12,5 [7,6; n.b.]	53/105 (50,5)	3,7 [2,8; 5,8]	0,4 [0,3; 0,6]	<,0001	
QLQ-LC13 Dyspnoe; Vorgeschichte einer Beteiligung des ZNS							
Nein	38/104 (36,5)	11,4 [7,6; n.b.]	50/86 (58,1)	3,0 [2,1; 4,4]	0,4 [0,2; 0,6]	<,0001	0,9875
Ja	20/54 (37,0)	13,8 [6,2; n.b.]	16/38 (42,1)	5,8 [2,1; 6,5]	0,3 [0,1; 0,7]	0,0036	
QLQ-LC13 Dyspnoe; Anzahl an vorherigen Therapielinien							
1	20/68 (29,4)	n.b. [6,9; n.b.]	31/56 (55,4)	3,0 [2,1; 5,8]	0,4 [0,2; 0,7]	0,0023	0,4057
2	22/62 (35,5)	13,1 [9,4; n.b.]	26/50 (52,0)	4,4 [2,1; n.b.]	0,3 [0,1; 0,6]	0,0002	
>2	16/28 (57,1)	4,5 [3,0; 14,0]	9/18 (50,0)	3,3 [1,6; n.b.]	0,6 [0,2; 1,4]	0,1969	
QLQ-LC13 Haarausfall; Alter bei Studienbeginn							
<65 Jahre	15/83 (18,1)	n.b. [19,4; n.b.]	58/67 (86,6)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	0,6241
≥65 Jahre	17/75 (22,7)	n.b. [14,7; n.b.]	52/57 (91,2)	0,7 [0,7; 0,8]	0,1 [0,0; 0,2]	<,0001	
QLQ-LC13 Haarausfall; Geschlecht							
Weiblich	18/58 (31,0)	14,7 [9,0; n.b.]	42/49 (85,7)	0,7 [0,7; 0,8]	0,1 [0,1; 0,3]	<,0001	0,0690
Männlich	14/100 (14,0)	n.b. [n.b.; n.b.]	68/75 (90,7)	0,8 [0,7; 1,3]	0,0 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; Region 2							
Nordamerika und Europa	27/133 (20,3)	n.b. [19,4; n.b.]	93/105 (88,6)	0,7 [0,7; 0,9]	0,1 [0,0; 0,1]	<,0001	0,3897
Rest der Welt	5/25 (20,0)	n.b. [4,8; n.b.]	17/19 (89,5)	0,8 [0,7; 0,8]	0,0 [0,0; n.b.]	<,0001	
QLQ-LC13 Haarausfall; Region 1							
Nordamerika	3/16 (18,8)	n.b. [4,1; n.b.]	15/15 (100,0)	0,7 [n.b.; n.b.]	0,1 [0,0; 0,5]	0,0014	0,6900
Europa	24/117 (20,5)	n.b. [19,4; n.b.]	78/90 (86,7)	0,8 [0,7; 1,4]	0,1 [0,0; 0,1]	<,0001	
Rest der Welt	5/25 (20,0)	n.b. [4,8; n.b.]	17/19 (89,5)	0,8 [0,7; 0,8]	0,0 [0,0; n.b.]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Haarausfall; ECOG Performance-Status							
0	10/55 (18,2)	n.b. [19,4; n.b.]	43/51 (84,3)	0,7 [0,7; 0,8]	0,1 [0,0; 0,1]	<,0001	0,7511
1	22/103 (21,4)	n.b. [14,7; n.b.]	67/73 (91,8)	0,7 [0,7; 1,4]	0,1 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; Lebermetastasen bei Studienbeginn							
Nein	29/131 (22,1)	n.b. [19,4; n.b.]	92/103 (89,3)	0,8 [0,7; 1,3]	0,1 [0,0; 0,1]	<,0001	0,1586
Ja	3/27 (11,1)	n.b. [6,9; n.b.]	18/21 (85,7)	0,7 [n.b.; n.b.]	0,0 [0,0; n.b.]	<,0001	
Nicht-plattenepithelial	32/156 (20,5)	n.b. [19,4; n.b.]	103/115 (89,6)	0,7 [0,7; 0,8]	0,1 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; Knochenmetastasen bei Studienbeginn							
Nein	22/86 (25,6)	n.b. [19,4; n.b.]	66/76 (86,8)	0,8 [0,7; 1,4]	0,1 [0,1; 0,2]	<,0001	0,0379
Ja	10/72 (13,9)	n.b. [14,7; n.b.]	44/48 (91,7)	0,7 [0,7; 0,8]	0,0 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; PD-L1-Proteinexpression							
<1%	12/52 (23,1)	19,4 [9,0; n.b.]	37/41 (90,2)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	0,3445
≥1% und <50%	5/42 (11,9)	n.b. [10,4; n.b.]	40/47 (85,1)	0,8 [0,7; 1,4]	0,0 [0,0; 0,1]	<,0001	
≥50%	13/57 (22,8)	n.b. [14,7; n.b.]	26/28 (92,9)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	
QLQ-LC13 Haarausfall; Ethnie-2							
Asiatisch	5/21 (23,8)	n.b. [4,1; n.b.]	16/18 (88,9)	0,7 [0,7; 0,8]	0,1 [0,0; 0,3]	<,0001	0,7194
Nicht asiatisch	27/136 (19,9)	n.b. [19,4; n.b.]	93/105 (88,6)	0,7 [0,7; 1,3]	0,1 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; Vorgeschichte einer Beteiligung des ZNS							
Nein	20/104 (19,2)	n.b. [19,4; n.b.]	77/86 (89,5)	0,7 [0,7; 0,8]	0,1 [0,0; 0,1]	<,0001	0,6502
Ja	12/54 (22,2)	n.b. [14,7; n.b.]	33/38 (86,8)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	
QLQ-LC13 Haarausfall; Anzahl an vorherigen Therapielinien							
1	9/68 (13,2)	n.b. [n.b.; n.b.]	49/56 (87,5)	1,0 [0,7; 1,4]	0,1 [0,0; 0,1]	<,0001	0,5866
2	13/62 (21,0)	n.b. [19,4; n.b.]	44/50 (88,0)	0,7 [0,7; 0,8]	0,1 [0,1; 0,2]	<,0001	
>2	10/28 (35,7)	9,0 [4,8; 14,7]	17/18 (94,4)	0,7 [0,7; 1,4]	0,0 [0,0; 0,2]	<,0001	
QLQ-LC13 Husten; Alter bei Studienbeginn							
<65 Jahre	23/83 (27,7)	19,4 [7,7; n.b.]	23/67 (34,3)	8,7 [2,8; n.b.]	0,6 [0,3; 1,1]	0,0962	0,7787
≥65 Jahre	29/75 (38,7)	14,5 [6,9; 17,2]	29/57 (50,9)	3,5 [2,3; n.b.]	0,5 [0,3; 0,9]	0,0232	
QLQ-LC13 Husten; Geschlecht							
Weiblich	20/58 (34,5)	14,8 [7,7; n.b.]	19/49 (38,8)	4,6 [2,8; n.b.]	0,6 [0,3; 1,2]	0,1219	0,4884
Männlich	32/100 (32,0)	16,6 [6,9; n.b.]	33/75 (44,0)	4,4 [2,8; n.b.]	0,4 [0,3; 0,8]	0,0027	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Husten; Region 2							
Nordamerika und Europa	41/133 (30,8)	16,6 [13,1; n.b.]	44/105 (41,9)	4,7 [2,8; n.b.]	0,5 [0,3; 0,7]	0,0011	0,4852
Rest der Welt	11/25 (44,0)	6,9 [2,1; n.b.]	8/19 (42,1)	3,5 [1,4; n.b.]	0,8 [0,3; 2,3]	0,6559	
QLQ-LC13 Husten; Region 1							
Nordamerika	4/16 (25,0)	n.b. [0,7; n.b.]	4/15 (26,7)	n.b. [2,8; n.b.]	0,6 [0,1; 3,2]	0,5611	0,5290
Europa	37/117 (31,6)	14,8 [11,9; 19,4]	40/90 (44,4)	4,4 [2,8; n.b.]	0,4 [0,2; 0,6]	<,0001	
Rest der Welt	11/25 (44,0)	6,9 [2,1; n.b.]	8/19 (42,1)	3,5 [1,4; n.b.]	0,8 [0,3; 2,3]	0,6559	
QLQ-LC13 Husten; ECOG Performance-Status							
0	13/55 (23,6)	19,4 [16,6; n.b.]	25/51 (49,0)	4,4 [2,8; n.b.]	0,3 [0,1; 0,6]	0,0006	0,0111
1	39/103 (37,9)	11,2 [5,6; 14,5]	27/73 (37,0)	n.b. [2,8; n.b.]	0,7 [0,4; 1,2]	0,2457	
QLQ-LC13 Husten; Lebermetastasen bei Studienbeginn							
Nein	46/131 (35,1)	14,8 [11,2; 19,4]	46/103 (44,7)	4,4 [2,8; n.b.]	0,5 [0,3; 0,8]	0,0040	0,8065
Ja	6/27 (22,2)	n.b. [5,6; n.b.]	6/21 (28,6)	n.b. [2,3; n.b.]	0,1 [0,0; 1,3]	0,0527	
QLQ-LC13 Husten; Knochenmetastasen bei Studienbeginn							
Nein	30/86 (34,9)	14,2 [7,6; n.b.]	33/76 (43,4)	4,6 [2,8; n.b.]	0,5 [0,3; 0,8]	0,0090	0,7635
Ja	22/72 (30,6)	17,2 [7,7; n.b.]	19/48 (39,6)	8,7 [2,8; n.b.]	0,5 [0,2; 0,9]	0,0236	
QLQ-LC13 Husten; PD-L1-Proteinexpression							
<1%	20/52 (38,5)	11,9 [5,0; n.b.]	13/41 (31,7)	n.b. [3,3; n.b.]	0,8 [0,4; 1,8]	0,6199	0,2287
≥1% und <50%	14/42 (33,3)	14,2 [7,6; n.b.]	22/47 (46,8)	2,8 [2,2; 4,6]	0,3 [0,1; 0,6]	0,0014	
≥50%	16/57 (28,1)	19,4 [5,6; n.b.]	12/28 (42,9)	4,7 [2,4; n.b.]	0,6 [0,3; 1,4]	0,2155	
QLQ-LC13 Husten; Ethnie-2							
Asiatisch	10/21 (47,6)	4,9 [2,1; n.b.]	9/18 (50,0)	2,8 [0,8; n.b.]	0,6 [0,2; 1,6]	0,2779	0,7269
Nicht asiatisch	42/136 (30,9)	16,6 [11,9; n.b.]	42/105 (40,0)	4,9 [3,0; n.b.]	0,5 [0,3; 0,8]	0,0031	
QLQ-LC13 Husten; Vorgeschichte einer Beteiligung des ZNS							
Nein	33/104 (31,7)	14,8 [11,2; n.b.]	39/86 (45,3)	4,4 [2,8; n.b.]	0,5 [0,3; 0,8]	0,0018	0,5270
Ja	19/54 (35,2)	17,2 [5,8; 19,4]	13/38 (34,2)	n.b. [3,0; n.b.]	0,6 [0,3; 1,3]	0,2164	
QLQ-LC13 Husten; Anzahl an vorherigen Therapielinien							
1	22/68 (32,4)	14,2 [5,8; n.b.]	24/56 (42,9)	3,5 [2,8; n.b.]	0,5 [0,3; 0,9]	0,0296	0,9970
2	21/62 (33,9)	17,2 [7,6; n.b.]	21/50 (42,0)	4,9 [2,8; n.b.]	0,5 [0,3; 1,0]	0,0508	
>2	9/28 (32,1)	14,5 [4,9; n.b.]	7/18 (38,9)	8,7 [2,1; n.b.]	0,4 [0,1; 1,3]	0,1185	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Periphere Neuropathie; Alter bei Studienbeginn							
<65 Jahre	31/83 (37,3)	13,4 [3,5; n.b.]	34/67 (50,7)	3,6 [2,8; 7,4]	0,7 [0,4; 1,2]	0,1625	0,8496
≥65 Jahre	34/75 (45,3)	8,5 [4,2; n.b.]	32/57 (56,1)	3,2 [2,2; 5,6]	0,6 [0,3; 1,0]	0,0464	
QLQ-LC13 Periphere Neuropathie; Geschlecht							
Weiblich	24/58 (41,4)	13,4 [2,8; n.b.]	30/49 (61,2)	3,2 [1,6; 5,6]	0,7 [0,4; 1,3]	0,2557	0,8206
Männlich	41/100 (41,0)	9,0 [5,6; n.b.]	36/75 (48,0)	3,7 [2,8; 5,7]	0,6 [0,4; 1,0]	0,0591	
QLQ-LC13 Periphere Neuropathie; Region 2							
Nordamerika und Europa	52/133 (39,1)	12,2 [5,6; n.b.]	56/105 (53,3)	3,7 [3,1; 5,6]	0,6 [0,4; 0,9]	0,0132	0,5706
Rest der Welt	13/25 (52,0)	7,6 [1,4; 10,3]	10/19 (52,6)	1,6 [1,4; n.b.]	0,6 [0,2; 1,7]	0,2917	
QLQ-LC13 Periphere Neuropathie; Region 1							
Nordamerika	6/16 (37,5)	n.b. [0,7; n.b.]	11/15 (73,3)	3,4 [2,0; 4,9]	0,5 [0,2; 1,5]	0,2110	0,5665
Europa	46/117 (39,3)	12,2 [5,5; n.b.]	45/90 (50,0)	3,7 [3,1; 5,8]	0,6 [0,4; 1,0]	0,0281	
Rest der Welt	13/25 (52,0)	7,6 [1,4; 10,3]	10/19 (52,6)	1,6 [1,4; n.b.]	0,6 [0,2; 1,7]	0,2917	
QLQ-LC13 Periphere Neuropathie; ECOG Performance-Status							
0	25/55 (45,5)	10,3 [5,6; n.b.]	30/51 (58,8)	3,7 [2,1; 5,6]	0,5 [0,3; 0,8]	0,0095	0,5060
1	40/103 (38,8)	7,6 [3,5; n.b.]	36/73 (49,3)	3,5 [2,3; 7,4]	0,7 [0,4; 1,1]	0,1619	
QLQ-LC13 Periphere Neuropathie; Lebermetastasen bei Studienbeginn							
Nein	57/131 (43,5)	9,0 [4,2; n.b.]	56/103 (54,4)	3,6 [2,8; 5,6]	0,6 [0,4; 0,9]	0,0170	0,6081
Ja	8/27 (29,6)	n.b. [3,5; n.b.]	10/21 (47,6)	3,5 [1,4; 7,9]	1,0 [0,3; 3,4]	0,9904	
QLQ-LC13 Periphere Neuropathie; Knochenmetastasen bei Studienbeginn							
Nein	43/86 (50,0)	6,2 [3,3; 13,4]	40/76 (52,6)	3,7 [3,2; 5,6]	0,7 [0,4; 1,1]	0,1471	0,1509
Ja	22/72 (30,6)	n.b. [5,6; n.b.]	26/48 (54,2)	2,8 [1,4; 7,4]	0,5 [0,3; 0,9]	0,0116	
QLQ-LC13 Periphere Neuropathie; PD-L1-Proteinexpression							
<1%	17/52 (32,7)	n.b. [5,9; n.b.]	27/41 (65,9)	3,5 [1,6; 5,6]	0,4 [0,2; 0,8]	0,0101	0,0349
≥1% und <50%	22/42 (52,4)	5,6 [3,0; 8,5]	18/47 (38,3)	4,4 [3,2; n.b.]	1,3 [0,6; 2,5]	0,5021	
≥50%	21/57 (36,8)	12,2 [3,5; n.b.]	15/28 (53,6)	3,7 [2,1; n.b.]	0,6 [0,3; 1,3]	0,1762	
QLQ-LC13 Periphere Neuropathie; Ethnie-2							
Asiatisch	9/21 (42,9)	7,6 [2,2; n.b.]	12/18 (66,7)	1,5 [0,8; 2,1]	0,4 [0,1; 1,0]	0,0523	0,2682
Nicht asiatisch	56/136 (41,2)	10,3 [4,2; n.b.]	54/105 (51,4)	3,7 [3,2; 5,6]	0,6 [0,4; 1,0]	0,0274	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Periphere Neuropathie; Vorgeschichte einer Beteiligung des ZNS							
Nein	45/104 (43,3)	8,5 [3,7; 13,4]	49/86 (57,0)	3,5 [2,3; 4,2]	0,6 [0,4; 0,9]	0,0121	0,9855
Ja	20/54 (37,0)	n.b. [3,5; n.b.]	17/38 (44,7)	5,7 [2,8; 8,8]	0,7 [0,3; 1,3]	0,2111	
QLQ-LC13 Periphere Neuropathie; Anzahl an vorherigen Therapielinien							
1	26/68 (38,2)	12,2 [2,8; n.b.]	30/56 (53,6)	3,4 [2,8; 5,6]	0,6 [0,3; 1,0]	0,0444	0,1290
2	22/62 (35,5)	n.b. [6,2; n.b.]	28/50 (56,0)	3,7 [2,1; 8,8]	0,5 [0,3; 0,9]	0,0110	
>2	17/28 (60,7)	3,5 [1,4; 5,9]	8/18 (44,4)	7,9 [0,8; n.b.]	1,1 [0,5; 2,6]	0,8414	
QLQ-LC13 Schmerzen (Arm/Schulter); Alter bei Studienbeginn							
<65 Jahre	44/83 (53,0)	5,1 [2,8; 9,7]	24/67 (35,8)	n.b. [2,8; n.b.]	1,3 [0,8; 2,2]	0,2859	0,4626
≥65 Jahre	41/75 (54,7)	5,2 [3,5; 9,7]	25/57 (43,9)	5,7 [2,8; 14,1]	0,9 [0,5; 1,6]	0,7466	
QLQ-LC13 Schmerzen (Arm/Schulter); Geschlecht							
Weiblich	32/58 (55,2)	4,9 [2,2; 9,2]	23/49 (46,9)	14,1 [1,4; 14,1]	1,1 [0,6; 2,0]	0,7137	0,8715
Männlich	53/100 (53,0)	6,1 [4,1; 10,3]	26/75 (34,7)	n.b. [3,7; n.b.]	1,1 [0,7; 1,8]	0,7025	
QLQ-LC13 Schmerzen (Arm/Schulter); Region 2							
Nordamerika und Europa	71/133 (53,4)	5,2 [3,6; 9,2]	41/105 (39,0)	14,1 [3,7; 14,1]	1,2 [0,8; 1,8]	0,3161	0,3617
Rest der Welt	14/25 (56,0)	4,9 [2,8; 15,4]	8/19 (42,1)	n.b. [0,7; n.b.]	0,7 [0,2; 2,1]	0,5412	
QLQ-LC13 Schmerzen (Arm/Schulter); Region 1							
Nordamerika	10/16 (62,5)	2,7 [1,4; 4,9]	4/15 (26,7)	n.b. [1,4; n.b.]	4,4 [0,9; 22,4]	0,0583	0,1927
Europa	61/117 (52,1)	6,4 [4,1; 9,7]	37/90 (41,1)	14,1 [2,8; 14,1]	1,1 [0,7; 1,6]	0,8216	
Rest der Welt	14/25 (56,0)	4,9 [2,8; 15,4]	8/19 (42,1)	n.b. [0,7; n.b.]	0,7 [0,2; 2,1]	0,5412	
QLQ-LC13 Schmerzen (Arm/Schulter); ECOG Performance-Status							
0	35/55 (63,6)	6,1 [4,2; 9,7]	19/51 (37,3)	14,1 [4,3; 14,1]	1,4 [0,8; 2,4]	0,2870	0,2263
1	50/103 (48,5)	4,9 [3,3; 13,8]	30/73 (41,1)	n.b. [2,8; n.b.]	0,9 [0,5; 1,5]	0,6505	
QLQ-LC13 Schmerzen (Arm/Schulter); Lebermetastasen bei Studienbeginn							
Nein	74/131 (56,5)	5,1 [3,6; 8,0]	40/103 (38,8)	14,1 [3,7; 14,1]	1,2 [0,8; 1,8]	0,3886	0,3749
Ja	11/27 (40,7)	14,5 [1,4; n.b.]	9/21 (42,9)	n.b. [0,7; n.b.]	0,7 [0,2; 2,3]	0,6129	
QLQ-LC13 Schmerzen (Arm/Schulter); Knochenmetastasen bei Studienbeginn							
Nein	49/86 (57,0)	5,6 [3,6; 9,2]	27/76 (35,5)	14,1 [4,3; 14,1]	1,3 [0,8; 2,1]	0,3378	0,2338
Ja	36/72 (50,0)	5,2 [3,3; 14,5]	22/48 (45,8)	3,7 [1,4; n.b.]	0,9 [0,5; 1,5]	0,5949	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (Arm/Schulter); PD-L1-Proteinexpression							
<1%	32/52 (61,5)	4,2 [2,4; 8,0]	19/41 (46,3)	14,1 [1,4; 14,1]	1,2 [0,6; 2,2]	0,5612	0,5833
≥1% und <50%	20/42 (47,6)	7,6 [4,1; 13,8]	14/47 (29,8)	n.b. [4,3; n.b.]	1,1 [0,5; 2,4]	0,7991	
≥50%	29/57 (50,9)	6,1 [2,8; 12,5]	13/28 (46,4)	3,5 [1,4; n.b.]	0,8 [0,4; 1,7]	0,5381	
QLQ-LC13 Schmerzen (Arm/Schulter); Ethnie-2							
Asiatisch	11/21 (52,4)	4,9 [2,8; n.b.]	8/18 (44,4)	3,5 [0,7; n.b.]	0,6 [0,2; 1,8]	0,3859	0,1753
Nicht asiatisch	74/136 (54,4)	5,1 [3,5; 9,0]	41/105 (39,0)	14,1 [3,7; 14,1]	1,2 [0,8; 1,8]	0,3529	
QLQ-LC13 Schmerzen (Arm/Schulter); Vorgeschichte einer Beteiligung des ZNS							
Nein	52/104 (50,0)	6,4 [3,5; 9,7]	32/86 (37,2)	14,1 [4,3; 14,1]	1,2 [0,8; 1,9]	0,4052	0,4424
Ja	33/54 (61,1)	4,8 [3,3; 10,3]	17/38 (44,7)	5,7 [1,6; n.b.]	0,9 [0,5; 1,7]	0,7289	
QLQ-LC13 Schmerzen (Arm/Schulter); Anzahl an vorherigen Therapielinien							
1	36/68 (52,9)	4,8 [2,1; 9,2]	21/56 (37,5)	14,1 [2,8; 14,1]	1,3 [0,8; 2,3]	0,2969	0,6027
2	32/62 (51,6)	9,0 [3,6; 10,3]	21/50 (42,0)	n.b. [2,1; n.b.]	1,0 [0,5; 1,7]	0,8903	
>2	17/28 (60,7)	4,1 [2,8; 5,2]	7/18 (38,9)	n.b. [1,4; n.b.]	1,1 [0,4; 2,7]	0,8691	
QLQ-LC13 Schmerzen (andere); Alter bei Studienbeginn							
<65 Jahre	48/83 (57,8)	3,5 [2,1; 9,1]	43/67 (64,2)	2,4 [1,4; 3,4]	0,7 [0,5; 1,1]	0,1390	0,2233
≥65 Jahre	42/75 (56,0)	5,2 [2,8; 10,1]	25/57 (43,9)	3,7 [2,8; n.b.]	1,1 [0,6; 1,9]	0,8345	
QLQ-LC13 Schmerzen (andere); Geschlecht							
Weiblich	37/58 (63,8)	2,8 [1,4; 12,5]	34/49 (69,4)	2,1 [1,4; 3,0]	0,6 [0,4; 1,1]	0,0835	0,1664
Männlich	53/100 (53,0)	4,9 [2,8; 8,2]	34/75 (45,3)	3,7 [2,8; n.b.]	1,0 [0,6; 1,6]	0,9551	
QLQ-LC13 Schmerzen (andere); Region 2							
Nordamerika und Europa	73/133 (54,9)	5,2 [2,8; 10,1]	59/105 (56,2)	3,0 [2,1; 4,0]	0,8 [0,6; 1,2]	0,2670	0,4649
Rest der Welt	17/25 (68,0)	2,8 [1,4; 8,2]	9/19 (47,4)	2,8 [1,4; n.b.]	1,4 [0,5; 3,7]	0,5072	
QLQ-LC13 Schmerzen (andere); Region 1							
Nordamerika	9/16 (56,2)	4,8 [0,7; n.b.]	9/15 (60,0)	3,0 [0,7; n.b.]	1,0 [0,3; 3,4]	0,9646	0,7532
Europa	64/117 (54,7)	5,2 [2,8; 10,1]	50/90 (55,6)	3,3 [2,1; 5,8]	0,8 [0,5; 1,1]	0,2039	
Rest der Welt	17/25 (68,0)	2,8 [1,4; 8,2]	9/19 (47,4)	2,8 [1,4; n.b.]	1,4 [0,5; 3,7]	0,5072	
QLQ-LC13 Schmerzen (andere); ECOG Performance-Status							
0	37/55 (67,3)	4,2 [2,0; 8,2]	30/51 (58,8)	2,8 [1,4; 6,2]	0,9 [0,5; 1,5]	0,5887	0,6956
1	53/103 (51,5)	4,8 [2,8; 12,5]	38/73 (52,1)	3,0 [2,1; 4,0]	0,7 [0,5; 1,1]	0,1727	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (andere); Lebermetastasen bei Studienbeginn							
Nein	77/131 (58,8)	3,6 [2,7; 6,9]	56/103 (54,4)	3,0 [2,1; 6,2]	0,9 [0,6; 1,3]	0,5148	0,4686
Ja	13/27 (48,1)	9,1 [2,1; n.b.]	12/21 (57,1)	2,7 [1,4; 3,7]	0,4 [0,1; 1,3]	0,1275	
QLQ-LC13 Schmerzen (andere); Knochenmetastasen bei Studienbeginn							
Nein	52/86 (60,5)	2,8 [2,1; 6,9]	38/76 (50,0)	3,7 [2,1; n.b.]	1,1 [0,7; 1,7]	0,7431	0,0614
Ja	38/72 (52,8)	4,9 [2,8; 10,3]	30/48 (62,5)	2,8 [1,4; 3,4]	0,5 [0,3; 0,9]	0,0248	
QLQ-LC13 Schmerzen (andere); PD-L1-Proteinexpression							
<1%	30/52 (57,7)	4,8 [2,7; 11,1]	21/41 (51,2)	3,7 [1,4; n.b.]	0,7 [0,4; 1,4]	0,3408	0,9659
≥1% und <50%	21/42 (50,0)	6,2 [1,4; n.b.]	24/47 (51,1)	3,0 [2,3; n.b.]	0,8 [0,4; 1,6]	0,5647	
≥50%	36/57 (63,2)	2,8 [1,4; 5,6]	17/28 (60,7)	2,1 [1,4; n.b.]	0,9 [0,5; 1,7]	0,6627	
QLQ-LC13 Schmerzen (andere); Ethnie-2							
Asiatisch	14/21 (66,7)	2,8 [1,4; 8,2]	10/18 (55,6)	2,8 [0,8; n.b.]	0,9 [0,4; 2,2]	0,8226	0,7585
Nicht asiatisch	76/136 (55,9)	4,9 [2,8; 9,1]	57/105 (54,3)	3,0 [2,1; 5,8]	0,8 [0,6; 1,2]	0,2943	
QLQ-LC13 Schmerzen (andere); Vorgeschichte einer Beteiligung des ZNS							
Nein	54/104 (51,9)	5,6 [2,8; 12,5]	44/86 (51,2)	3,4 [2,3; 8,7]	0,8 [0,6; 1,3]	0,3978	0,8044
Ja	36/54 (66,7)	2,8 [1,4; 5,6]	24/38 (63,2)	2,8 [1,4; 5,8]	0,8 [0,4; 1,3]	0,3449	
QLQ-LC13 Schmerzen (andere); Anzahl an vorherigen Therapielinien							
1	35/68 (51,5)	3,6 [2,1; 14,5]	27/56 (48,2)	3,5 [1,6; n.b.]	0,9 [0,5; 1,6]	0,7531	0,7841
2	36/62 (58,1)	5,6 [2,2; 10,3]	27/50 (54,0)	3,0 [2,1; n.b.]	0,8 [0,5; 1,4]	0,4714	
>2	19/28 (67,9)	3,1 [1,8; 6,9]	14/18 (77,8)	2,7 [0,8; 3,7]	0,6 [0,3; 1,3]	0,1975	
QLQ-LC13 Schmerzen (Thorax); Alter bei Studienbeginn							
<65 Jahre	26/83 (31,3)	13,8 [5,9; n.b.]	24/67 (35,8)	8,7 [2,8; n.b.]	0,8 [0,5; 1,5]	0,5842	0,8100
≥65 Jahre	33/75 (44,0)	9,7 [5,6; 14,7]	24/57 (42,1)	6,3 [3,5; n.b.]	0,7 [0,4; 1,3]	0,2392	
QLQ-LC13 Schmerzen (Thorax); Geschlecht							
Weiblich	19/58 (32,8)	14,7 [5,1; n.b.]	14/49 (28,6)	n.b. [7,3; n.b.]	1,1 [0,5; 2,3]	0,8305	0,4476
Männlich	40/100 (40,0)	10,9 [5,6; 14,5]	34/75 (45,3)	5,7 [2,8; 11,6]	0,7 [0,4; 1,1]	0,1518	
QLQ-LC13 Schmerzen (Thorax); Region 2							
Nordamerika und Europa	48/133 (36,1)	13,1 [6,4; n.b.]	41/105 (39,0)	7,3 [4,4; n.b.]	0,8 [0,5; 1,3]	0,3680	0,7853
Rest der Welt	11/25 (44,0)	10,9 [2,2; n.b.]	7/19 (36,8)	n.b. [2,1; n.b.]	0,8 [0,2; 2,5]	0,6654	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (Thorax); Region 1							
Nordamerika	7/16 (43,8)	10,4 [3,3; n.b.]	4/15 (26,7)	11,6 [2,7; n.b.]	1,4 [0,3; 6,9]	0,6568	0,3693
Europa	41/117 (35,0)	13,8 [6,2; n.b.]	37/90 (41,1)	6,9 [3,5; n.b.]	0,7 [0,4; 1,1]	0,1309	
Rest der Welt	11/25 (44,0)	10,9 [2,2; n.b.]	7/19 (36,8)	n.b. [2,1; n.b.]	0,8 [0,2; 2,5]	0,6654	
QLQ-LC13 Schmerzen (Thorax); ECOG Performance-Status							
0	23/55 (41,8)	13,8 [5,9; n.b.]	23/51 (45,1)	6,9 [3,5; n.b.]	0,7 [0,4; 1,3]	0,2875	0,6872
1	36/103 (35,0)	13,1 [5,6; n.b.]	25/73 (34,2)	11,6 [3,4; n.b.]	0,8 [0,5; 1,4]	0,4691	
QLQ-LC13 Schmerzen (Thorax); Lebermetastasen bei Studienbeginn							
Nein	50/131 (38,2)	13,1 [6,4; n.b.]	43/103 (41,7)	6,9 [3,5; n.b.]	0,7 [0,5; 1,1]	0,1090	0,3004
Ja	9/27 (33,3)	n.b. [2,8; n.b.]	5/21 (23,8)	n.b. [2,7; n.b.]	1,3 [0,3; 5,0]	0,7136	
QLQ-LC13 Schmerzen (Thorax); Knochenmetastasen bei Studienbeginn							
Nein	34/86 (39,5)	13,1 [6,2; n.b.]	32/76 (42,1)	6,9 [3,5; n.b.]	0,7 [0,4; 1,2]	0,2481	0,8817
Ja	25/72 (34,7)	13,8 [5,6; n.b.]	16/48 (33,3)	8,7 [3,5; n.b.]	0,9 [0,4; 1,8]	0,7610	
QLQ-LC13 Schmerzen (Thorax); PD-L1-Proteinexpression							
<1%	20/52 (38,5)	13,8 [4,8; n.b.]	19/41 (46,3)	5,7 [2,8; n.b.]	0,6 [0,3; 1,2]	0,1688	0,6610
≥1% und <50%	12/42 (28,6)	n.b. [5,6; n.b.]	13/47 (27,7)	n.b. [2,8; n.b.]	0,8 [0,3; 1,8]	0,5983	
≥50%	23/57 (40,4)	13,1 [4,9; n.b.]	11/28 (39,3)	7,3 [3,5; n.b.]	1,1 [0,5; 2,3]	0,8953	
QLQ-LC13 Schmerzen (Thorax); Ethnie-2							
Asiatisch	9/21 (42,9)	7,6 [2,1; n.b.]	6/18 (33,3)	n.b. [2,7; n.b.]	0,8 [0,3; 2,6]	0,7730	0,4841
Nicht asiatisch	50/136 (36,8)	13,8 [6,2; n.b.]	42/105 (40,0)	7,3 [4,4; n.b.]	0,8 [0,5; 1,2]	0,2575	
QLQ-LC13 Schmerzen (Thorax); Vorgeschichte einer Beteiligung des ZNS							
Nein	36/104 (34,6)	13,1 [6,4; n.b.]	38/86 (44,2)	6,3 [3,4; n.b.]	0,6 [0,4; 1,0]	0,0535	0,1192
Ja	23/54 (42,6)	10,9 [3,4; n.b.]	10/38 (26,3)	n.b. [3,5; n.b.]	1,3 [0,6; 2,8]	0,4849	
QLQ-LC13 Schmerzen (Thorax); Anzahl an vorherigen Therapielinien							
1	23/68 (33,8)	13,8 [4,9; n.b.]	22/56 (39,3)	5,6 [2,8; n.b.]	0,8 [0,4; 1,4]	0,4148	0,9494
2	24/62 (38,7)	13,1 [8,0; n.b.]	19/50 (38,0)	7,3 [4,4; n.b.]	0,7 [0,4; 1,3]	0,2990	
>2	12/28 (42,9)	6,2 [3,4; 14,7]	7/18 (38,9)	8,7 [1,6; n.b.]	1,1 [0,4; 2,8]	0,8978	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Alter bei Studienbeginn							
<65 Jahre	24/71 (33,8)	12,2 [5,6; n.b.]	20/56 (35,7)	7,3 [2,8; n.b.]	0,8 [0,4; 1,6]	0,5621	0,8621
≥65 Jahre	24/66 (36,4)	10,3 [7,6; n.b.]	12/45 (26,7)	n.b. [3,5; n.b.]	0,9 [0,4; 2,1]	0,8868	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Geschlecht							
Weiblich	20/52 (38,5)	10,3 [2,9; n.b.]	14/40 (35,0)	n.b. [2,8; n.b.]	0,9 [0,4; 1,9]	0,7867	0,8583
Männlich	28/85 (32,9)	12,2 [9,4; n.b.]	18/61 (29,5)	n.b. [2,8; n.b.]	0,7 [0,4; 1,4]	0,3595	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Region 2							
Nordamerika und Europa	44/115 (38,3)	10,3 [7,6; n.b.]	28/85 (32,9)	7,3 [3,5; n.b.]	0,9 [0,6; 1,6]	0,8461	0,2798
Rest der Welt	4/22 (18,2)	n.b. [3,4; n.b.]	4/16 (25,0)	n.b. [2,1; n.b.]	0,3 [0,1; 1,7]	0,1476	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Region 1							
Nordamerika	2/14 (14,3)	n.b. [12,2; n.b.]	4/12 (33,3)	n.b. [2,1; n.b.]	0,6 [0,0; 8,1]	0,7227	0,2536
Europa	42/101 (41,6)	9,4 [4,3; 11,0]	24/73 (32,9)	7,3 [3,5; n.b.]	1,0 [0,6; 1,8]	0,9368	
Rest der Welt	4/22 (18,2)	n.b. [3,4; n.b.]	4/16 (25,0)	n.b. [2,1; n.b.]	0,3 [0,1; 1,7]	0,1476	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; ECOG Performance-Status							
0	16/47 (34,0)	11,0 [9,4; n.b.]	14/40 (35,0)	7,3 [3,3; n.b.]	0,5 [0,2; 1,2]	0,1093	0,3365
1	32/90 (35,6)	13,1 [4,2; n.b.]	18/61 (29,5)	n.b. [2,8; n.b.]	1,2 [0,6; 2,2]	0,6601	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Lebermetastasen bei Studienbeginn							
Nein	40/113 (35,4)	11,0 [7,6; n.b.]	25/80 (31,2)	n.b. [3,5; n.b.]	0,9 [0,5; 1,5]	0,5809	0,7141
Ja	8/24 (33,3)	n.b. [2,1; n.b.]	7/21 (33,3)	2,8 [2,3; n.b.]	0,9 [0,3; 3,2]	0,8999	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Knochenmetastasen bei Studienbeginn							
Nein	21/73 (28,8)	13,1 [10,3; n.b.]	15/56 (26,8)	n.b. [7,3; n.b.]	0,5 [0,2; 1,2]	0,1190	0,3103
Ja	27/64 (42,2)	7,6 [2,2; n.b.]	17/45 (37,8)	3,5 [2,4; n.b.]	1,0 [0,6; 2,0]	0,8890	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; PD-L1-Proteinexpression							
<1%	20/47 (42,6)	7,6 [4,0; n.b.]	14/34 (41,2)	3,5 [2,1; n.b.]	0,7 [0,3; 1,6]	0,3929	0,2871
≥1% und <50%	9/36 (25,0)	n.b. [10,3; n.b.]	12/38 (31,6)	5,7 [2,6; n.b.]	0,7 [0,3; 1,7]	0,4274	
≥50%	18/49 (36,7)	10,3 [4,3; n.b.]	4/21 (19,0)	7,3 [3,5; n.b.]	1,7 [0,5; 5,4]	0,3628	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Ethnie-2							
Asiatisch	3/18 (16,7)	n.b. [3,4; n.b.]	4/15 (26,7)	n.b. [1,5; n.b.]	0,3 [0,1; 1,8]	0,1802	0,2453
Nicht asiatisch	45/118 (38,1)	10,3 [7,6; n.b.]	27/85 (31,8)	7,3 [3,5; n.b.]	1,0 [0,6; 1,6]	0,8979	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Vorgeschichte einer Beteiligung des ZNS							
Nein	33/92 (35,9)	10,4 [7,6; n.b.]	21/70 (30,0)	n.b. [3,5; n.b.]	0,9 [0,5; 1,7]	0,7889	0,7847
Ja	15/45 (33,3)	n.b. [4,3; n.b.]	11/31 (35,5)	5,7 [2,3; n.b.]	0,7 [0,3; 1,6]	0,3914	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Anzahl an vorherigen Therapielinien							
1	21/59 (35,6)	n.b. [2,2; n.b.]	12/45 (26,7)	n.b. [2,8; n.b.]	1,5 [0,7; 3,0]	0,2994	0,3982
2	17/53 (32,1)	12,2 [10,3; n.b.]	15/42 (35,7)	7,3 [3,3; n.b.]	0,5 [0,2; 1,1]	0,0806	
>2	10/25 (40,0)	7,6 [4,0; n.b.]	5/14 (35,7)	n.b. [0,8; n.b.]	0,7 [0,2; 2,2]	0,5520	
QLQ-LC13 Wunder Mund; Alter bei Studienbeginn							
<65 Jahre	24/83 (28,9)	n.b. [9,8; n.b.]	30/67 (44,8)	5,8 [2,3; n.b.]	0,5 [0,3; 0,9]	0,0154	0,6168
≥65 Jahre	18/75 (24,0)	n.b. [16,0; n.b.]	27/57 (47,4)	3,5 [1,4; n.b.]	0,4 [0,2; 0,8]	0,0043	
QLQ-LC13 Wunder Mund; Geschlecht							
Weiblich	20/58 (34,5)	16,0 [6,4; n.b.]	24/49 (49,0)	3,5 [1,9; n.b.]	0,6 [0,3; 1,1]	0,0899	0,1518
Männlich	22/100 (22,0)	n.b. [14,5; n.b.]	33/75 (44,0)	6,2 [2,8; n.b.]	0,3 [0,2; 0,6]	<,0001	
QLQ-LC13 Wunder Mund; Region 2							
Nordamerika und Europa	32/133 (24,1)	n.b. [16,0; n.b.]	46/105 (43,8)	5,8 [3,4; n.b.]	0,4 [0,2; 0,6]	<,0001	0,5358
Rest der Welt	10/25 (40,0)	14,5 [2,8; n.b.]	11/19 (57,9)	1,9 [0,8; n.b.]	0,6 [0,2; 1,7]	0,2921	
QLQ-LC13 Wunder Mund; Region 1							
Nordamerika	6/16 (37,5)	n.b. [2,8; n.b.]	6/15 (40,0)	n.b. [0,7; n.b.]	1,4 [0,3; 6,9]	0,6648	0,2538
Europa	26/117 (22,2)	n.b. [16,0; n.b.]	40/90 (44,4)	5,8 [2,9; n.b.]	0,3 [0,2; 0,5]	<,0001	
Rest der Welt	10/25 (40,0)	14,5 [2,8; n.b.]	11/19 (57,9)	1,9 [0,8; n.b.]	0,6 [0,2; 1,7]	0,2921	
QLQ-LC13 Wunder Mund; ECOG Performance-Status							
0	11/55 (20,0)	n.b. [14,5; n.b.]	26/51 (51,0)	4,4 [2,8; 8,7]	0,2 [0,1; 0,5]	<,0001	0,0643
1	31/103 (30,1)	16,0 [9,8; n.b.]	31/73 (42,5)	4,2 [2,1; n.b.]	0,6 [0,3; 1,0]	0,0393	
QLQ-LC13 Wunder Mund; Lebermetastasen bei Studienbeginn							
Nein	33/131 (25,2)	n.b. [14,5; n.b.]	48/103 (46,6)	5,8 [2,8; n.b.]	0,4 [0,2; 0,6]	<,0001	0,6093
Ja	9/27 (33,3)	n.b. [3,4; n.b.]	9/21 (42,9)	3,5 [1,5; n.b.]	0,6 [0,2; 1,9]	0,3596	
QLQ-LC13 Wunder Mund; Knochenmetastasen bei Studienbeginn							
Nein	19/86 (22,1)	n.b. [14,5; n.b.]	37/76 (48,7)	5,8 [1,5; n.b.]	0,3 [0,2; 0,6]	<,0001	0,1289
Ja	23/72 (31,9)	16,0 [5,6; n.b.]	20/48 (41,7)	3,5 [2,9; 8,7]	0,6 [0,3; 1,1]	0,0959	
QLQ-LC13 Wunder Mund; PD-L1-Proteinexpression							
<1%	14/52 (26,9)	n.b. [10,4; n.b.]	20/41 (48,8)	5,8 [1,5; n.b.]	0,4 [0,2; 0,9]	0,0171	0,5076
≥1% und <50%	13/42 (31,0)	14,5 [6,2; n.b.]	18/47 (38,3)	4,4 [2,1; n.b.]	0,6 [0,3; 1,3]	0,1723	
≥50%	11/57 (19,3)	n.b. [16,0; n.b.]	14/28 (50,0)	4,2 [0,7; n.b.]	0,3 [0,1; 0,8]	0,0121	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wunder Mund; Ethnie-2							
Asiatisch	8/21 (38,1)	14,5 [2,8; n.b.]	12/18 (66,7)	1,4 [0,7; 3,5]	0,3 [0,1; 1,0]	0,0329	0,6609
Nicht asiatisch	34/136 (25,0)	n.b. [16,0; n.b.]	45/105 (42,9)	5,8 [3,4; n.b.]	0,4 [0,3; 0,7]	0,0001	
QLQ-LC13 Wunder Mund; Vorgeschichte einer Beteiligung des ZNS							
Nein	25/104 (24,0)	n.b. [10,4; n.b.]	37/86 (43,0)	8,7 [2,8; n.b.]	0,4 [0,3; 0,7]	0,0017	0,6670
Ja	17/54 (31,5)	16,0 [14,5; n.b.]	20/38 (52,6)	3,5 [1,4; 6,2]	0,3 [0,1; 0,6]	0,0013	
QLQ-LC13 Wunder Mund; Anzahl an vorherigen Therapielinien							
1	21/68 (30,9)	14,5 [6,4; n.b.]	27/56 (48,2)	2,8 [1,5; n.b.]	0,4 [0,2; 0,7]	0,0025	0,6369
2	13/62 (21,0)	n.b. [n.b.; n.b.]	24/50 (48,0)	6,2 [2,9; n.b.]	0,4 [0,2; 0,7]	0,0038	
>2	8/28 (28,6)	16,0 [6,9; 16,0]	6/18 (33,3)	8,7 [2,3; n.b.]	0,4 [0,1; 1,4]	0,1328	
QLQ-LC13 Bluthusten; Alter bei Studienbeginn							
<65 Jahre	10/83 (12,0)	n.b. [n.b.; n.b.]	12/67 (17,9)	n.b. [7,9; n.b.]	0,5 [0,2; 1,3]	0,1590	0,6757
≥65 Jahre	8/75 (10,7)	n.b. [15,4; n.b.]	9/57 (15,8)	n.b. [9,9; n.b.]	0,3 [0,1; 1,1]	0,0544	
QLQ-LC13 Bluthusten; Geschlecht							
Weiblich	7/58 (12,1)	n.b. [n.b.; n.b.]	8/49 (16,3)	n.b. [7,9; n.b.]	0,4 [0,1; 1,2]	0,0858	0,8018
Männlich	11/100 (11,0)	n.b. [n.b.; n.b.]	13/75 (17,3)	n.b. [n.b.; n.b.]	0,3 [0,1; 0,8]	0,0129	
QLQ-LC13 Bluthusten; Region 2							
Nordamerika und Europa	16/133 (12,0)	n.b. [n.b.; n.b.]	18/105 (17,1)	n.b. [9,9; n.b.]	0,5 [0,2; 1,0]	0,0536	0,6368
Rest der Welt	2/25 (8,0)	15,4 [n.b.; n.b.]	3/19 (15,8)	n.b. [2,8; n.b.]	0,2 [0,0; 2,1]	0,1526	
QLQ-LC13 Bluthusten; Region 1							
Nordamerika	3/16 (18,8)	n.b. [9,7; n.b.]	3/15 (20,0)	n.b. [7,9; n.b.]	207640000,0 [0,0; n.b.]	0,1573	0,8306
Europa	13/117 (11,1)	n.b. [n.b.; n.b.]	15/90 (16,7)	n.b. [9,9; n.b.]	0,4 [0,2; 0,9]	0,0286	
Rest der Welt	2/25 (8,0)	15,4 [n.b.; n.b.]	3/19 (15,8)	n.b. [2,8; n.b.]	0,2 [0,0; 2,1]	0,1526	
QLQ-LC13 Bluthusten; ECOG Performance-Status							
0	4/55 (7,3)	n.b. [n.b.; n.b.]	8/51 (15,7)	n.b. [9,9; n.b.]	0,1 [0,0; 0,7]	0,0071	0,4655
1	14/103 (13,6)	n.b. [13,5; n.b.]	13/73 (17,8)	n.b. [7,9; n.b.]	0,4 [0,2; 1,0]	0,0523	
QLQ-LC13 Bluthusten; Lebermetastasen bei Studienbeginn							
Nein	16/131 (12,2)	n.b. [n.b.; n.b.]	15/103 (14,6)	n.b. [n.b.; n.b.]	0,5 [0,2; 1,1]	0,0746	0,2506
Ja	2/27 (7,4)	n.b. [n.b.; n.b.]	6/21 (28,6)	7,9 [2,7; n.b.]	0,4 [0,1; 2,7]	0,3540	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Bluthusten; Knochenmetastasen bei Studienbeginn							
Nein	13/86 (15,1)	n.b. [n.b.; n.b.]	12/76 (15,8)	n.b. [9,9; n.b.]	0,6 [0,3; 1,5]	0,2747	0,0373
Ja	5/72 (6,9)	n.b. [n.b.; n.b.]	9/48 (18,8)	n.b. [7,9; n.b.]	0,2 [0,0; 0,8]	0,0102	
QLQ-LC13 Bluthusten; PD-L1-Proteinexpression							
<1%	11/52 (21,2)	n.b. [11,1; n.b.]	10/41 (24,4)	n.b. [6,9; n.b.]	0,8 [0,3; 1,9]	0,5483	0,0458
≥1% und <50%	4/42 (9,5)	n.b. [15,4; n.b.]	2/47 (4,3)	n.b. [7,9; n.b.]	0,3 [0,0; 3,9]	0,3392	
≥50%	3/57 (5,3)	n.b. [n.b.; n.b.]	9/28 (32,1)	n.b. [2,8; n.b.]	0,1 [0,0; 0,6]	0,0018	
QLQ-LC13 Bluthusten; Ethnie-2							
Asiatisch	2/21 (9,5)	n.b. [4,3; n.b.]	4/18 (22,2)	n.b. [2,7; n.b.]	0,1 [0,0; 1,4]	0,0530	0,6818
Nicht asiatisch	16/136 (11,8)	n.b. [n.b.; n.b.]	17/105 (16,2)	n.b. [9,9; n.b.]	0,4 [0,2; 0,9]	0,0279	
QLQ-LC13 Bluthusten; Vorgeschichte einer Beteiligung des ZNS							
Nein	13/104 (12,5)	n.b. [n.b.; n.b.]	14/86 (16,3)	n.b. [9,9; n.b.]	0,5 [0,2; 1,1]	0,0618	0,3968
Ja	5/54 (9,3)	n.b. [n.b.; n.b.]	7/38 (18,4)	7,9 [6,9; n.b.]	0,3 [0,1; 0,9]	0,0228	
QLQ-LC13 Bluthusten; Anzahl an vorherigen Therapielinien							
1	8/68 (11,8)	n.b. [n.b.; n.b.]	9/56 (16,1)	n.b. [9,9; n.b.]	0,5 [0,2; 1,4]	0,1938	0,7677
2	7/62 (11,3)	n.b. [n.b.; n.b.]	7/50 (14,0)	n.b. [n.b.; n.b.]	0,4 [0,1; 1,2]	0,0841	
>2	3/28 (10,7)	n.b. [11,1; n.b.]	5/18 (27,8)	7,9 [2,7; n.b.]	0,2 [0,1; 1,0]	0,0391	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-LC13 = Quality of Life Questionnaire Lung Cancer 13; ZNS = Zentrales Nervensystem

2.3.2.5 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-LC13 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-LC13 Dysphagie								
158	69 (43,7)	9,3 [5,8; 18,7]	124	55 (44,4)	5,1 [3,5; 15,2]	0,72 [0,50; 1,05]	0,0851	0,0839
QLQ-LC13 Dyspnoe								
158	105 (66,5)	3,4 [2,1; 5,0]	124	96 (77,4)	1,5 [1,4; 2,1]	0,58 [0,43; 0,78]	0,0004	0,0003
QLQ-LC13 Haarausfall								
158	60 (38,0)	11,7 [6,9; n.b.]	124	113 (91,1)	0,7 [0,7; 0,8]	0,12 [0,08; 0,17]	<,0001	<,0001
QLQ-LC13 Husten								
158	75 (47,5)	7,7 [5,8; 14,5]	124	61 (49,2)	3,5 [2,8; 8,7]	0,63 [0,44; 0,90]	0,0118	0,0112
QLQ-LC13 Periphere Neuropathie								
158	84 (53,2)	5,8 [3,4; 8,5]	124	74 (59,7)	3,4 [2,5; 4,2]	0,68 [0,49; 0,94]	0,0195	0,0188
QLQ-LC13 Schmerzen (Arm/Schulter)								
158	102 (64,6)	4,1 [3,2; 5,8]	124	55 (44,4)	5,7 [2,8; 14,1]	1,17 [0,83; 1,64]	0,3722	0,3717
QLQ-LC13 Schmerzen (andere)								
158	106 (67,1)	3,3 [2,7; 5,2]	124	73 (58,9)	2,8 [2,1; 3,7]	0,87 [0,64; 1,19]	0,3885	0,3882
QLQ-LC13 Schmerzen (Thorax)								
158	83 (52,5)	6,3 [4,9; 10,2]	124	55 (44,4)	6,9 [3,4; 11,6]	0,92 [0,65; 1,31]	0,6639	0,6638
QLQ-LC13 Wirksamkeit der Schmerzmedikation								
137	66 (48,2)	6,9 [4,2; 10,4]	101	36 (35,6)	5,7 [3,5; n.b.]	0,96 [0,62; 1,48]	0,8509	0,8514
QLQ-LC13 Wunder Mund								
158	66 (41,8)	10,4 [6,3; n.b.]	124	65 (52,4)	3,5 [2,3; 5,8]	0,51 [0,35; 0,73]	0,0003	0,0002
QLQ-LC13 Bluthusten								
158	45 (28,5)	18,6 [13,5; n.b.]	124	34 (27,4)	11,2 [7,9; n.b.]	0,64 [0,40; 1,03]	0,0648	0,0629

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; n.b. = nicht berechenbar; QLQ-LC13 = Quality of Life Questionnaire Lung Cancer 13

2.3.2.6 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-LC13 (präspezifizierte Analyse inkl. Tod als Ereignis)

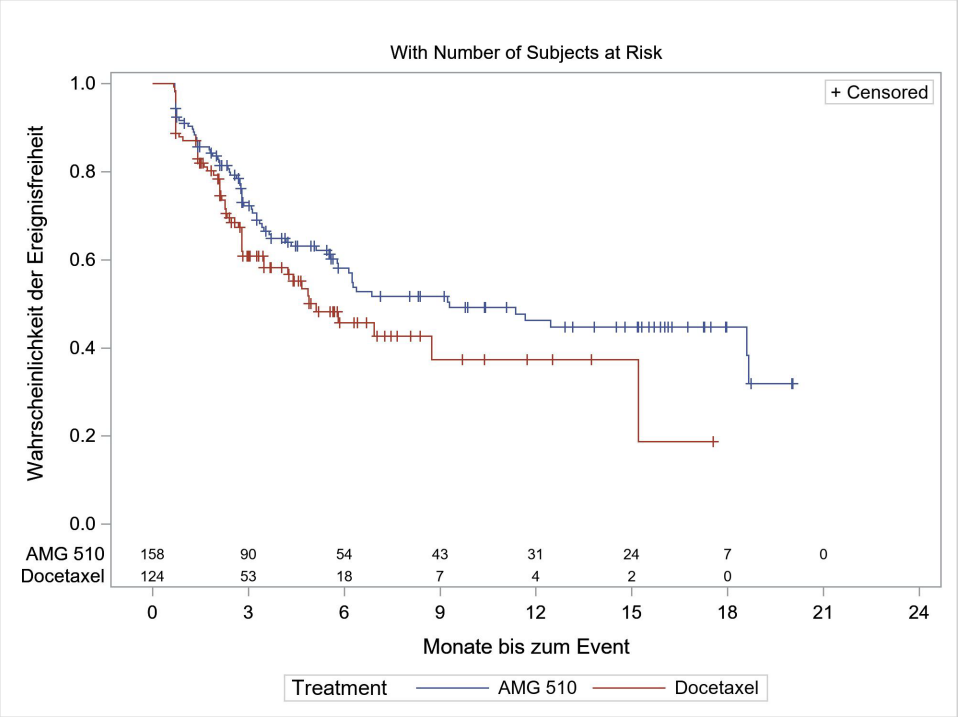

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dysphagie, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

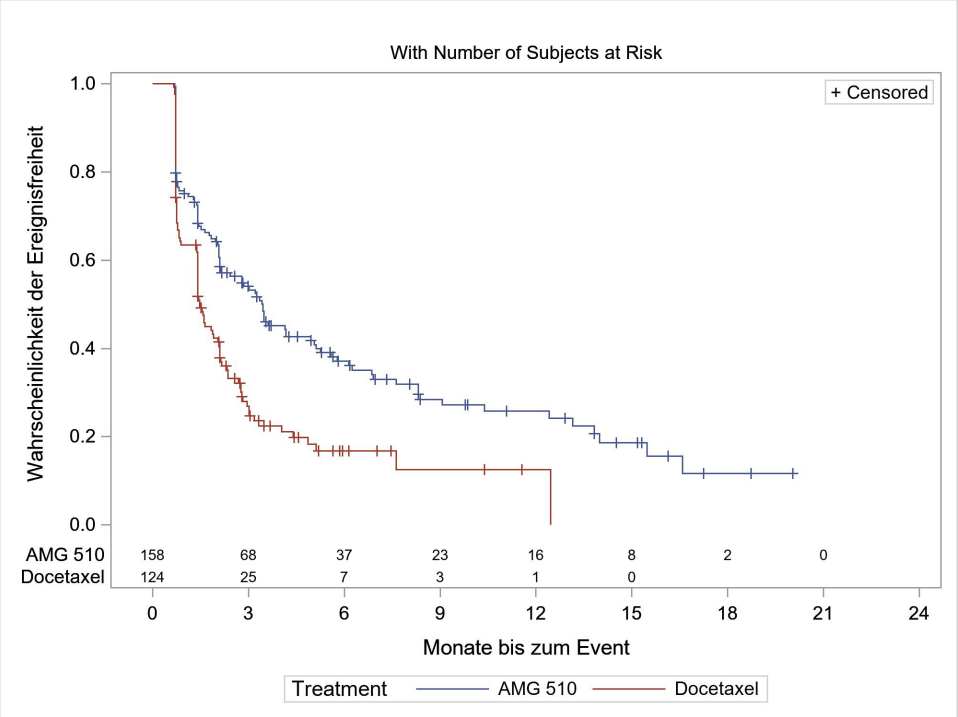

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dyspnoe, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

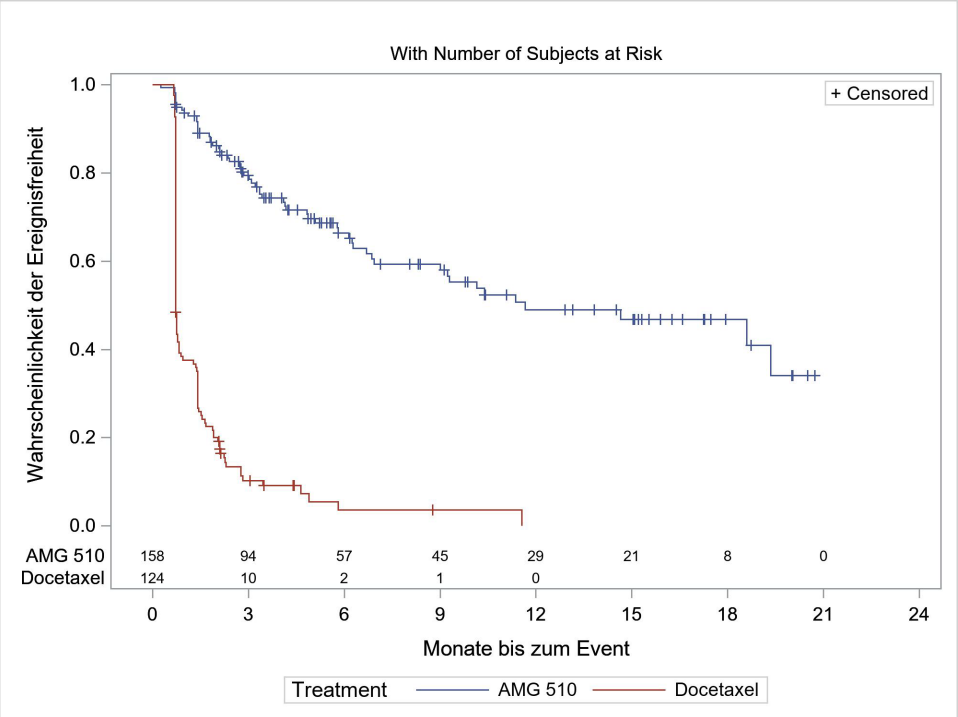

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Haarausfall, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

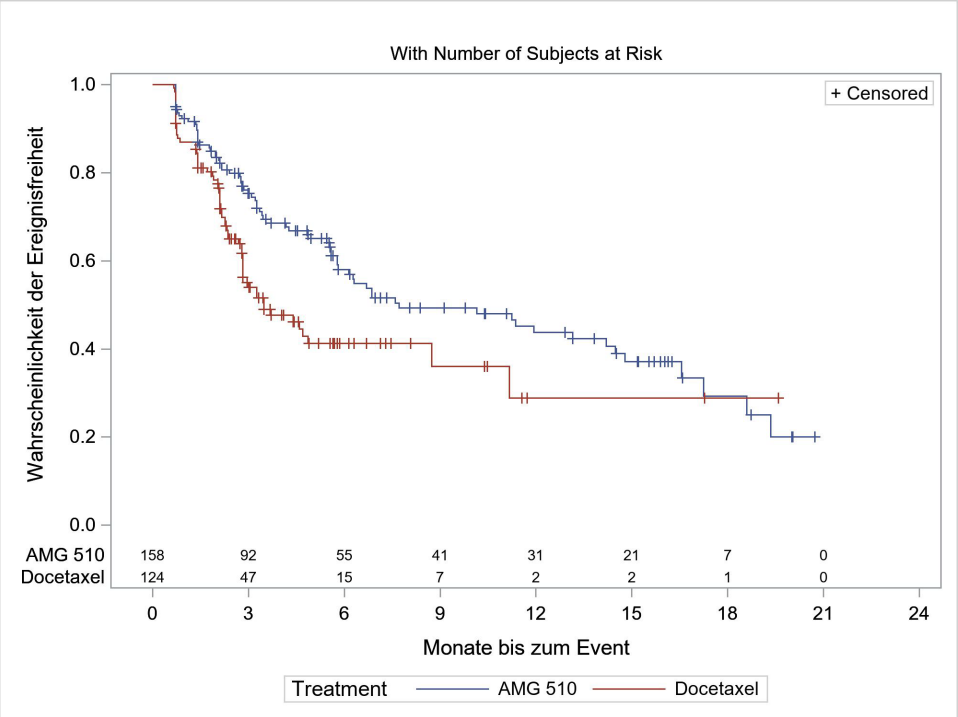

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Husten, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

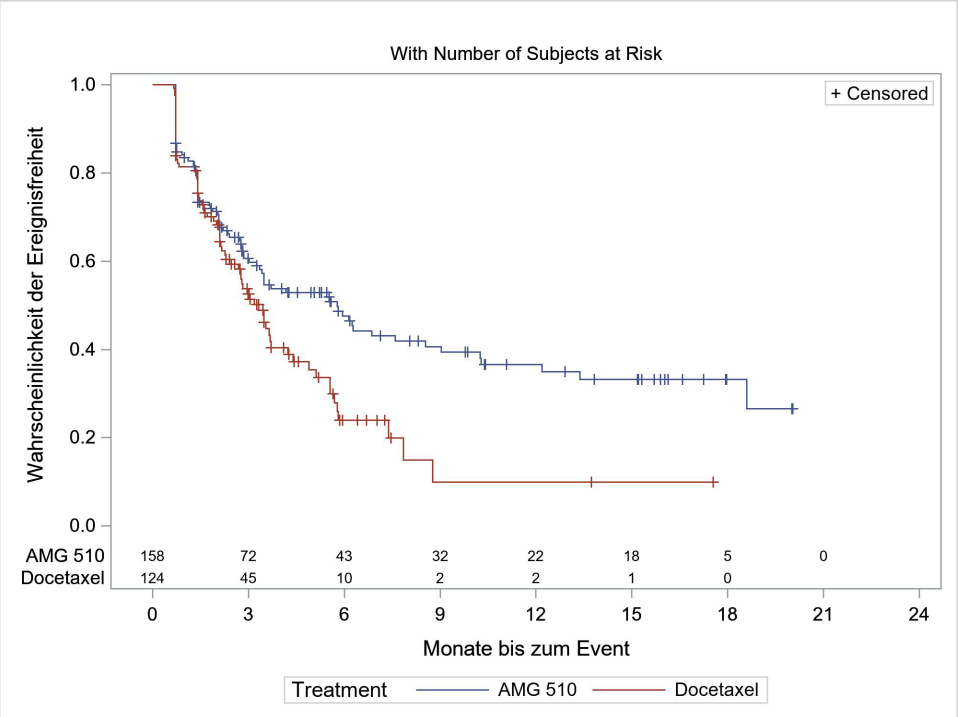

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Periphere Neuropathie, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

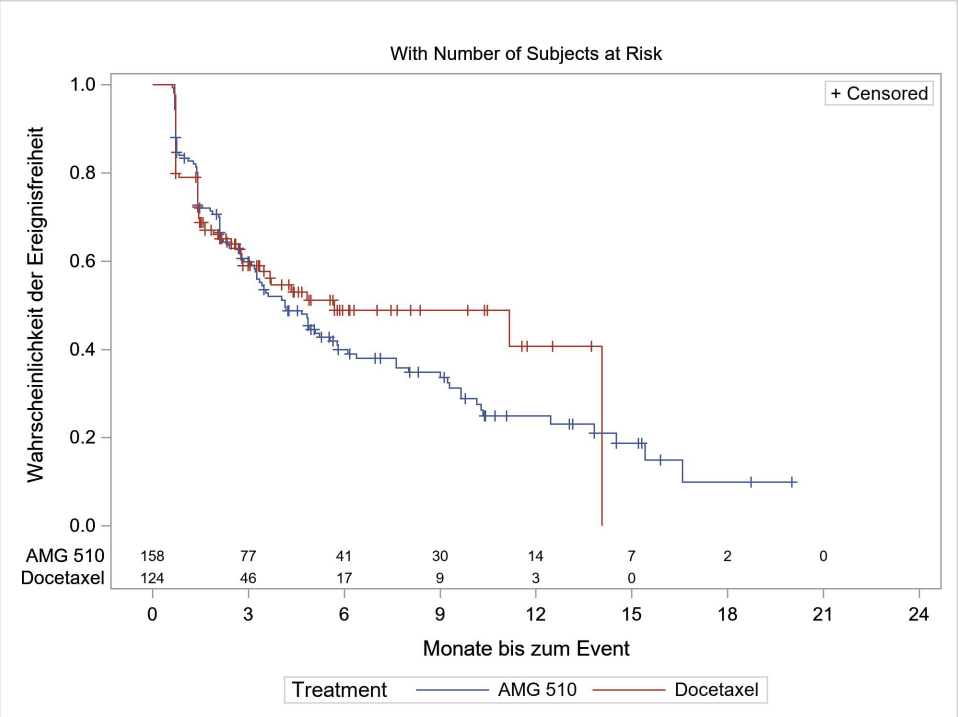

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Arm/Schulter), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

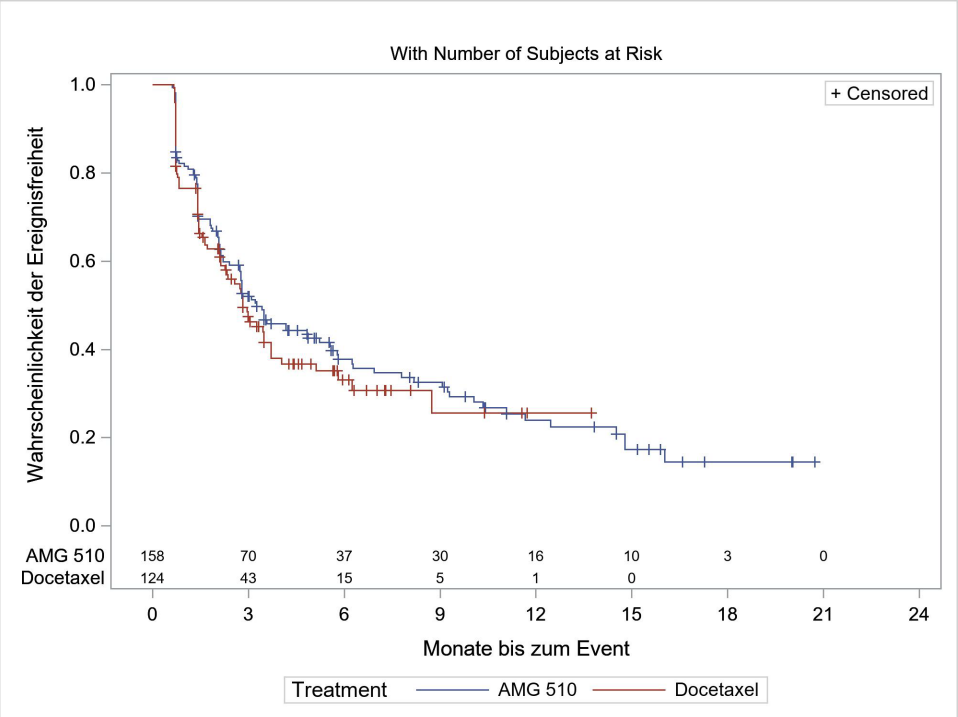

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (andere), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

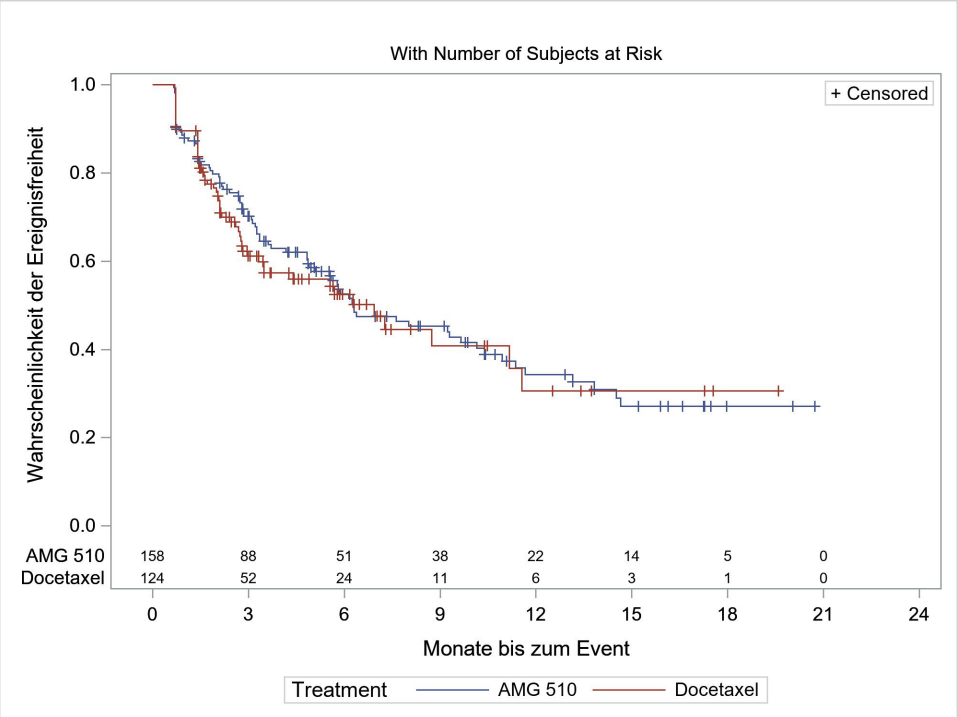

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Thorax), Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

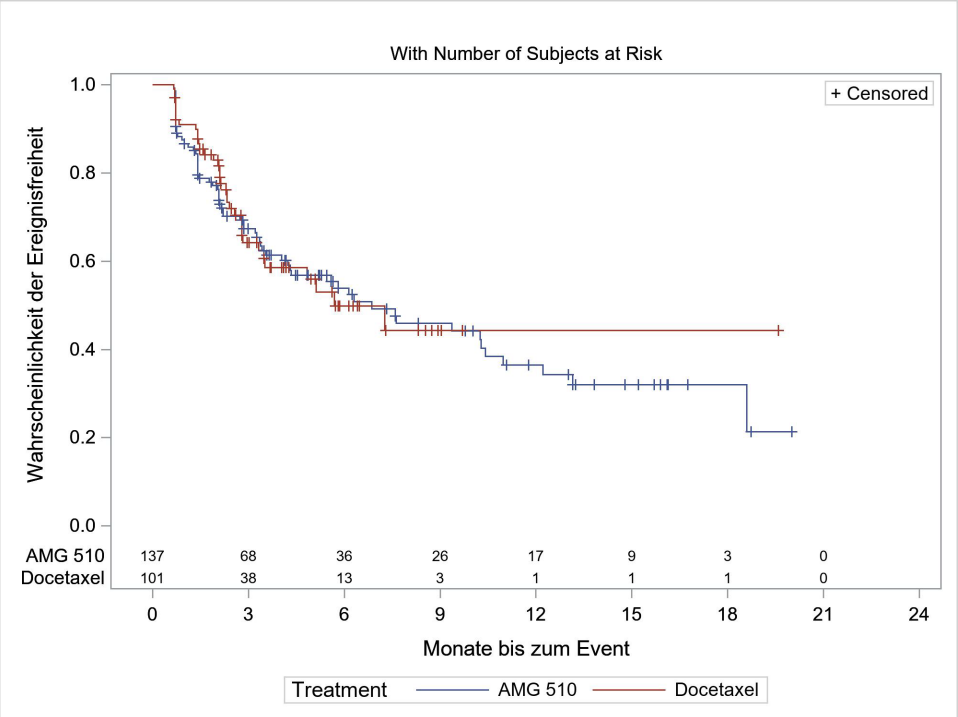

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wirksamkeit der Schmerzmedikation, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

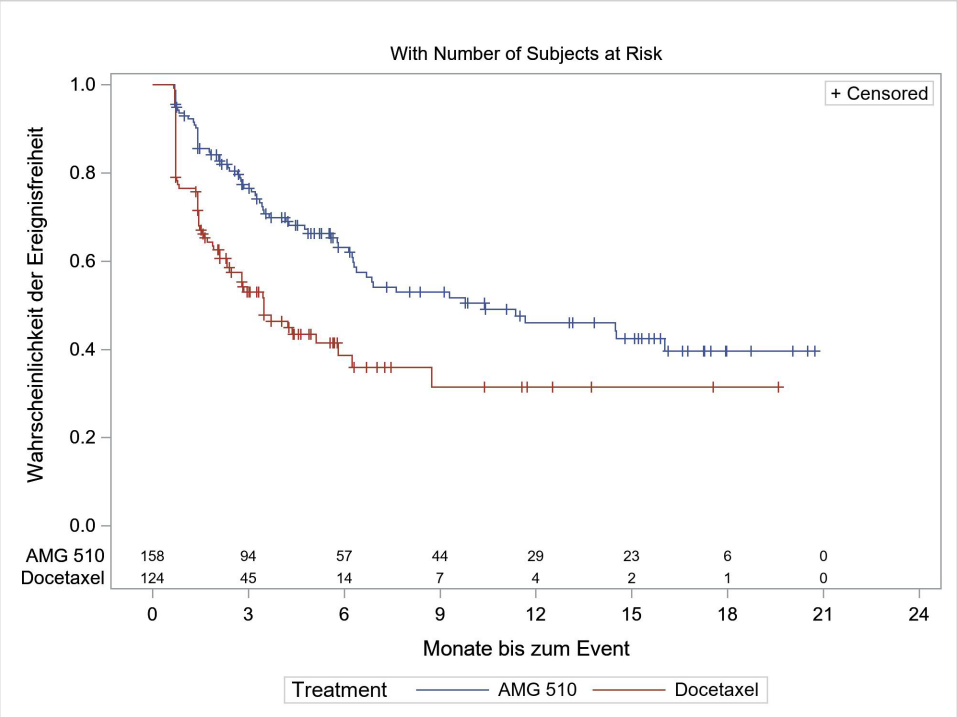

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wunder Mund, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

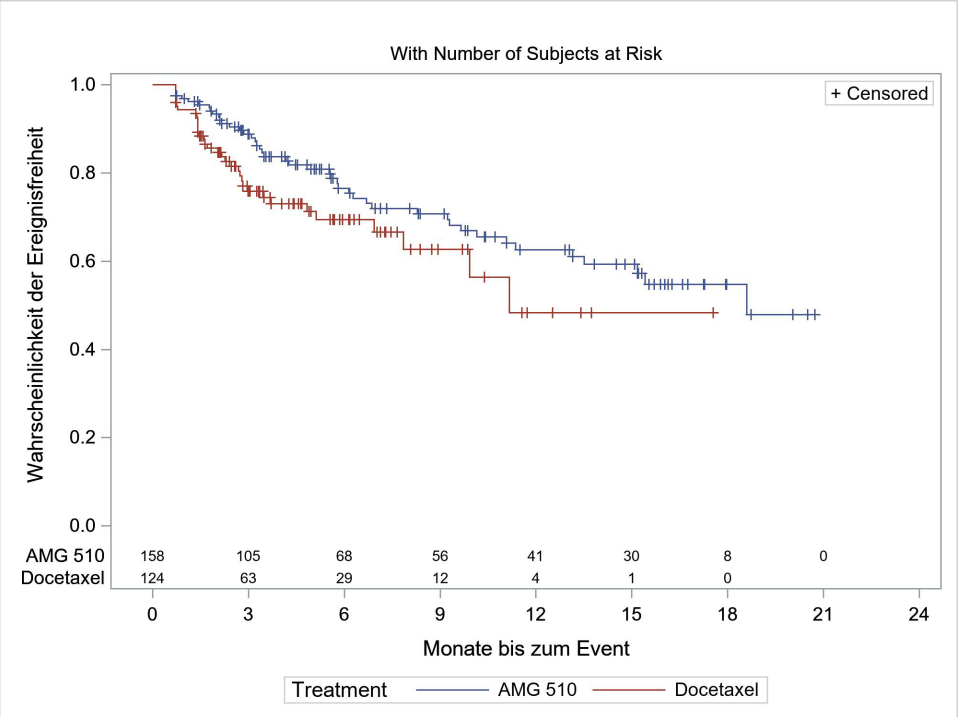

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Bluthusten, Zeit bis zur Verschlechterung um ≥10%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.2.7 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-LC13 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-LC13 Dysphagie								
158	69 (43,7)	9,3 [5,8; 18,7]	124	55 (44,4)	5,1 [3,5; 15,2]	0,72 [0,50; 1,05]	0,0851	0,0839
QLQ-LC13 Dyspnoe								
158	74 (46,8)	7,7 [5,9; 13,1]	124	75 (60,5)	2,8 [2,1; 4,2]	0,44 [0,31; 0,63]	<,0001	<,0001
QLQ-LC13 Haarausfall								
158	60 (38,0)	11,7 [6,9; n.b.]	124	113 (91,1)	0,7 [0,7; 0,8]	0,12 [0,08; 0,17]	<,0001	<,0001
QLQ-LC13 Husten								
158	75 (47,5)	7,7 [5,8; 14,5]	124	61 (49,2)	3,5 [2,8; 8,7]	0,63 [0,44; 0,90]	0,0118	0,0112
QLQ-LC13 Periphere Neuropathie								
158	84 (53,2)	5,8 [3,4; 8,5]	124	74 (59,7)	3,4 [2,5; 4,2]	0,68 [0,49; 0,94]	0,0195	0,0188
QLQ-LC13 Schmerzen (Arm/Schulter)								
158	102 (64,6)	4,1 [3,2; 5,8]	124	55 (44,4)	5,7 [2,8; 14,1]	1,17 [0,83; 1,64]	0,3722	0,3717
QLQ-LC13 Schmerzen (andere)								
158	106 (67,1)	3,3 [2,7; 5,2]	124	73 (58,9)	2,8 [2,1; 3,7]	0,87 [0,64; 1,19]	0,3885	0,3882
QLQ-LC13 Schmerzen (Thorax)								
158	83 (52,5)	6,3 [4,9; 10,2]	124	55 (44,4)	6,9 [3,4; 11,6]	0,92 [0,65; 1,31]	0,6639	0,6638
QLQ-LC13 Wirksamkeit der Schmerzmedikation								
137	66 (48,2)	6,9 [4,2; 10,4]	101	36 (35,6)	5,7 [3,5; n.b.]	0,96 [0,62; 1,48]	0,8509	0,8514
QLQ-LC13 Wunder Mund								
158	66 (41,8)	10,4 [6,3; n.b.]	124	65 (52,4)	3,5 [2,3; 5,8]	0,51 [0,35; 0,73]	0,0003	0,0002
QLQ-LC13 Bluthusten								
158	45 (28,5)	18,6 [13,5; n.b.]	124	34 (27,4)	11,2 [7,9; n.b.]	0,64 [0,40; 1,03]	0,0648	0,0629
1) p-Wert des Cox-Modells 2) p-Wert des Logrank-Tests Die Auswertung erfolgte auf Grundlage der ITT-Population.								
KI = Konfidenzintervall; n.b. = nicht berechenbar; QLQ-LC13 = Quality of Life Questionnaire Lung Cancer 13								

2.3.2.8 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-LC13 (präspezifizierte Analyse inkl. Tod als Ereignis)

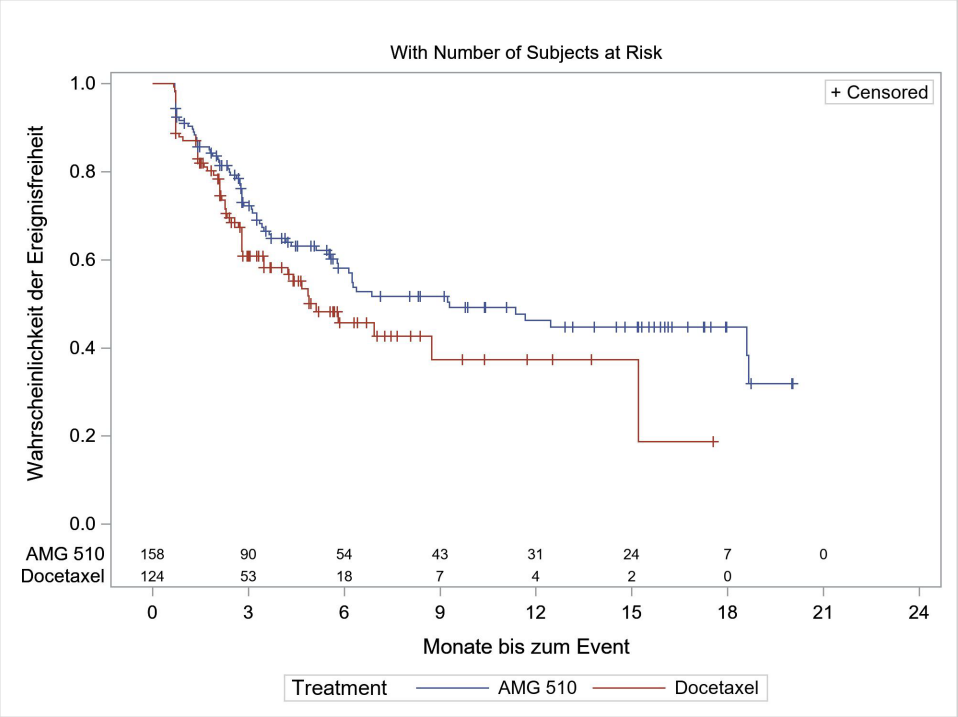

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dysphagie, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

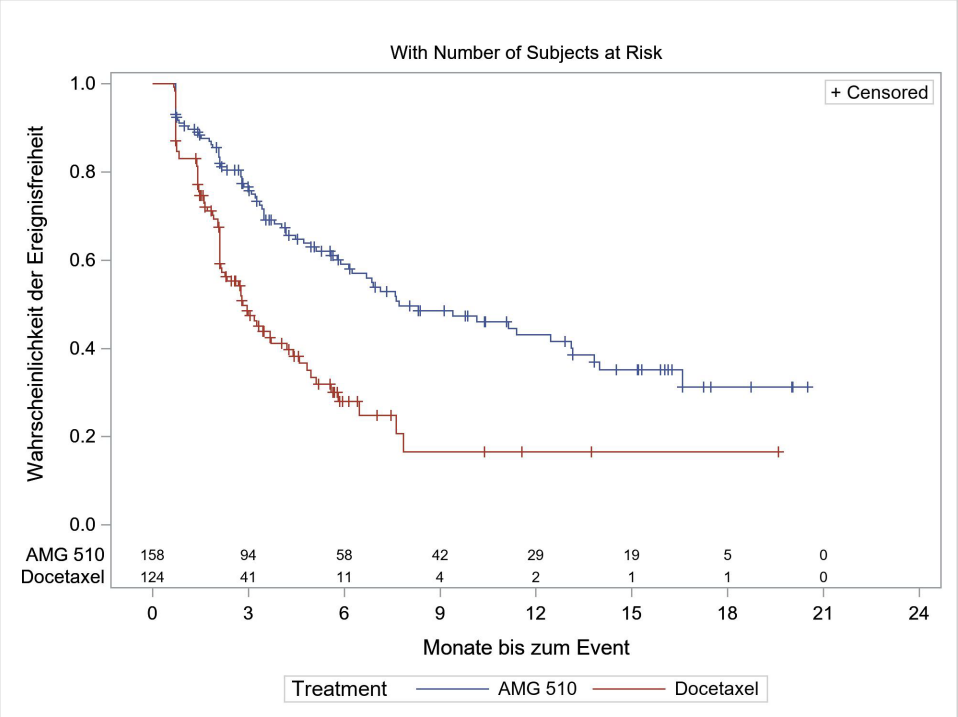

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Dyspnoe, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

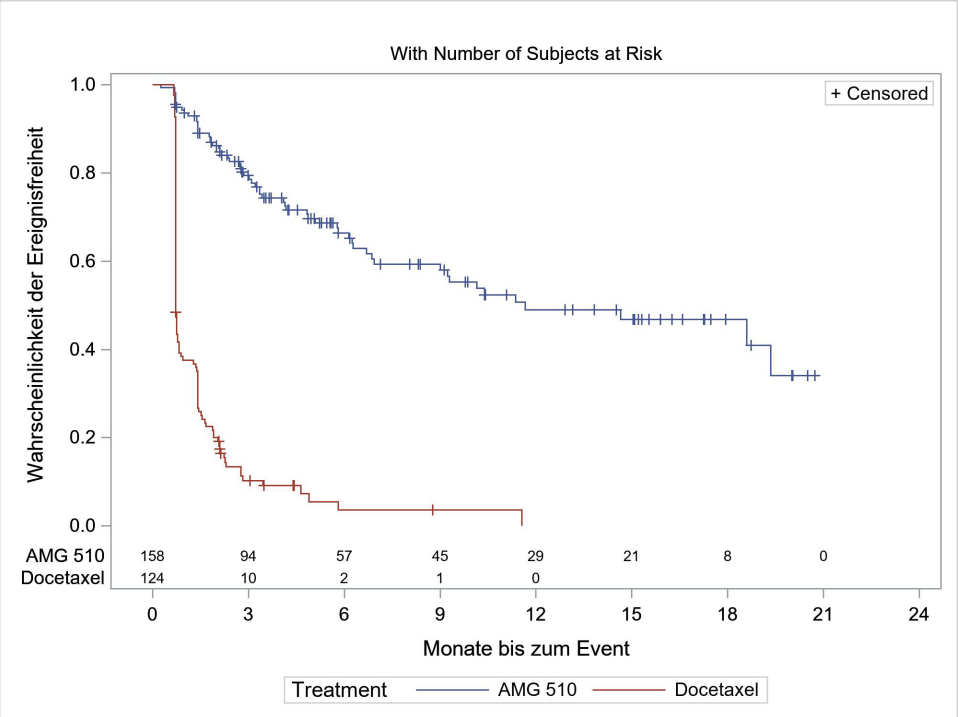

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Haarausfall, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

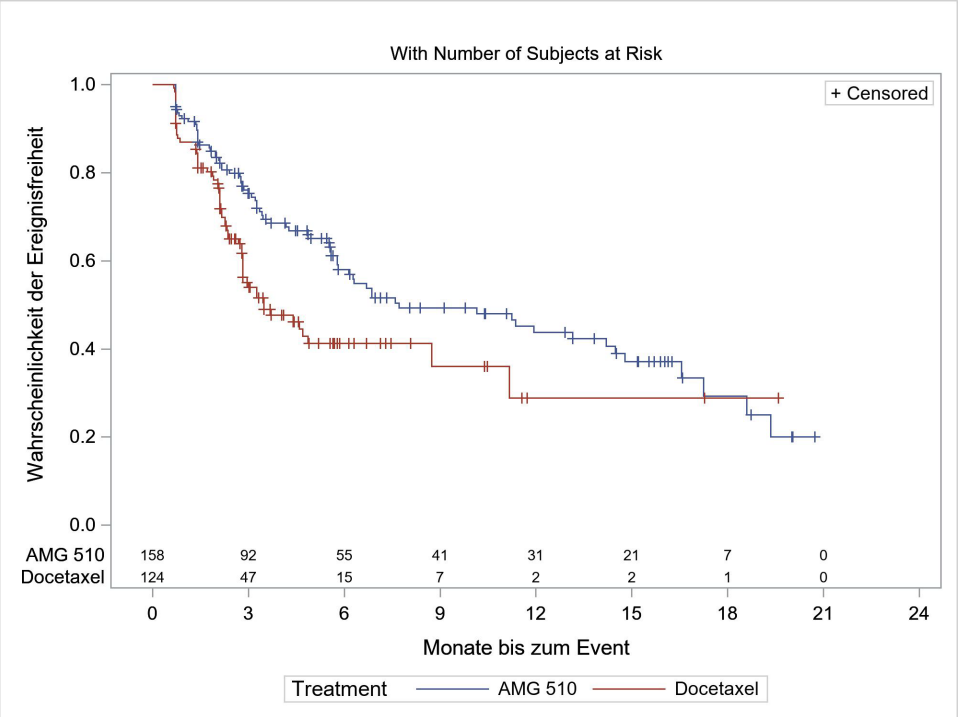

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Husten, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

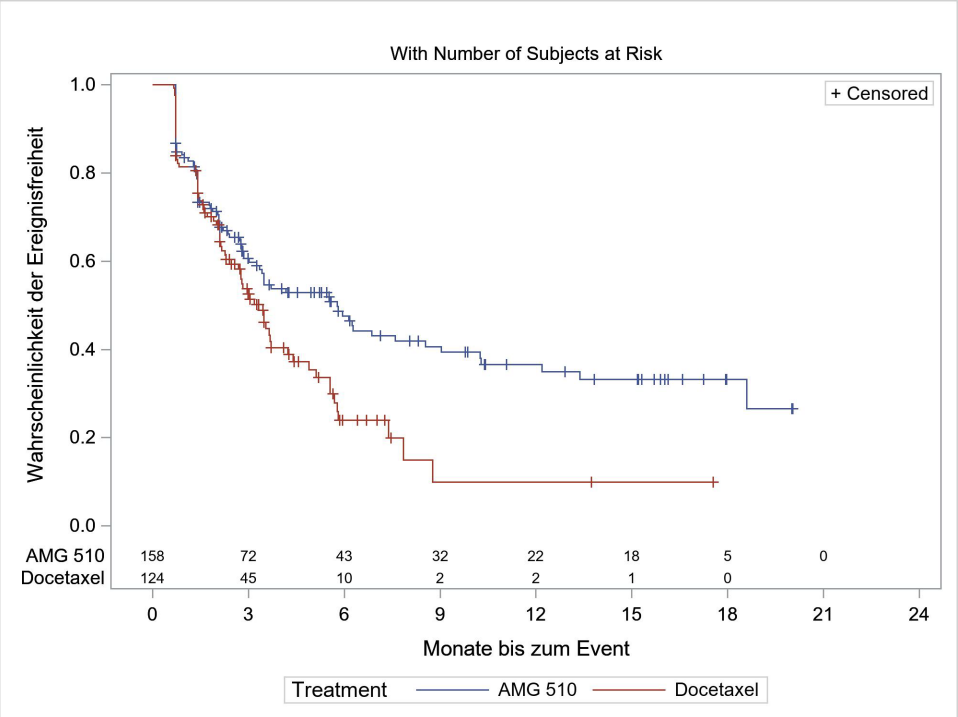

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Periphere Neuropathie, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

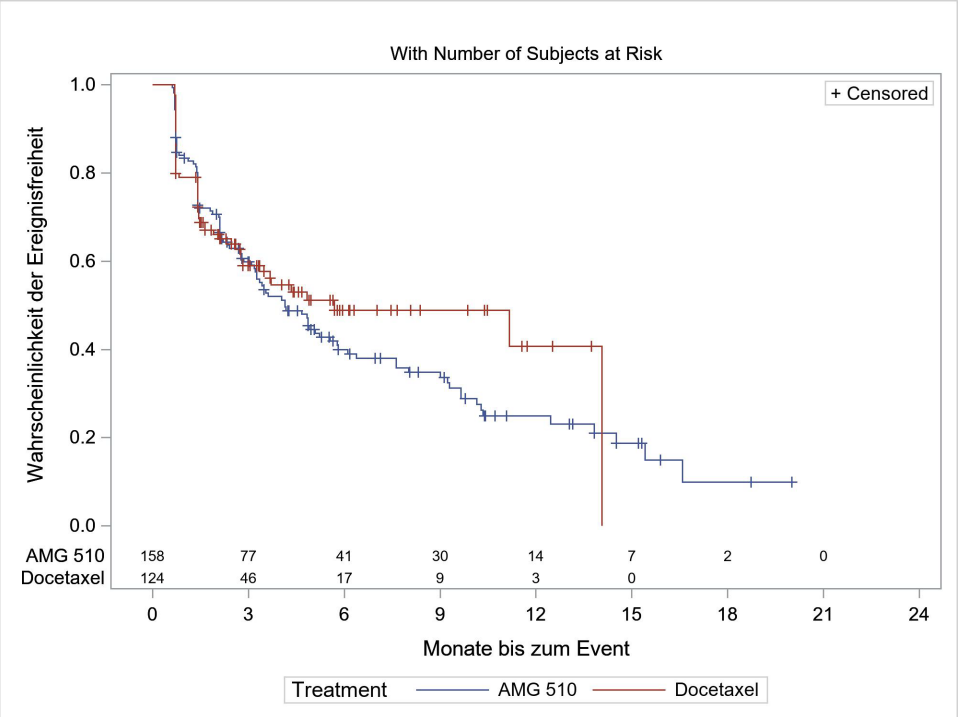

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Arm/Schulter), Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

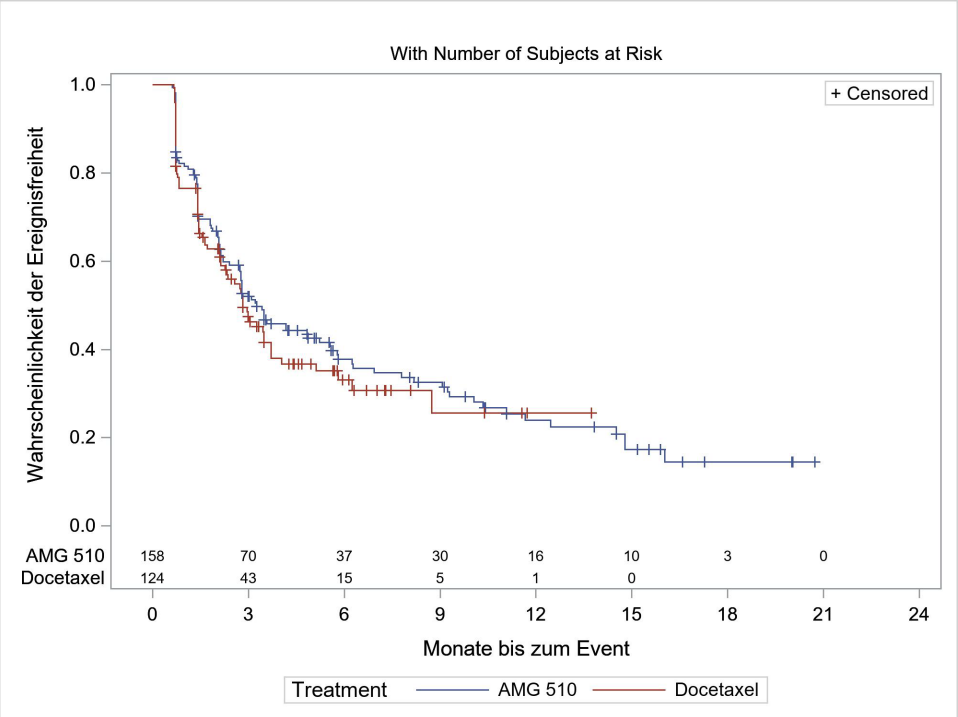

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (andere), Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

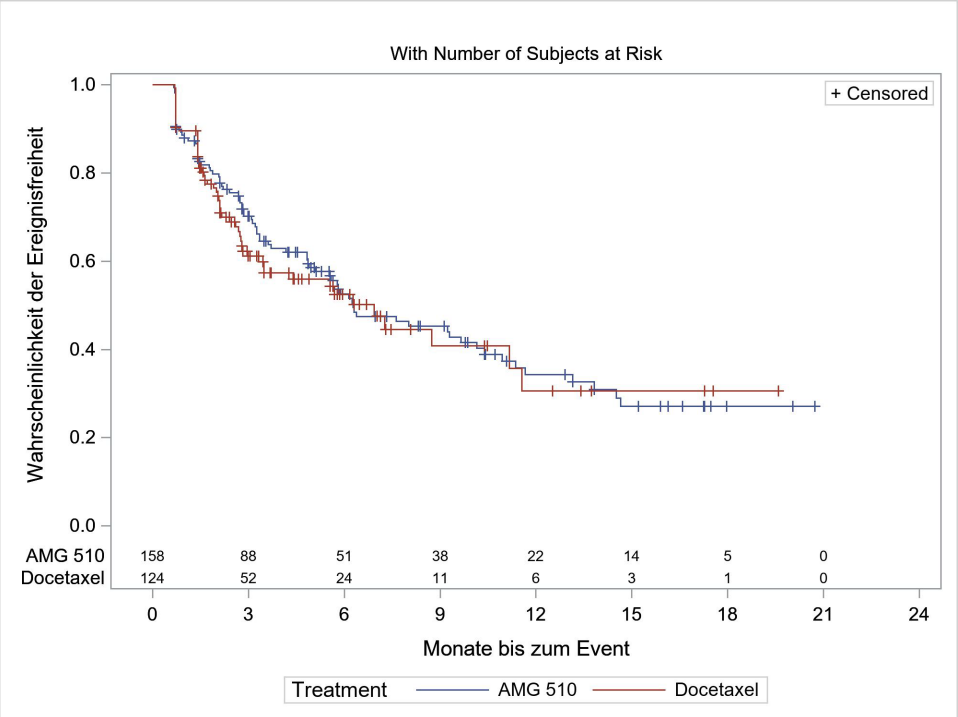

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Schmerzen (Thorax), Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

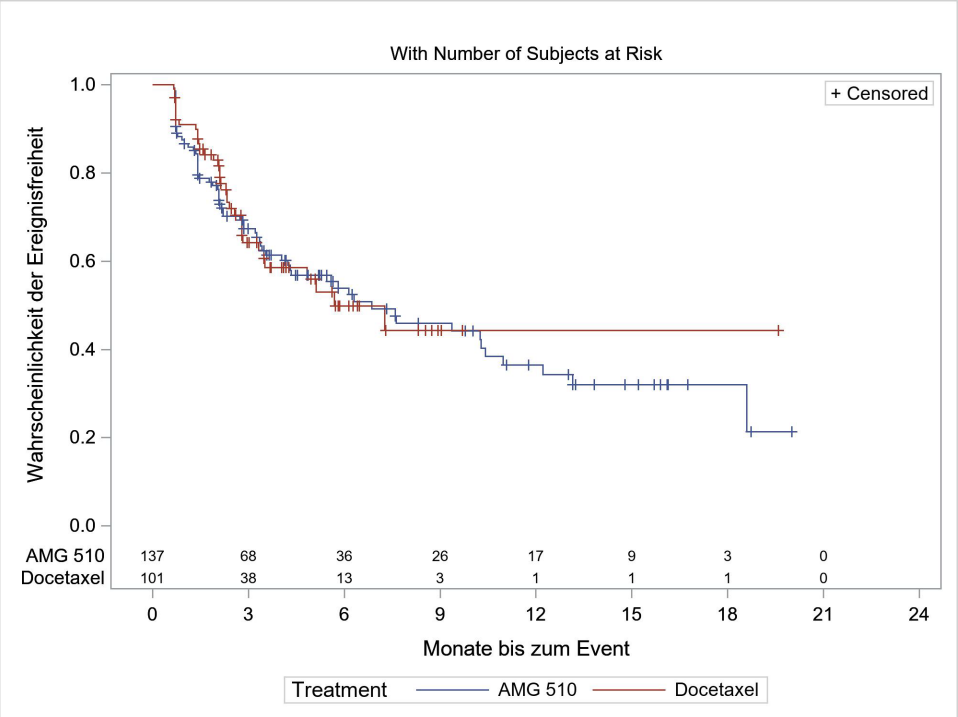

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wirksamkeit der Schmerzmedikation, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

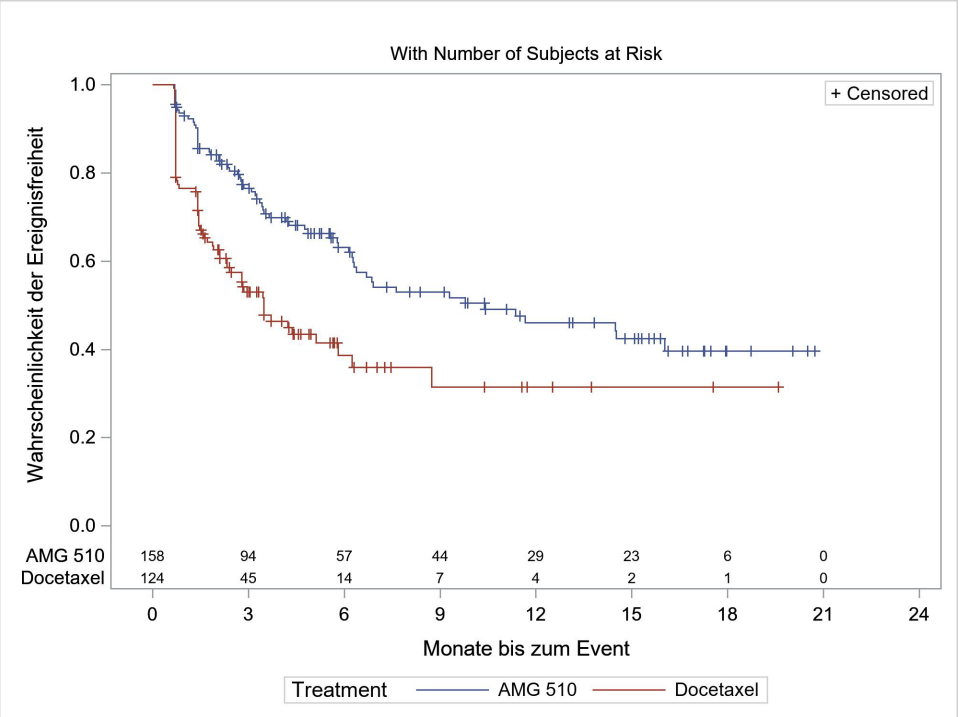

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Wunder Mund, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

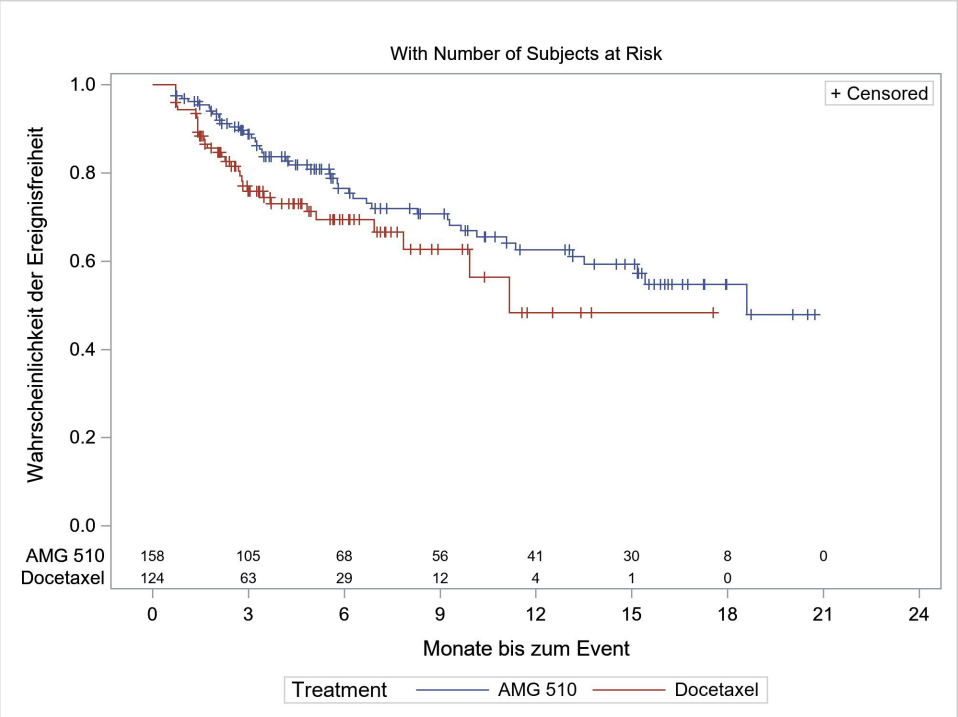

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-LC13 Bluthusten, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.2.9 Subgruppenanalysen für den Endpunkt EORTC QLQ-LC13 (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dysphagie; Alter bei Studienbeginn							
<65 Jahre	40/83 (48,2)	9,2 [3,4; 18,7]	30/67 (44,8)	5,8 [2,8; n.b.]	0,8 [0,5; 1,4]	0,4798	0,4242
≥65 Jahre	29/75 (38,7)	11,7 [5,8; n.b.]	25/57 (43,9)	4,9 [2,8; n.b.]	0,5 [0,3; 1,0]	0,0486	
QLQ-LC13 Dysphagie; Geschlecht							
Weiblich	24/58 (41,4)	18,7 [3,5; n.b.]	25/49 (51,0)	4,7 [2,7; n.b.]	0,6 [0,3; 1,1]	0,0879	0,9083
Männlich	45/100 (45,0)	6,9 [5,6; 18,6]	30/75 (40,0)	6,9 [3,5; n.b.]	0,7 [0,4; 1,2]	0,1598	
QLQ-LC13 Dysphagie; Region 2							
Nordamerika und Europa	55/133 (41,4)	12,5 [6,2; n.b.]	46/105 (43,8)	5,1 [3,5; 15,2]	0,7 [0,5; 1,0]	0,0718	0,4360
Rest der Welt	14/25 (56,0)	3,6 [2,7; 9,3]	9/19 (47,4)	2,8 [1,0; n.b.]	0,9 [0,3; 2,2]	0,7612	
QLQ-LC13 Dysphagie; Region 1							
Nordamerika	4/16 (25,0)	n.b. [6,1; n.b.]	6/15 (40,0)	15,2 [2,1; 15,2]	0,5 [0,1; 2,6]	0,4343	0,6309
Europa	51/117 (43,6)	11,4 [5,8; 18,7]	40/90 (44,4)	5,1 [2,8; 8,7]	0,7 [0,4; 1,0]	0,0781	
Rest der Welt	14/25 (56,0)	3,6 [2,7; 9,3]	9/19 (47,4)	2,8 [1,0; n.b.]	0,9 [0,3; 2,2]	0,7612	
QLQ-LC13 Dysphagie; ECOG Performance-Status							
0	21/55 (38,2)	18,6 [6,4; n.b.]	21/51 (41,2)	6,9 [4,4; n.b.]	0,5 [0,2; 0,9]	0,0303	0,4646
1	48/103 (46,6)	5,8 [3,5; n.b.]	34/73 (46,6)	4,2 [2,7; 15,2]	0,9 [0,5; 1,4]	0,5040	
QLQ-LC13 Dysphagie; Lebermetastasen bei Studienbeginn							
Nein	56/131 (42,7)	11,7 [5,8; n.b.]	43/103 (41,7)	5,8 [4,2; n.b.]	0,8 [0,5; 1,2]	0,2792	0,2092
Ja	13/27 (48,1)	5,8 [3,4; n.b.]	12/21 (57,1)	2,8 [1,6; 15,2]	0,2 [0,1; 0,9]	0,0229	
QLQ-LC13 Dysphagie; Knochenmetastasen bei Studienbeginn							
Nein	39/86 (45,3)	11,7 [4,3; 18,7]	34/76 (44,7)	5,1 [3,5; n.b.]	0,7 [0,5; 1,2]	0,2604	0,4834
Ja	30/72 (41,7)	6,4 [5,1; n.b.]	21/48 (43,8)	4,2 [2,8; 15,2]	0,6 [0,3; 1,1]	0,0795	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dysphagie; PD-L1-Proteinexpression							
<1%	24/52 (46,2)	18,6 [3,7; 18,7]	18/41 (43,9)	5,8 [2,8; n.b.]	0,9 [0,5; 1,7]	0,6920	0,7177
≥1% und <50%	22/42 (52,4)	6,3 [2,8; n.b.]	19/47 (40,4)	4,4 [2,5; n.b.]	0,8 [0,4; 1,6]	0,5993	
≥50%	18/57 (31,6)	n.b. [4,3; n.b.]	13/28 (46,4)	4,9 [2,8; n.b.]	0,5 [0,2; 1,2]	0,1282	
QLQ-LC13 Dysphagie; Ethnie-2							
Asiatisch	12/21 (57,1)	4,2 [2,7; 9,3]	10/18 (55,6)	2,8 [1,0; n.b.]	0,8 [0,3; 1,9]	0,5998	0,7422
Nicht asiatisch	57/136 (41,9)	11,7 [6,1; n.b.]	44/105 (41,9)	5,1 [4,2; 15,2]	0,7 [0,5; 1,1]	0,1186	
QLQ-LC13 Dysphagie; Vorgeschichte einer Beteiligung des ZNS							
Nein	42/104 (40,4)	12,5 [5,8; n.b.]	38/86 (44,2)	4,9 [3,5; n.b.]	0,7 [0,4; 1,0]	0,0648	0,5621
Ja	27/54 (50,0)	6,9 [3,5; n.b.]	17/38 (44,7)	5,8 [2,2; 15,2]	0,8 [0,4; 1,6]	0,5700	
QLQ-LC13 Dysphagie; Anzahl an vorherigen Therapielinien							
1	34/68 (50,0)	6,1 [2,8; 18,6]	28/56 (50,0)	3,5 [2,3; 5,8]	0,7 [0,4; 1,2]	0,2309	0,9351
2	24/62 (38,7)	18,7 [6,2; n.b.]	20/50 (40,0)	6,9 [2,8; n.b.]	0,7 [0,4; 1,3]	0,2126	
>2	11/28 (39,3)	n.b. [3,4; n.b.]	7/18 (38,9)	8,7 [2,3; 15,2]	0,8 [0,3; 2,3]	0,7287	
QLQ-LC13 Dyspnoe; Alter bei Studienbeginn							
<65 Jahre	44/83 (53,0)	6,9 [4,5; 12,5]	41/67 (61,2)	3,3 [2,1; 4,8]	0,5 [0,3; 0,8]	0,0054	0,2029
≥65 Jahre	30/75 (40,0)	13,1 [6,7; n.b.]	34/57 (59,6)	2,8 [2,1; 4,4]	0,4 [0,2; 0,7]	0,0010	
QLQ-LC13 Dyspnoe; Geschlecht							
Weiblich	32/58 (55,2)	6,2 [3,5; 10,2]	32/49 (65,3)	2,7 [1,9; 5,0]	0,5 [0,3; 0,9]	0,0179	0,4616
Männlich	42/100 (42,0)	11,4 [6,1; 14,0]	43/75 (57,3)	3,0 [2,1; 4,6]	0,4 [0,2; 0,6]	0,0001	
QLQ-LC13 Dyspnoe; Region 2							
Nordamerika und Europa	63/133 (47,4)	8,3 [5,6; 13,8]	63/105 (60,0)	3,2 [2,3; 4,6]	0,5 [0,3; 0,7]	<,0001	0,8664
Rest der Welt	11/25 (44,0)	6,9 [4,7; n.b.]	12/19 (63,2)	1,6 [0,8; n.b.]	0,5 [0,2; 1,3]	0,1232	
QLQ-LC13 Dyspnoe; Region 1							
Nordamerika	5/16 (31,3)	n.b. [6,1; n.b.]	8/15 (53,3)	3,4 [0,7; n.b.]	0,5 [0,1; 2,2]	0,3610	0,8395
Europa	58/117 (49,6)	8,3 [5,0; 12,5]	55/90 (61,1)	3,0 [2,1; 4,4]	0,5 [0,3; 0,7]	0,0002	
Rest der Welt	11/25 (44,0)	6,9 [4,7; n.b.]	12/19 (63,2)	1,6 [0,8; n.b.]	0,5 [0,2; 1,3]	0,1232	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Dyspnoe; ECOG Performance-Status							
0	28/55 (50,9)	11,4 [4,7; 16,6]	35/51 (68,6)	3,0 [2,1; 4,8]	0,3 [0,2; 0,6]	0,0004	0,7519
1	46/103 (44,7)	6,9 [5,1; 13,1]	40/73 (54,8)	2,8 [2,1; 5,1]	0,5 [0,3; 0,8]	0,0019	
QLQ-LC13 Dyspnoe; Lebermetastasen bei Studienbeginn							
Nein	59/131 (45,0)	10,2 [6,7; 14,0]	61/103 (59,2)	3,0 [2,1; 4,6]	0,4 [0,3; 0,6]	<,0001	0,5743
Ja	15/27 (55,6)	5,0 [3,0; 7,7]	14/21 (66,7)	2,3 [1,4; 4,2]	0,5 [0,2; 1,4]	0,1868	
QLQ-LC13 Dyspnoe; Knochenmetastasen bei Studienbeginn							
Nein	44/86 (51,2)	8,3 [4,7; 13,1]	43/76 (56,6)	3,7 [2,7; 5,1]	0,5 [0,3; 0,8]	0,0027	0,1895
Ja	30/72 (41,7)	7,7 [5,9; 16,6]	32/48 (66,7)	2,1 [1,6; 3,0]	0,3 [0,2; 0,6]	<,0001	
QLQ-LC13 Dyspnoe; PD-L1-Proteinexpression							
<1%	29/52 (55,8)	6,1 [3,4; 13,8]	28/41 (68,3)	2,1 [1,4; 3,4]	0,4 [0,2; 0,8]	0,0078	0,8165
≥1% und <50%	19/42 (45,2)	8,3 [3,5; n.b.]	25/47 (53,2)	3,2 [2,3; 5,0]	0,5 [0,2; 1,0]	0,0325	
≥50%	22/57 (38,6)	10,2 [4,5; n.b.]	16/28 (57,1)	3,7 [1,9; n.b.]	0,4 [0,2; 0,9]	0,0264	
QLQ-LC13 Dyspnoe; Ethnie-2							
Asiatisch	9/21 (42,9)	6,9 [4,7; n.b.]	12/18 (66,7)	1,5 [0,7; n.b.]	0,4 [0,1; 1,0]	0,0438	0,3594
Nicht asiatisch	65/136 (47,8)	8,3 [5,6; 13,1]	62/105 (59,0)	3,2 [2,3; 4,6]	0,5 [0,3; 0,7]	<,0001	
QLQ-LC13 Dyspnoe; Vorgeschichte einer Beteiligung des ZNS							
Nein	47/104 (45,2)	8,3 [4,2; 13,1]	57/86 (66,3)	2,8 [2,1; 3,7]	0,4 [0,3; 0,7]	<,0001	0,7911
Ja	27/54 (50,0)	7,1 [5,6; 14,0]	18/38 (47,4)	4,8 [2,1; 6,5]	0,4 [0,2; 0,8]	0,0047	
QLQ-LC13 Dyspnoe; Anzahl an vorherigen Therapielinien							
1	29/68 (42,6)	7,6 [4,0; n.b.]	34/56 (60,7)	2,8 [2,1; 5,0]	0,5 [0,3; 0,9]	0,0142	0,6815
2	28/62 (45,2)	11,4 [6,2; n.b.]	29/50 (58,0)	3,2 [2,1; 5,1]	0,3 [0,2; 0,6]	0,0004	
>2	17/28 (60,7)	4,5 [3,0; 14,0]	12/18 (66,7)	2,8 [1,6; 6,5]	0,5 [0,2; 1,1]	0,0614	
QLQ-LC13 Haarausfall; Alter bei Studienbeginn							
<65 Jahre	34/83 (41,0)	11,4 [5,1; n.b.]	60/67 (89,6)	0,7 [0,7; 1,4]	0,2 [0,1; 0,3]	<,0001	0,0727
≥65 Jahre	26/75 (34,7)	11,7 [6,7; n.b.]	53/57 (93,0)	0,7 [0,7; 0,8]	0,1 [0,0; 0,2]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Haarausfall; Geschlecht							
Weiblich	28/58 (48,3)	9,2 [4,8; 19,4]	44/49 (89,8)	0,7 [0,7; 0,8]	0,2 [0,1; 0,4]	<,0001	0,0817
Männlich	32/100 (32,0)	18,6 [6,9; n.b.]	69/75 (92,0)	0,8 [0,7; 1,3]	0,1 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; Region 2							
Nordamerika und Europa	50/133 (37,6)	14,7 [9,0; n.b.]	95/105 (90,5)	0,7 [0,7; 0,9]	0,1 [0,1; 0,2]	<,0001	0,1407
Rest der Welt	10/25 (40,0)	6,9 [4,1; n.b.]	18/19 (94,7)	0,8 [0,7; 0,8]	0,0 [0,0; n.b.]	<,0001	
QLQ-LC13 Haarausfall; Region 1							
Nordamerika	5/16 (31,3)	n.b. [4,1; n.b.]	15/15 (100,0)	0,7 [n.b.; n.b.]	0,1 [0,0; 0,5]	0,0014	0,3249
Europa	45/117 (38,5)	11,7 [9,0; n.b.]	80/90 (88,9)	0,8 [0,7; 1,4]	0,1 [0,1; 0,2]	<,0001	
Rest der Welt	10/25 (40,0)	6,9 [4,1; n.b.]	18/19 (94,7)	0,8 [0,7; 0,8]	0,0 [0,0; n.b.]	<,0001	
QLQ-LC13 Haarausfall; ECOG Performance-Status							
0	18/55 (32,7)	19,4 [11,4; n.b.]	44/51 (86,3)	0,7 [0,7; 0,8]	0,1 [0,0; 0,2]	<,0001	0,3623
1	42/103 (40,8)	9,0 [5,8; n.b.]	69/73 (94,5)	0,7 [0,7; 1,3]	0,1 [0,1; 0,2]	<,0001	
QLQ-LC13 Haarausfall; Lebermetastasen bei Studienbeginn							
Nein	49/131 (37,4)	14,7 [9,0; n.b.]	93/103 (90,3)	0,8 [0,7; 1,3]	0,1 [0,1; 0,2]	<,0001	0,4851
Ja	11/27 (40,7)	6,9 [3,4; n.b.]	20/21 (95,2)	0,7 [n.b.; n.b.]	0,0 [0,0; 0,3]	<,0001	
QLQ-LC13 Haarausfall; Knochenmetastasen bei Studienbeginn							
Nein	34/86 (39,5)	18,6 [6,3; n.b.]	67/76 (88,2)	0,8 [0,7; 1,4]	0,1 [0,1; 0,3]	<,0001	0,1753
Ja	26/72 (36,1)	9,2 [6,7; n.b.]	46/48 (95,8)	0,7 [0,7; 0,8]	0,0 [0,0; 0,1]	<,0001	
QLQ-LC13 Haarausfall; PD-L1-Proteinexpression							
<1%	25/52 (48,1)	9,0 [4,1; 19,4]	39/41 (95,1)	0,7 [0,7; 1,4]	0,1 [0,1; 0,2]	<,0001	0,4963
≥1% und <50%	14/42 (33,3)	10,4 [6,3; n.b.]	40/47 (85,1)	0,8 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	
≥50%	18/57 (31,6)	14,7 [6,7; n.b.]	27/28 (96,4)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	
QLQ-LC13 Haarausfall; Ethnie-2							
Asiatisch	9/21 (42,9)	6,9 [2,9; n.b.]	17/18 (94,4)	0,7 [0,7; 0,8]	0,1 [0,0; 0,3]	<,0001	0,5371
Nicht asiatisch	51/136 (37,5)	14,7 [9,0; n.b.]	95/105 (90,5)	0,7 [0,7; 1,3]	0,1 [0,1; 0,2]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Haarausfall; Vorgeschichte einer Beteiligung des ZNS							
Nein	37/104 (35,6)	19,4 [6,3; n.b.]	80/86 (93,0)	0,7 [0,7; 0,8]	0,1 [0,1; 0,2]	<,0001	0,2718
Ja	23/54 (42,6)	11,7 [6,7; 18,6]	33/38 (86,8)	0,7 [0,7; 1,4]	0,1 [0,1; 0,3]	<,0001	
QLQ-LC13 Haarausfall; Anzahl an vorherigen Therapielinien							
1	25/68 (36,8)	10,4 [6,9; n.b.]	51/56 (91,1)	1,0 [0,7; 1,4]	0,1 [0,1; 0,2]	<,0001	0,7850
2	23/62 (37,1)	19,4 [6,3; n.b.]	44/50 (88,0)	0,7 [0,7; 0,8]	0,1 [0,1; 0,3]	<,0001	
>2	12/28 (42,9)	6,7 [4,8; 14,7]	18/18 (100,0)	0,7 [0,7; 1,4]	0,1 [0,0; 0,2]	<,0001	
QLQ-LC13 Husten; Alter bei Studienbeginn							
<65 Jahre	38/83 (45,8)	7,7 [5,6; 19,4]	28/67 (41,8)	4,9 [2,8; n.b.]	0,8 [0,5; 1,4]	0,4635	0,3205
≥65 Jahre	37/75 (49,3)	6,9 [5,6; 14,8]	33/57 (57,9)	3,0 [2,2; 4,6]	0,6 [0,3; 1,0]	0,0372	
QLQ-LC13 Husten; Geschlecht							
Weiblich	28/58 (48,3)	10,2 [3,7; 19,4]	24/49 (49,0)	3,5 [2,7; n.b.]	0,7 [0,4; 1,2]	0,1967	0,5035
Männlich	47/100 (47,0)	6,9 [5,6; 16,6]	37/75 (49,3)	3,7 [2,8; 8,7]	0,6 [0,4; 0,9]	0,0163	
QLQ-LC13 Husten; Region 2							
Nordamerika und Europa	61/133 (45,9)	11,4 [5,8; 16,6]	52/105 (49,5)	3,7 [2,8; 8,7]	0,6 [0,4; 0,9]	0,0100	0,4253
Rest der Welt	14/25 (56,0)	4,9 [2,0; 6,9]	9/19 (47,4)	2,8 [1,3; n.b.]	0,9 [0,3; 2,3]	0,8104	
QLQ-LC13 Husten; Region 1							
Nordamerika	5/16 (31,3)	n.b. [0,7; n.b.]	4/15 (26,7)	n.b. [2,8; n.b.]	0,6 [0,1; 3,2]	0,5611	0,4671
Europa	56/117 (47,9)	11,2 [5,8; 14,5]	48/90 (53,3)	3,3 [2,4; 4,9]	0,5 [0,3; 0,8]	0,0011	
Rest der Welt	14/25 (56,0)	4,9 [2,0; 6,9]	9/19 (47,4)	2,8 [1,3; n.b.]	0,9 [0,3; 2,3]	0,8104	
QLQ-LC13 Husten; ECOG Performance-Status							
0	21/55 (38,2)	16,6 [10,2; 19,4]	28/51 (54,9)	3,5 [2,4; 8,7]	0,4 [0,2; 0,7]	0,0018	0,0288
1	54/103 (52,4)	5,8 [4,3; 7,7]	33/73 (45,2)	3,7 [2,8; n.b.]	0,8 [0,5; 1,3]	0,4467	
QLQ-LC13 Husten; Lebermetastasen bei Studienbeginn							
Nein	62/131 (47,3)	11,2 [5,8; 14,8]	52/103 (50,5)	3,5 [2,8; 8,7]	0,6 [0,4; 0,9]	0,0168	0,8536
Ja	13/27 (48,1)	5,8 [3,4; n.b.]	9/21 (42,9)	3,0 [1,9; n.b.]	0,3 [0,1; 1,1]	0,0632	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Husten; Knochenmetastasen bei Studienbeginn							
Nein	40/86 (46,5)	11,4 [5,8; 16,6]	38/76 (50,0)	4,4 [2,8; n.b.]	0,5 [0,3; 0,9]	0,0142	0,7746
Ja	35/72 (48,6)	6,7 [4,2; 17,2]	23/48 (47,9)	3,0 [2,3; n.b.]	0,6 [0,4; 1,1]	0,1270	
QLQ-LC13 Husten; PD-L1-Proteinexpression							
<1%	30/52 (57,7)	5,8 [3,4; 14,5]	17/41 (41,5)	n.b. [2,8; n.b.]	1,0 [0,5; 1,9]	0,9801	0,2198
≥1% und <50%	20/42 (47,6)	7,7 [6,3; 14,8]	25/47 (53,2)	2,8 [2,2; 4,4]	0,4 [0,2; 0,8]	0,0093	
≥50%	22/57 (38,6)	10,2 [5,6; n.b.]	14/28 (50,0)	4,7 [2,1; n.b.]	0,6 [0,3; 1,3]	0,1960	
QLQ-LC13 Husten; Ethnie-2							
Asiatisch	12/21 (57,1)	4,9 [2,0; n.b.]	11/18 (61,1)	2,3 [0,8; n.b.]	0,6 [0,3; 1,6]	0,3497	0,9291
Nicht asiatisch	63/136 (46,3)	11,2 [5,8; 14,8]	49/105 (46,7)	4,4 [2,8; 11,2]	0,6 [0,4; 1,0]	0,0266	
QLQ-LC13 Husten; Vorgeschichte einer Beteiligung des ZNS							
Nein	47/104 (45,2)	7,7 [5,6; 14,8]	46/86 (53,5)	3,3 [2,7; 8,7]	0,6 [0,4; 0,9]	0,0080	0,3978
Ja	28/54 (51,9)	7,6 [5,6; 17,2]	15/38 (39,5)	4,9 [3,0; n.b.]	0,8 [0,4; 1,6]	0,4942	
QLQ-LC13 Husten; Anzahl an vorherigen Therapielinien							
1	33/68 (48,5)	6,9 [3,7; 14,2]	29/56 (51,8)	3,5 [2,3; 11,2]	0,6 [0,4; 1,0]	0,0713	0,9108
2	30/62 (48,4)	11,2 [5,6; 19,4]	23/50 (46,0)	4,7 [2,8; n.b.]	0,7 [0,4; 1,3]	0,2599	
>2	12/28 (42,9)	11,9 [4,9; n.b.]	9/18 (50,0)	3,3 [1,9; n.b.]	0,5 [0,2; 1,2]	0,0993	
QLQ-LC13 Periphere Neuropathie; Alter bei Studienbeginn							
<65 Jahre	45/83 (54,2)	3,5 [2,4; 13,4]	39/67 (58,2)	3,5 [2,1; 5,1]	0,8 [0,5; 1,3]	0,4582	0,5024
≥65 Jahre	39/75 (52,0)	6,2 [3,7; 10,3]	35/57 (61,4)	3,1 [2,2; 4,9]	0,6 [0,3; 0,9]	0,0274	
QLQ-LC13 Periphere Neuropathie; Geschlecht							
Weiblich	29/58 (50,0)	3,5 [2,4; n.b.]	34/49 (69,4)	2,8 [1,4; 3,7]	0,7 [0,4; 1,2]	0,2076	0,7189
Männlich	55/100 (55,0)	5,9 [3,4; 8,5]	40/75 (53,3)	3,5 [2,5; 5,1]	0,7 [0,4; 1,1]	0,1172	
QLQ-LC13 Periphere Neuropathie; Region 2							
Nordamerika und Europa	68/133 (51,1)	5,8 [3,4; 12,2]	63/105 (60,0)	3,5 [2,8; 4,4]	0,7 [0,5; 1,0]	0,0398	0,7662
Rest der Welt	16/25 (64,0)	3,5 [1,4; 8,5]	11/19 (57,9)	1,5 [1,3; n.b.]	0,6 [0,2; 1,6]	0,2954	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Periphere Neuropathie; Region 1							
Nordamerika	8/16 (50,0)	6,1 [0,7; n.b.]	11/15 (73,3)	3,4 [2,0; 4,9]	0,6 [0,2; 1,7]	0,3029	0,7360
Europa	60/117 (51,3)	5,8 [3,3; 12,2]	52/90 (57,8)	3,5 [2,7; 5,6]	0,7 [0,5; 1,0]	0,0620	
Rest der Welt	16/25 (64,0)	3,5 [1,4; 8,5]	11/19 (57,9)	1,5 [1,3; n.b.]	0,6 [0,2; 1,6]	0,2954	
QLQ-LC13 Periphere Neuropathie; ECOG Performance-Status							
0	28/55 (50,9)	10,3 [3,3; 18,6]	33/51 (64,7)	3,2 [2,1; 5,6]	0,5 [0,3; 0,8]	0,0074	0,2529
1	56/103 (54,4)	3,5 [2,7; 5,9]	41/73 (56,2)	3,5 [2,2; 5,1]	0,8 [0,5; 1,2]	0,3181	
QLQ-LC13 Periphere Neuropathie; Lebermetastasen bei Studienbeginn							
Nein	70/131 (53,4)	5,8 [3,0; 10,3]	60/103 (58,3)	3,5 [2,8; 4,9]	0,7 [0,5; 1,0]	0,0683	0,5149
Ja	14/27 (51,9)	3,5 [1,4; n.b.]	14/21 (66,7)	2,3 [1,4; 3,5]	0,8 [0,3; 2,0]	0,5754	
QLQ-LC13 Periphere Neuropathie; Knochenmetastasen bei Studienbeginn							
Nein	51/86 (59,3)	5,5 [2,8; 9,0]	44/76 (57,9)	3,5 [2,8; 5,1]	0,8 [0,5; 1,2]	0,2517	0,1767
Ja	33/72 (45,8)	5,8 [3,0; n.b.]	30/48 (62,5)	2,2 [1,4; 4,2]	0,5 [0,3; 0,8]	0,0087	
QLQ-LC13 Periphere Neuropathie; PD-L1-Proteinexpression							
<1%	27/52 (51,9)	5,9 [2,4; 18,6]	29/41 (70,7)	3,4 [1,6; 3,7]	0,6 [0,3; 1,0]	0,0613	0,0650
≥1% und <50%	28/42 (66,7)	3,5 [1,4; 6,3]	22/47 (46,8)	3,5 [2,7; 7,9]	1,3 [0,7; 2,4]	0,4375	
≥50%	24/57 (42,1)	9,0 [3,3; n.b.]	17/28 (60,7)	3,7 [2,1; 5,8]	0,6 [0,3; 1,1]	0,1104	
QLQ-LC13 Periphere Neuropathie; Ethnie-2							
Asiatisch	12/21 (57,1)	6,9 [1,8; 10,3]	13/18 (72,2)	1,4 [0,8; 2,1]	0,4 [0,2; 1,0]	0,0554	0,2159
Nicht asiatisch	72/136 (52,9)	5,8 [3,3; 9,0]	60/105 (57,1)	3,5 [2,8; 4,9]	0,7 [0,5; 1,1]	0,0894	
QLQ-LC13 Periphere Neuropathie; Vorgeschichte einer Beteiligung des ZNS							
Nein	58/104 (55,8)	5,5 [2,9; 7,6]	56/86 (65,1)	2,8 [2,1; 3,7]	0,6 [0,4; 0,9]	0,0222	0,8791
Ja	26/54 (48,1)	6,9 [2,8; n.b.]	18/38 (47,4)	5,7 [2,8; 7,9]	0,7 [0,4; 1,3]	0,2656	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Periphere Neuropathie; Anzahl an vorherigen Therapielinien							
1	36/68 (52,9)	5,6 [2,2; 12,2]	33/56 (58,9)	3,1 [2,1; 4,9]	0,7 [0,4; 1,2]	0,1592	0,3112
2	30/62 (48,4)	9,0 [5,5; n.b.]	31/50 (62,0)	3,2 [2,1; 5,1]	0,6 [0,3; 0,9]	0,0227	
>2	18/28 (64,3)	3,4 [1,4; 5,9]	10/18 (55,6)	3,7 [1,4; n.b.]	1,0 [0,4; 2,1]	0,9406	
QLQ-LC13 Schmerzen (Arm/Schulter); Alter bei Studienbeginn							
<65 Jahre	56/83 (67,5)	3,4 [2,2; 5,6]	28/67 (41,8)	11,2 [2,7; n.b.]	1,4 [0,9; 2,3]	0,1549	0,2839
≥65 Jahre	46/75 (61,3)	4,9 [3,3; 7,6]	27/57 (47,4)	4,3 [2,5; 14,1]	0,9 [0,5; 1,6]	0,7419	
QLQ-LC13 Schmerzen (Arm/Schulter); Geschlecht							
Weiblich	39/58 (67,2)	3,1 [2,2; 5,1]	25/49 (51,0)	2,8 [1,4; 14,1]	1,2 [0,7; 2,1]	0,5299	0,7162
Männlich	63/100 (63,0)	4,8 [3,4; 6,4]	30/75 (40,0)	5,7 [3,5; n.b.]	1,1 [0,7; 1,8]	0,5932	
QLQ-LC13 Schmerzen (Arm/Schulter); Region 2							
Nordamerika und Europa	86/133 (64,7)	4,0 [2,8; 5,8]	47/105 (44,8)	5,7 [2,8; 14,1]	1,3 [0,9; 1,9]	0,1863	0,3598
Rest der Welt	16/25 (64,0)	4,9 [2,8; 12,5]	8/19 (42,1)	n.b. [0,7; n.b.]	0,8 [0,3; 2,3]	0,6799	
QLQ-LC13 Schmerzen (Arm/Schulter); Region 1							
Nordamerika	11/16 (68,8)	2,1 [1,4; 4,9]	4/15 (26,7)	n.b. [1,4; n.b.]	4,6 [0,9; 23,1]	0,0477	0,1498
Europa	75/117 (64,1)	4,2 [3,1; 6,4]	43/90 (47,8)	4,8 [2,7; 14,1]	1,1 [0,7; 1,6]	0,6371	
Rest der Welt	16/25 (64,0)	4,9 [2,8; 12,5]	8/19 (42,1)	n.b. [0,7; n.b.]	0,8 [0,3; 2,3]	0,6799	
QLQ-LC13 Schmerzen (Arm/Schulter); ECOG Performance-Status							
0	39/55 (70,9)	5,1 [2,2; 9,2]	22/51 (43,1)	11,2 [2,5; 14,1]	1,4 [0,8; 2,3]	0,2725	0,3690
1	63/103 (61,2)	3,5 [2,8; 5,2]	33/73 (45,2)	3,7 [2,7; n.b.]	1,0 [0,6; 1,6]	0,9973	
QLQ-LC13 Schmerzen (Arm/Schulter); Lebermetastasen bei Studienbeginn							
Nein	85/131 (64,9)	4,8 [2,8; 6,1]	44/103 (42,7)	11,2 [3,5; 14,1]	1,3 [0,9; 1,8]	0,2473	0,4579
Ja	17/27 (63,0)	3,4 [2,2; 14,5]	11/21 (52,4)	2,5 [0,7; n.b.]	0,7 [0,3; 2,0]	0,5423	
QLQ-LC13 Schmerzen (Arm/Schulter); Knochenmetastasen bei Studienbeginn							
Nein	57/86 (66,3)	4,8 [2,8; 7,6]	30/76 (39,5)	11,2 [4,3; 14,1]	1,4 [0,8; 2,2]	0,2196	0,2009
Ja	45/72 (62,5)	3,5 [2,4; 5,8]	25/48 (52,1)	2,8 [1,4; n.b.]	0,9 [0,5; 1,5]	0,6126	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (Arm/Schulter); PD-L1-Proteinexpression							
<1%	40/52 (76,9)	3,4 [2,1; 5,2]	20/41 (48,8)	3,7 [1,4; 14,1]	1,4 [0,8; 2,6]	0,2260	0,3448
≥1% und <50%	26/42 (61,9)	4,9 [2,2; 10,3]	16/47 (34,0)	n.b. [2,7; n.b.]	1,1 [0,6; 2,2]	0,7613	
≥50%	32/57 (56,1)	4,9 [3,3; 10,2]	15/28 (53,6)	3,5 [1,4; n.b.]	0,8 [0,4; 1,5]	0,4521	
QLQ-LC13 Schmerzen (Arm/Schulter); Ethnie-2							
Asiatisch	13/21 (61,9)	4,9 [2,8; 12,5]	8/18 (44,4)	3,5 [0,7; n.b.]	0,7 [0,3; 1,9]	0,5033	0,2437
Nicht asiatisch	89/136 (65,4)	3,6 [2,8; 5,6]	46/105 (43,8)	5,7 [2,8; 14,1]	1,3 [0,9; 1,8]	0,1955	
QLQ-LC13 Schmerzen (Arm/Schulter); Vorgeschichte einer Beteiligung des ZNS							
Nein	65/104 (62,5)	4,1 [2,7; 6,4]	37/86 (43,0)	11,2 [2,8; 14,1]	1,3 [0,8; 1,9]	0,2651	0,3766
Ja	37/54 (68,5)	4,2 [2,8; 9,7]	18/38 (47,4)	4,8 [1,6; n.b.]	0,9 [0,5; 1,7]	0,8206	
QLQ-LC13 Schmerzen (Arm/Schulter); Anzahl an vorherigen Therapielinien							
1	46/68 (67,6)	3,2 [2,1; 5,6]	23/56 (41,1)	11,2 [2,8; 14,1]	1,5 [0,9; 2,5]	0,1157	0,3616
2	38/62 (61,3)	5,8 [2,8; 9,7]	23/50 (46,0)	4,8 [2,1; n.b.]	1,0 [0,6; 1,7]	0,9964	
>2	18/28 (64,3)	4,0 [2,8; 5,2]	9/18 (50,0)	2,7 [1,4; n.b.]	0,9 [0,4; 2,1]	0,8006	
QLQ-LC13 Schmerzen (andere); Alter bei Studienbeginn							
<65 Jahre	57/83 (68,7)	2,8 [2,0; 4,2]	45/67 (67,2)	2,4 [1,4; 3,3]	0,8 [0,5; 1,2]	0,2291	0,2608
≥65 Jahre	49/75 (65,3)	4,8 [2,7; 6,9]	28/57 (49,1)	3,7 [2,3; n.b.]	1,1 [0,6; 1,8]	0,7902	
QLQ-LC13 Schmerzen (andere); Geschlecht							
Weiblich	41/58 (70,7)	2,8 [1,4; 9,2]	35/49 (71,4)	2,1 [1,4; 3,0]	0,7 [0,4; 1,1]	0,1101	0,1344
Männlich	65/100 (65,0)	3,5 [2,4; 5,6]	38/75 (50,7)	3,7 [2,8; 8,7]	1,0 [0,7; 1,6]	0,8635	
QLQ-LC13 Schmerzen (andere); Region 2							
Nordamerika und Europa	88/133 (66,2)	3,5 [2,7; 5,8]	64/105 (61,0)	2,8 [2,1; 3,7]	0,9 [0,6; 1,2]	0,3894	0,4359
Rest der Welt	18/25 (72,0)	2,8 [1,4; 8,2]	9/19 (47,4)	2,8 [1,4; n.b.]	1,5 [0,6; 4,0]	0,3777	
QLQ-LC13 Schmerzen (andere); Region 1							
Nordamerika	10/16 (62,5)	4,8 [0,7; n.b.]	9/15 (60,0)	3,0 [0,7; n.b.]	1,0 [0,3; 3,3]	0,9945	0,6857
Europa	78/117 (66,7)	3,5 [2,7; 5,8]	55/90 (61,1)	2,8 [1,7; 3,7]	0,8 [0,6; 1,2]	0,2452	
Rest der Welt	18/25 (72,0)	2,8 [1,4; 8,2]	9/19 (47,4)	2,8 [1,4; n.b.]	1,5 [0,6; 4,0]	0,3777	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (andere); ECOG Performance-Status							
0	41/55 (74,5)	2,8 [2,0; 6,3]	32/51 (62,7)	2,8 [1,4; 5,8]	0,9 [0,5; 1,4]	0,5453	0,9070
1	65/103 (63,1)	3,5 [2,7; 5,6]	41/73 (56,2)	3,0 [2,1; 3,7]	0,8 [0,5; 1,2]	0,3458	
QLQ-LC13 Schmerzen (andere); Lebermetastasen bei Studienbeginn							
Nein	89/131 (67,9)	2,8 [2,2; 5,2]	59/103 (57,3)	3,0 [2,1; 5,1]	1,0 [0,7; 1,4]	0,8137	0,3459
Ja	17/27 (63,0)	4,8 [2,1; 9,2]	14/21 (66,7)	2,3 [1,4; 3,5]	0,4 [0,1; 1,1]	0,0635	
QLQ-LC13 Schmerzen (andere); Knochenmetastasen bei Studienbeginn							
Nein	61/86 (70,9)	2,8 [2,1; 5,6]	41/76 (53,9)	3,5 [2,1; 6,2]	1,2 [0,8; 1,8]	0,5161	0,0368
Ja	45/72 (62,5)	4,2 [2,4; 9,1]	32/48 (66,7)	2,8 [1,4; 3,4]	0,6 [0,3; 0,9]	0,0232	
QLQ-LC13 Schmerzen (andere); PD-L1-Proteinexpression							
<1%	38/52 (73,1)	3,2 [2,1; 5,6]	23/41 (56,1)	3,7 [1,4; n.b.]	0,8 [0,5; 1,5]	0,5393	0,9197
≥1% und <50%	27/42 (64,3)	4,9 [1,4; 9,3]	26/47 (55,3)	3,0 [2,3; 4,0]	0,9 [0,5; 1,6]	0,6465	
≥50%	38/57 (66,7)	2,8 [1,4; 5,6]	18/28 (64,3)	2,1 [1,4; 5,1]	0,9 [0,5; 1,7]	0,7785	
QLQ-LC13 Schmerzen (andere); Ethnie-2							
Asiatisch	15/21 (71,4)	2,8 [1,4; 8,2]	10/18 (55,6)	2,8 [0,8; n.b.]	1,0 [0,4; 2,4]	0,9970	0,6626
Nicht asiatisch	91/136 (66,9)	3,5 [2,7; 5,6]	62/105 (59,0)	3,0 [2,1; 3,7]	0,9 [0,6; 1,2]	0,3996	
QLQ-LC13 Schmerzen (andere); Vorgeschichte einer Beteiligung des ZNS							
Nein	67/104 (64,4)	3,6 [2,7; 6,2]	48/86 (55,8)	3,3 [2,1; 5,1]	0,9 [0,6; 1,3]	0,5991	0,6282
Ja	39/54 (72,2)	2,8 [1,4; 4,2]	25/38 (65,8)	2,8 [1,4; 3,5]	0,8 [0,5; 1,3]	0,3505	
QLQ-LC13 Schmerzen (andere); Anzahl an vorherigen Therapielinien							
1	43/68 (63,2)	2,8 [2,1; 9,1]	30/56 (53,6)	2,6 [1,6; 6,2]	1,0 [0,6; 1,6]	0,9488	0,7523
2	43/62 (69,4)	4,2 [2,2; 6,3]	29/50 (58,0)	3,0 [2,1; n.b.]	0,9 [0,5; 1,4]	0,5483	
>2	20/28 (71,4)	3,1 [1,8; 6,9]	14/18 (77,8)	2,7 [0,8; 3,7]	0,7 [0,3; 1,3]	0,2466	
QLQ-LC13 Schmerzen (Thorax); Alter bei Studienbeginn							
<65 Jahre	42/83 (50,6)	6,3 [3,4; 13,1]	28/67 (41,8)	7,3 [2,8; n.b.]	1,1 [0,7; 1,8]	0,7239	0,3945
≥65 Jahre	41/75 (54,7)	6,3 [4,8; 10,9]	27/57 (47,4)	5,7 [2,8; n.b.]	0,7 [0,4; 1,3]	0,2873	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (Thorax); Geschlecht							
Weiblich	29/58 (50,0)	7,6 [3,3; n.b.]	18/49 (36,7)	n.b. [2,8; n.b.]	1,2 [0,6; 2,2]	0,5952	0,3716
Männlich	54/100 (54,0)	6,1 [4,9; 10,9]	37/75 (49,3)	5,6 [2,8; 8,7]	0,8 [0,5; 1,3]	0,3233	
QLQ-LC13 Schmerzen (Thorax); Region 2							
Nordamerika und Europa	69/133 (51,9)	6,3 [5,6; 10,4]	48/105 (45,7)	6,9 [2,8; 11,2]	0,9 [0,6; 1,4]	0,7016	0,9383
Rest der Welt	14/25 (56,0)	4,9 [2,1; n.b.]	7/19 (36,8)	n.b. [2,1; n.b.]	1,1 [0,4; 3,1]	0,8681	
QLQ-LC13 Schmerzen (Thorax); Region 1							
Nordamerika	9/16 (56,3)	6,9 [1,9; n.b.]	4/15 (26,7)	11,6 [2,7; n.b.]	1,6 [0,4; 7,3]	0,5430	0,2720
Europa	60/117 (51,3)	6,3 [5,1; 11,4]	44/90 (48,9)	5,6 [2,7; 8,7]	0,8 [0,5; 1,2]	0,2817	
Rest der Welt	14/25 (56,0)	4,9 [2,1; n.b.]	7/19 (36,8)	n.b. [2,1; n.b.]	1,1 [0,4; 3,1]	0,8681	
QLQ-LC13 Schmerzen (Thorax); ECOG Performance-Status							
0	30/55 (54,5)	9,7 [5,1; 13,8]	26/51 (51,0)	6,9 [2,8; 11,2]	0,7 [0,4; 1,3]	0,2890	0,5414
1	53/103 (51,5)	5,8 [3,6; 9,3]	29/73 (39,7)	11,6 [2,8; n.b.]	1,0 [0,6; 1,6]	0,9996	
QLQ-LC13 Schmerzen (Thorax); Lebermetastasen bei Studienbeginn							
Nein	67/131 (51,1)	7,6 [5,1; 11,4]	46/103 (44,7)	6,9 [3,5; 11,2]	0,8 [0,6; 1,3]	0,3940	0,5470
Ja	16/27 (59,3)	5,6 [2,8; 9,2]	9/21 (42,9)	3,0 [1,9; n.b.]	0,9 [0,3; 2,8]	0,9046	
QLQ-LC13 Schmerzen (Thorax); Knochenmetastasen bei Studienbeginn							
Nein	47/86 (54,7)	6,3 [4,2; 11,4]	35/76 (46,1)	6,9 [2,8; 11,6]	0,9 [0,5; 1,4]	0,5561	0,9074
Ja	36/72 (50,0)	5,8 [4,8; 10,2]	20/48 (41,7)	6,3 [2,8; n.b.]	0,9 [0,5; 1,7]	0,7925	
QLQ-LC13 Schmerzen (Thorax); PD-L1-Proteinexpression							
<1%	30/52 (57,7)	5,1 [3,2; 11,7]	19/41 (46,3)	5,7 [2,8; n.b.]	0,9 [0,5; 1,7]	0,7722	0,9930
≥1% und <50%	21/42 (50,0)	6,3 [4,9; 10,4]	18/47 (38,3)	4,4 [2,6; n.b.]	0,9 [0,5; 1,8]	0,7442	
≥50%	27/57 (47,4)	10,2 [4,2; 14,7]	13/28 (46,4)	7,3 [2,1; n.b.]	1,0 [0,5; 2,1]	0,9301	
QLQ-LC13 Schmerzen (Thorax); Ethnie-2							
Asiatisch	12/21 (57,1)	7,6 [2,1; 10,9]	6/18 (33,3)	n.b. [2,7; n.b.]	1,2 [0,4; 3,3]	0,7751	0,3744
Nicht asiatisch	71/136 (52,2)	6,3 [4,9; 10,4]	48/105 (45,7)	6,9 [3,0; 11,6]	0,9 [0,6; 1,3]	0,6069	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Schmerzen (Thorax); Vorgeschichte einer Beteiligung des ZNS							
Nein	52/104 (50,0)	6,3 [5,1; 10,4]	44/86 (51,2)	5,6 [2,6; 11,2]	0,8 [0,5; 1,1]	0,1843	0,0921
Ja	31/54 (57,4)	5,6 [3,3; 11,7]	11/38 (28,9)	n.b. [3,5; n.b.]	1,5 [0,7; 3,0]	0,2949	
QLQ-LC13 Schmerzen (Thorax); Anzahl an vorherigen Therapielinien							
1	37/68 (54,4)	5,1 [2,8; 9,2]	24/56 (42,9)	5,6 [2,8; 11,6]	1,0 [0,6; 1,8]	0,8667	0,7543
2	33/62 (53,2)	9,7 [5,6; 14,5]	21/50 (42,0)	6,9 [3,5; n.b.]	0,9 [0,5; 1,5]	0,6320	
>2	13/28 (46,4)	6,2 [3,4; 14,7]	10/18 (55,6)	2,7 [1,6; n.b.]	0,8 [0,3; 1,8]	0,5710	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Alter bei Studienbeginn							
<65 Jahre	37/71 (52,1)	5,6 [2,9; 12,2]	24/56 (42,9)	4,8 [2,6; n.b.]	1,0 [0,5; 1,7]	0,8629	0,9232
>=65 Jahre	29/66 (43,9)	7,6 [4,3; n.b.]	12/45 (26,7)	n.b. [3,5; n.b.]	1,0 [0,5; 2,3]	0,9356	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Geschlecht							
Weiblich	27/52 (51,9)	4,3 [2,2; n.b.]	16/40 (40,0)	7,3 [2,4; n.b.]	1,0 [0,5; 2,0]	0,9628	0,7473
Männlich	39/85 (45,9)	9,4 [4,2; 12,2]	20/61 (32,8)	5,1 [2,8; n.b.]	0,8 [0,4; 1,4]	0,4468	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Region 2							
Nordamerika und Europa	59/115 (51,3)	6,1 [3,5; 10,3]	31/85 (36,5)	5,7 [3,5; n.b.]	1,1 [0,7; 1,7]	0,7391	0,2532
Rest der Welt	7/22 (31,8)	n.b. [2,9; n.b.]	5/16 (31,2)	n.b. [2,1; n.b.]	0,4 [0,1; 1,7]	0,2148	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Region 1							
Nordamerika	4/14 (28,6)	n.b. [6,1; n.b.]	4/12 (33,3)	n.b. [2,1; n.b.]	1,0 [0,1; 8,2]	0,9688	0,3085
Europa	55/101 (54,5)	5,6 [3,3; 9,4]	27/73 (37,0)	5,1 [3,3; n.b.]	1,1 [0,7; 1,8]	0,6494	
Rest der Welt	7/22 (31,8)	n.b. [2,9; n.b.]	5/16 (31,2)	n.b. [2,1; n.b.]	0,4 [0,1; 1,7]	0,2148	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; ECOG Performance-Status							
0	19/47 (40,4)	10,4 [7,6; n.b.]	15/40 (37,5)	7,3 [3,3; n.b.]	0,5 [0,2; 1,1]	0,0720	0,1478
1	47/90 (52,2)	4,2 [2,9; 6,9]	21/61 (34,4)	n.b. [2,8; n.b.]	1,3 [0,7; 2,2]	0,3619	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Lebermetastasen bei Studienbeginn							
Nein	50/113 (44,2)	10,3 [5,6; 13,1]	28/80 (35,0)	7,3 [3,5; n.b.]	0,9 [0,5; 1,5]	0,6807	0,3519
Ja	16/24 (66,7)	3,3 [2,1; 5,8]	8/21 (38,1)	2,8 [1,9; n.b.]	1,1 [0,4; 3,4]	0,8549	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Knochenmetastasen bei Studienbeginn							
Nein	27/73 (37,0)	12,2 [7,6; n.b.]	17/56 (30,4)	7,3 [4,8; n.b.]	0,6 [0,3; 1,2]	0,1697	0,2212
Ja	39/64 (60,9)	3,4 [2,2; 6,1]	19/45 (42,2)	3,5 [2,3; n.b.]	1,1 [0,6; 2,0]	0,6454	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; PD-L1-Proteinexpression							
<1%	28/47 (59,6)	4,3 [3,2; 10,4]	15/34 (44,1)	3,5 [2,1; n.b.]	0,9 [0,4; 1,8]	0,6644	0,5969
>=1% und <50%	15/36 (41,7)	10,3 [2,2; n.b.]	12/38 (31,6)	5,7 [2,6; n.b.]	1,0 [0,4; 2,2]	0,9277	
>=50%	22/49 (44,9)	6,9 [3,5; 13,1]	6/21 (28,6)	7,3 [3,5; n.b.]	1,3 [0,5; 3,5]	0,5893	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Ethnie-2							
Asiatisch	6/18 (33,3)	n.b. [2,9; n.b.]	5/15 (33,3)	n.b. [1,5; n.b.]	0,4 [0,1; 1,7]	0,2316	0,2541
Nicht asiatisch	60/118 (50,8)	6,1 [3,5; 10,3]	30/85 (35,3)	5,7 [3,5; n.b.]	1,1 [0,7; 1,8]	0,6735	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Vorgeschichte einer Beteiligung des ZNS							
Nein	44/92 (47,8)	7,6 [3,4; 10,4]	24/70 (34,3)	7,3 [3,3; n.b.]	1,0 [0,6; 1,8]	0,8911	0,8781
Ja	22/45 (48,9)	6,3 [2,2; 18,6]	12/31 (38,7)	4,8 [2,3; n.b.]	0,8 [0,4; 1,6]	0,4805	
QLQ-LC13 Wirksamkeit der Schmerzmedikation; Anzahl an vorherigen Therapielinien							
1	30/59 (50,8)	3,4 [2,1; 18,6]	13/45 (28,9)	n.b. [2,8; n.b.]	1,7 [0,9; 3,3]	0,1268	0,2711
2	24/53 (45,3)	10,3 [5,6; 13,1]	17/42 (40,5)	5,1 [3,3; n.b.]	0,6 [0,3; 1,2]	0,1331	
>2	12/25 (48,0)	7,6 [3,5; n.b.]	6/14 (42,9)	2,3 [0,8; n.b.]	0,7 [0,2; 1,9]	0,4775	
QLQ-LC13 Wunder Mund; Alter bei Studienbeginn							
<65 Jahre	38/83 (45,8)	9,8 [3,5; n.b.]	33/67 (49,3)	4,2 [2,3; 8,7]	0,7 [0,4; 1,2]	0,1792	0,1745
≥65 Jahre	28/75 (37,3)	11,7 [6,3; n.b.]	32/57 (56,1)	2,8 [1,4; n.b.]	0,4 [0,2; 0,7]	0,0027	
QLQ-LC13 Wunder Mund; Geschlecht							
Weiblich	28/58 (48,3)	6,7 [3,1; n.b.]	28/49 (57,1)	2,3 [1,4; n.b.]	0,6 [0,3; 1,1]	0,0948	0,3114
Männlich	38/100 (38,0)	11,7 [6,3; n.b.]	37/75 (49,3)	3,7 [2,8; 8,7]	0,4 [0,2; 0,7]	0,0003	
QLQ-LC13 Wunder Mund; Region 2							
Nordamerika und Europa	51/133 (38,3)	11,7 [6,3; n.b.]	53/105 (50,5)	3,7 [2,5; 6,2]	0,5 [0,3; 0,7]	0,0005	0,4734
Rest der Welt	15/25 (60,0)	6,7 [1,8; 14,5]	12/19 (63,2)	1,9 [0,8; n.b.]	0,7 [0,3; 1,8]	0,4321	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wunder Mund; Region 1							
Nordamerika	7/16 (43,8)	6,1 [2,8; n.b.]	6/15 (40,0)	n.b. [0,7; n.b.]	1,4 [0,3; 6,9]	0,6648	0,3171
Europa	44/117 (37,6)	11,7 [6,4; n.b.]	47/90 (52,2)	3,7 [2,5; 6,2]	0,4 [0,3; 0,7]	<,0001	
Rest der Welt	15/25 (60,0)	6,7 [1,8; 14,5]	12/19 (63,2)	1,9 [0,8; n.b.]	0,7 [0,3; 1,8]	0,4321	
QLQ-LC13 Wunder Mund; ECOG Performance-Status							
0	18/55 (32,7)	n.b. [11,4; n.b.]	27/51 (52,9)	3,5 [2,5; 8,7]	0,3 [0,1; 0,6]	0,0004	0,1404
1	48/103 (46,6)	6,7 [4,3; 10,4]	38/73 (52,1)	2,8 [1,9; n.b.]	0,7 [0,4; 1,1]	0,0829	
QLQ-LC13 Wunder Mund; Lebermetastasen bei Studienbeginn							
Nein	50/131 (38,2)	14,5 [6,9; n.b.]	53/103 (51,5)	3,7 [2,8; 8,7]	0,5 [0,3; 0,7]	0,0003	0,7069
Ja	16/27 (59,3)	3,6 [2,9; 6,1]	12/21 (57,1)	2,3 [1,5; 3,5]	0,5 [0,2; 1,6]	0,2485	
QLQ-LC13 Wunder Mund; Knochenmetastasen bei Studienbeginn							
Nein	31/86 (36,0)	14,5 [9,3; n.b.]	39/76 (51,3)	5,1 [1,5; n.b.]	0,4 [0,2; 0,7]	0,0011	0,2889
Ja	35/72 (48,6)	6,1 [3,6; 10,4]	26/48 (54,2)	3,4 [2,3; 4,2]	0,6 [0,4; 1,1]	0,0961	
QLQ-LC13 Wunder Mund; PD-L1-Proteinexpression							
<1%	25/52 (48,1)	10,4 [3,4; n.b.]	22/41 (53,7)	3,7 [1,4; n.b.]	0,6 [0,3; 1,2]	0,1815	0,4365
≥1% und <50%	20/42 (47,6)	6,3 [3,5; n.b.]	22/47 (46,8)	2,8 [1,9; n.b.]	0,6 [0,3; 1,3]	0,1933	
≥50%	16/57 (28,1)	16,0 [6,4; n.b.]	16/28 (57,1)	2,8 [0,7; n.b.]	0,4 [0,2; 0,9]	0,0250	
QLQ-LC13 Wunder Mund; Ethnie-2							
Asiatisch	12/21 (57,1)	4,3 [1,8; 14,5]	13/18 (72,2)	1,4 [0,7; 3,5]	0,4 [0,2; 1,1]	0,0754	0,5143
Nicht asiatisch	54/136 (39,7)	11,4 [6,3; n.b.]	51/105 (48,6)	4,2 [2,8; 8,7]	0,5 [0,4; 0,8]	0,0017	
QLQ-LC13 Wunder Mund; Vorgeschichte einer Beteiligung des ZNS							
Nein	41/104 (39,4)	9,3 [5,8; n.b.]	44/86 (51,2)	3,5 [2,1; n.b.]	0,5 [0,3; 0,8]	0,0054	0,6155
Ja	25/54 (46,3)	11,7 [6,3; n.b.]	21/38 (55,3)	3,5 [1,4; 6,2]	0,4 [0,2; 0,7]	0,0036	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Wunder Mund; Anzahl an vorherigen Therapielinien							
1	32/68 (47,1)	9,3 [3,6; 14,5]	31/56 (55,4)	2,8 [1,5; 5,8]	0,5 [0,3; 0,8]	0,0077	0,9713
2	23/62 (37,1)	n.b. [6,2; n.b.]	26/50 (52,0)	4,2 [2,5; n.b.]	0,5 [0,3; 1,0]	0,0361	
>2	11/28 (39,3)	6,9 [4,2; 16,0]	8/18 (44,4)	8,7 [1,6; n.b.]	0,4 [0,2; 1,2]	0,1000	
QLQ-LC13 Bluthusten; Alter bei Studienbeginn							
<65 Jahre	27/83 (32,5)	18,6 [10,2; n.b.]	18/67 (26,9)	11,2 [6,9; n.b.]	0,9 [0,4; 1,6]	0,6292	0,2034
≥65 Jahre	18/75 (24,0)	n.b. [11,1; n.b.]	16/57 (28,1)	n.b. [9,9; n.b.]	0,4 [0,2; 1,0]	0,0409	
QLQ-LC13 Bluthusten; Geschlecht							
Weiblich	16/58 (27,6)	n.b. [9,7; n.b.]	13/49 (26,5)	n.b. [7,9; n.b.]	0,6 [0,2; 1,4]	0,1962	0,8477
Männlich	29/100 (29,0)	18,6 [13,1; n.b.]	21/75 (28,0)	11,2 [5,1; n.b.]	0,5 [0,3; 1,0]	0,0371	
QLQ-LC13 Bluthusten; Region 2							
Nordamerika und Europa	38/133 (28,6)	18,6 [13,1; n.b.]	30/105 (28,6)	11,2 [7,9; n.b.]	0,7 [0,4; 1,1]	0,1462	0,6047
Rest der Welt	7/25 (28,0)	15,4 [6,7; 15,4]	4/19 (21,1)	n.b. [2,8; n.b.]	0,8 [0,2; 3,0]	0,7176	
QLQ-LC13 Bluthusten; Region 1							
Nordamerika	5/16 (31,3)	n.b. [6,1; n.b.]	3/15 (20,0)	n.b. [7,9; n.b.]	108920000,0 [0,0; n.b.]	0,1521	0,5959
Europa	33/117 (28,2)	n.b. [13,5; n.b.]	27/90 (30,0)	11,2 [6,9; n.b.]	0,6 [0,3; 1,0]	0,0577	
Rest der Welt	7/25 (28,0)	15,4 [6,7; 15,4]	4/19 (21,1)	n.b. [2,8; n.b.]	0,8 [0,2; 3,0]	0,7176	
QLQ-LC13 Bluthusten; ECOG Performance-Status							
0	11/55 (20,0)	n.b. [18,6; n.b.]	13/51 (25,5)	11,2 [9,9; n.b.]	0,3 [0,1; 0,8]	0,0136	0,4423
1	34/103 (33,0)	13,5 [6,9; n.b.]	21/73 (28,8)	n.b. [5,1; n.b.]	0,7 [0,4; 1,2]	0,2150	
QLQ-LC13 Bluthusten; Lebermetastasen bei Studienbeginn							
Nein	34/131 (26,0)	n.b. [15,2; n.b.]	24/103 (23,3)	n.b. [9,9; n.b.]	0,7 [0,4; 1,2]	0,1628	0,5216
Ja	11/27 (40,7)	9,2 [3,4; n.b.]	10/21 (47,6)	3,0 [1,6; n.b.]	0,5 [0,2; 1,6]	0,2273	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-LC13 Bluthusten; Knochenmetastasen bei Studienbeginn							
Nein	24/86 (27,9)	18,6 [13,5; n.b.]	19/76 (25,0)	11,2 [9,9; n.b.]	0,7 [0,3; 1,3]	0,2548	0,2394
Ja	21/72 (29,2)	n.b. [6,9; n.b.]	15/48 (31,3)	n.b. [3,5; n.b.]	0,5 [0,2; 1,0]	0,0452	
QLQ-LC13 Bluthusten; PD-L1-Proteinexpression							
<1%	22/52 (42,3)	15,2 [5,6; n.b.]	14/41 (34,1)	9,9 [3,7; n.b.]	1,0 [0,5; 2,1]	0,9550	0,0713
≥1% und <50%	13/42 (31,0)	15,4 [9,2; n.b.]	8/47 (17,0)	n.b. [7,9; n.b.]	0,8 [0,3; 2,2]	0,6131	
≥50%	9/57 (15,8)	n.b. [13,1; n.b.]	11/28 (39,3)	11,2 [2,8; n.b.]	0,2 [0,1; 0,7]	0,0051	
QLQ-LC13 Bluthusten; Ethnie-2							
Asiatisch	6/21 (28,6)	9,7 [4,3; n.b.]	6/18 (33,3)	n.b. [2,2; n.b.]	0,5 [0,2; 1,8]	0,2904	0,8920
Nicht asiatisch	39/136 (28,7)	18,6 [13,5; n.b.]	27/105 (25,7)	11,2 [7,9; n.b.]	0,7 [0,4; 1,2]	0,1617	
QLQ-LC13 Bluthusten; Vorgeschichte einer Beteiligung des ZNS							
Nein	30/104 (28,8)	n.b. [11,1; n.b.]	23/86 (26,7)	n.b. [9,9; n.b.]	0,7 [0,4; 1,3]	0,2743	0,4434
Ja	15/54 (27,8)	18,6 [10,2; n.b.]	11/38 (28,9)	6,9 [4,8; n.b.]	0,4 [0,2; 1,0]	0,0453	
QLQ-LC13 Bluthusten; Anzahl an vorherigen Therapielinien							
1	23/68 (33,8)	15,4 [9,3; n.b.]	15/56 (26,8)	11,2 [9,9; n.b.]	0,8 [0,4; 1,7]	0,6275	0,4030
2	16/62 (25,8)	n.b. [13,1; n.b.]	12/50 (24,0)	n.b. [6,9; n.b.]	0,7 [0,3; 1,4]	0,2955	
>2	6/28 (21,4)	15,2 [11,1; n.b.]	7/18 (38,9)	7,9 [1,6; n.b.]	0,3 [0,1; 1,0]	0,0320	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-LC13 = Quality of Life Questionnaire Lung Cancer 13; ZNS = Zentrales Nervensystem

2.3.3 EQ-5D VAS

2.3.3.1 Verlaufskurve für den Endpunkt EQ-5D VAS

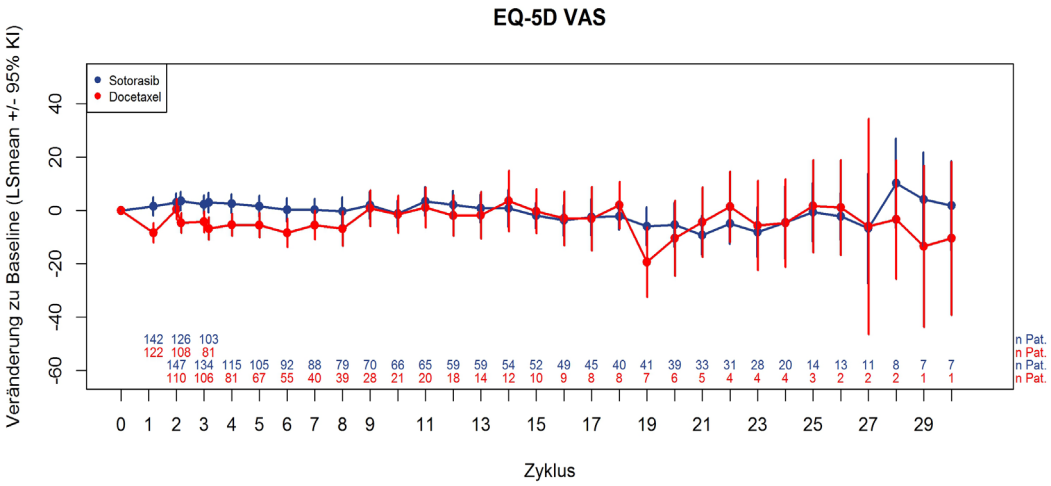

Abbildung 27: Verlaufskurve für den Endpunkt EQ-5D VAS, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.3.2 Subgruppenanalysen für den Endpunkt EQ-5D VAS (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
EQ-5D VAS; Alter bei Studienbeginn							
<65 Jahre	47/85 (55,3)	4,4 [2,8; 11,1]	44/78 (56,4)	1,6 [0,9; 4,6]	0,6 [0,4; 1,0]	0,0518	0,2256
≥65 Jahre	36/75 (48,0)	6,1 [3,7; 13,1]	39/60 (65,0)	1,6 [0,7; 3,7]	0,5 [0,3; 0,8]	0,0020	
EQ-5D VAS; Geschlecht							
Weiblich	33/58 (56,9)	3,3 [1,6; 13,8]	35/59 (59,3)	1,6 [0,7; 3,7]	0,7 [0,4; 1,1]	0,1448	0,4287
Männlich	50/102 (49,0)	6,1 [4,4; 11,0]	48/79 (60,8)	1,8 [0,9; 4,4]	0,5 [0,3; 0,7]	0,0004	
EQ-5D VAS; Region 2							
Nordamerika und Europa	70/135 (51,9)	5,2 [3,5; 10,4]	72/116 (62,1)	1,6 [0,9; 2,8]	0,5 [0,4; 0,8]	0,0004	0,9404
Rest der Welt	13/25 (52,0)	6,1 [3,6; 14,5]	11/22 (50,0)	3,5 [0,2; n.b.]	0,5 [0,2; 1,2]	0,0947	
EQ-5D VAS; Region 1							
Nordamerika	6/16 (37,5)	9,9 [0,9; n.b.]	8/16 (50,0)	3,7 [0,2; n.b.]	0,4 [0,1; 1,6]	0,1826	0,8432
Europa	64/119 (53,8)	4,7 [3,3; 10,4]	64/100 (64,0)	1,6 [0,9; 2,8]	0,5 [0,4; 0,7]	0,0003	
Rest der Welt	13/25 (52,0)	6,1 [3,6; 14,5]	11/22 (50,0)	3,5 [0,2; n.b.]	0,5 [0,2; 1,2]	0,0947	
EQ-5D VAS; ECOG Performance-Status							
0	28/56 (50,0)	9,9 [4,1; n.b.]	36/51 (70,6)	2,1 [0,9; 3,7]	0,4 [0,2; 0,7]	0,0007	0,3516
1	55/104 (52,9)	4,7 [3,4; 9,0]	47/87 (54,0)	1,6 [0,7; 4,6]	0,6 [0,4; 0,9]	0,0242	
EQ-5D VAS; Lebermetastasen bei Studienbeginn							
Nein	66/131 (50,4)	6,1 [4,1; 11,0]	69/110 (62,7)	1,6 [0,9; 3,3]	0,5 [0,4; 0,7]	0,0001	0,3538
Ja	17/29 (58,6)	3,5 [1,4; 11,1]	14/28 (50,0)	1,8 [0,3; n.b.]	0,6 [0,2; 1,5]	0,2520	
EQ-5D VAS; Knochenmetastasen bei Studienbeginn							
Nein	41/86 (47,7)	9,9 [4,7; 18,0]	48/85 (56,5)	1,6 [1,0; 5,1]	0,5 [0,3; 0,7]	0,0006	0,3916
Ja	42/74 (56,8)	3,5 [1,7; 6,1]	35/53 (66,0)	1,6 [0,8; 3,3]	0,6 [0,3; 0,9]	0,0181	
EQ-5D VAS; PD-L1-Proteinexpression							
<1%	29/52 (55,8)	4,4 [3,0; 11,1]	26/45 (57,8)	2,8 [0,7; 7,6]	0,6 [0,4; 1,1]	0,1124	0,5210
≥1% und <50%	21/43 (48,8)	9,8 [2,0; n.b.]	29/54 (53,7)	2,4 [0,7; 4,6]	0,5 [0,2; 0,9]	0,0178	
≥50%	28/58 (48,3)	6,1 [3,6; 11,1]	21/30 (70,0)	1,4 [0,7; 3,7]	0,4 [0,2; 0,8]	0,0124	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
EQ-5D VAS; Ethnie-2							
Asiatisch	13/21 (61,9)	4,9 [2,0; 11,1]	9/19 (47,4)	3,5 [0,2; n.b.]	0,8 [0,3; 1,9]	0,5811	0,2503
Nicht asiatisch	69/138 (50,0)	5,6 [3,5; 11,0]	73/118 (61,9)	1,6 [0,9; 2,8]	0,5 [0,4; 0,7]	0,0002	
EQ-5D VAS; Vorgeschichte einer Beteiligung des ZNS							
Nein	49/105 (46,7)	5,2 [3,5; 13,8]	57/93 (61,3)	1,6 [0,9; 3,9]	0,5 [0,3; 0,7]	0,0005	0,5013
Ja	34/55 (61,8)	5,6 [2,8; 11,0]	26/45 (57,8)	1,6 [0,3; 3,7]	0,6 [0,3; 1,0]	0,0481	
EQ-5D VAS; Anzahl an vorherigen Therapielinien							
1	30/69 (43,5)	9,8 [3,5; n.b.]	36/61 (59,0)	2,4 [0,7; 3,9]	0,5 [0,3; 0,8]	0,0042	0,7625
2	36/63 (57,1)	6,1 [3,3; 11,0]	34/56 (60,7)	1,6 [0,7; 4,4]	0,6 [0,4; 1,0]	0,0352	
>2	17/28 (60,7)	4,7 [1,7; 13,1]	13/21 (61,9)	1,6 [0,3; 4,6]	0,6 [0,3; 1,3]	0,1905	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; VAS = Visuelle Analogskala; ZNS = Zentrales Nervensystem

2.3.3.3 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EQ-5D VAS (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**N**	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**Hazard Ratio [95% KI]**	**p(Cox)[1]**	**p(logrank)[2]**
EQ-5D VAS, Zeit bis zur Verschlechterung um ≥15%								
160	102 (63,8)	3,7 [3,1; 6,1]	138	92 (66,7)	1,6 [0,9; 2,1]	0,60 [0,45; 0,81]	0,0007	0,0006
1) p-Wert des Cox-Modells 2) p-Wert des Logrank-Tests Die Auswertung erfolgte auf Grundlage der ITT-Population.								
KI = Konfidenzintervall; VAS = Visuelle Analogskala								

2.3.3.4 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EQ-5D VAS (präspezifizierte Analyse inkl. Tod als Ereignis)

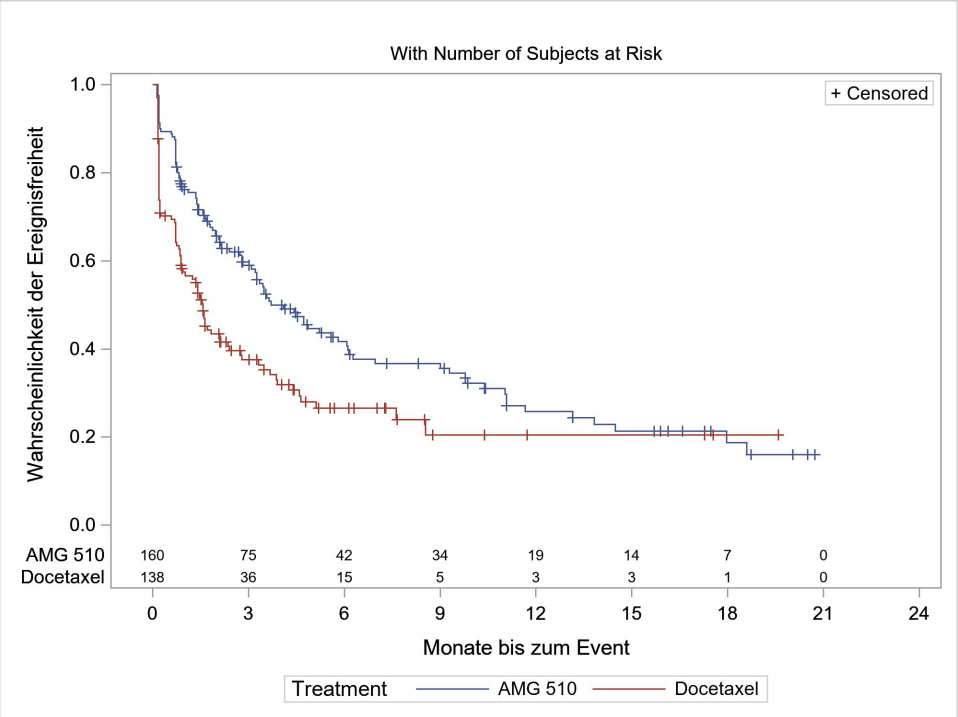

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "EQ-5D VAS, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.3.5 Subgruppenanalysen für den Endpunkt EQ-5D VAS (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
EQ-5D VAS; Alter bei Studienbeginn							
<65 Jahre	58/85 (68,2)	3,2 [2,0; 5,6]	51/78 (65,4)	1,4 [0,9; 2,8]	0,7 [0,5; 1,0]	0,0754	0,2896
≥65 Jahre	44/75 (58,7)	5,2 [3,4; 7,0]	41/60 (68,3)	1,6 [0,7; 2,8]	0,5 [0,3; 0,8]	0,0042	
EQ-5D VAS; Geschlecht							
Weiblich	37/58 (63,8)	2,8 [1,4; 10,4]	43/59 (72,9)	1,5 [0,8; 1,7]	0,6 [0,4; 1,0]	0,0424	0,9783
Männlich	65/102 (63,7)	4,7 [3,5; 6,1]	49/79 (62,0)	1,8 [0,9; 4,4]	0,6 [0,4; 0,8]	0,0050	
EQ-5D VAS; Region 2							
Nordamerika und Europa	87/135 (64,4)	3,5 [2,8; 5,8]	79/116 (68,1)	1,6 [0,9; 2,4]	0,6 [0,4; 0,8]	0,0017	0,6367
Rest der Welt	15/25 (60,0)	6,1 [2,0; 9,3]	13/22 (59,1)	1,3 [0,2; n.b.]	0,5 [0,2; 1,1]	0,0811	
EQ-5D VAS; Region 1							
Nordamerika	8/16 (50,0)	6,1 [0,9; n.b.]	9/16 (56,3)	3,7 [0,7; n.b.]	0,4 [0,1; 1,5]	0,1700	0,7382
Europa	79/119 (66,4)	3,4 [2,7; 5,2]	70/100 (70,0)	1,4 [0,9; 2,1]	0,6 [0,4; 0,8]	0,0014	
Rest der Welt	15/25 (60,0)	6,1 [2,0; 9,3]	13/22 (59,1)	1,3 [0,2; n.b.]	0,5 [0,2; 1,1]	0,0811	
EQ-5D VAS; ECOG Performance-Status							
0	34/56 (60,7)	6,3 [3,1; 11,7]	36/51 (70,6)	2,1 [0,9; 3,7]	0,5 [0,3; 0,8]	0,0023	0,4853
1	68/104 (65,4)	3,5 [2,1; 4,9]	56/87 (64,4)	1,4 [0,7; 1,6]	0,7 [0,5; 0,9]	0,0244	
EQ-5D VAS; Lebermetastasen bei Studienbeginn							
Nein	80/131 (61,1)	4,7 [3,2; 7,0]	73/110 (66,4)	1,6 [0,9; 2,8]	0,6 [0,4; 0,8]	0,0009	0,5869
Ja	22/29 (75,9)	3,0 [0,8; 5,8]	19/28 (67,9)	1,5 [0,7; 3,5]	0,5 [0,2; 1,1]	0,0769	
EQ-5D VAS; Knochenmetastasen bei Studienbeginn							
Nein	51/86 (59,3)	6,1 [3,6; 11,1]	54/85 (63,5)	1,6 [0,9; 4,4]	0,5 [0,3; 0,8]	0,0013	0,3884
Ja	51/74 (68,9)	3,0 [1,6; 4,4]	38/53 (71,7)	1,5 [0,8; 2,8]	0,6 [0,4; 1,0]	0,0296	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
EQ-5D VAS; PD-L1-Proteinexpression							
<1%	39/52 (75,0)	3,4 [2,4; 4,5]	29/45 (64,4)	1,6 [0,9; 4,6]	0,8 [0,5; 1,3]	0,3103	0,4214
≥1% und <50%	27/43 (62,8)	6,3 [1,8; 9,8]	34/54 (63,0)	1,6 [0,7; 3,3]	0,5 [0,3; 0,9]	0,0237	
≥50%	31/58 (53,4)	5,8 [3,3; 11,0]	22/30 (73,3)	1,4 [0,8; 2,4]	0,5 [0,2; 0,9]	0,0156	
EQ-5D VAS; Ethnie-2							
Asiatisch	15/21 (71,4)	4,9 [1,8; 9,3]	10/19 (52,6)	3,5 [0,2; n.b.]	0,7 [0,3; 1,7]	0,4865	0,2852
Nicht asiatisch	86/138 (62,3)	3,7 [2,8; 6,1]	81/118 (68,6)	1,5 [0,9; 2,1]	0,6 [0,4; 0,8]	0,0008	
EQ-5D VAS; Vorgeschichte einer Beteiligung des ZNS							
Nein	63/105 (60,0)	3,6 [2,8; 6,1]	63/93 (67,7)	1,6 [1,0; 2,4]	0,6 [0,4; 0,8]	0,0020	0,7672
Ja	39/55 (70,9)	4,4 [2,1; 9,0]	29/45 (64,4)	1,6 [0,6; 3,5]	0,6 [0,3; 1,0]	0,0395	
EQ-5D VAS; Anzahl an vorherigen Therapielinien							
1	42/69 (60,9)	3,5 [2,1; 9,3]	39/61 (63,9)	1,7 [0,7; 3,7]	0,6 [0,4; 1,0]	0,0275	0,9503
2	43/63 (68,3)	4,5 [2,2; 6,3]	39/56 (69,6)	1,4 [0,7; 2,1]	0,6 [0,4; 1,0]	0,0338	
>2	17/28 (60,7)	4,7 [1,7; 13,1]	14/21 (66,7)	1,6 [0,3; 4,6]	0,6 [0,3; 1,2]	0,1210	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; VAS = Visuelle Analogskala; ZNS = Zentrales Nervensystem

2.3.4 PGI-C

2.3.4.1 Verlaufskurve für den Endpunkt PGI-C

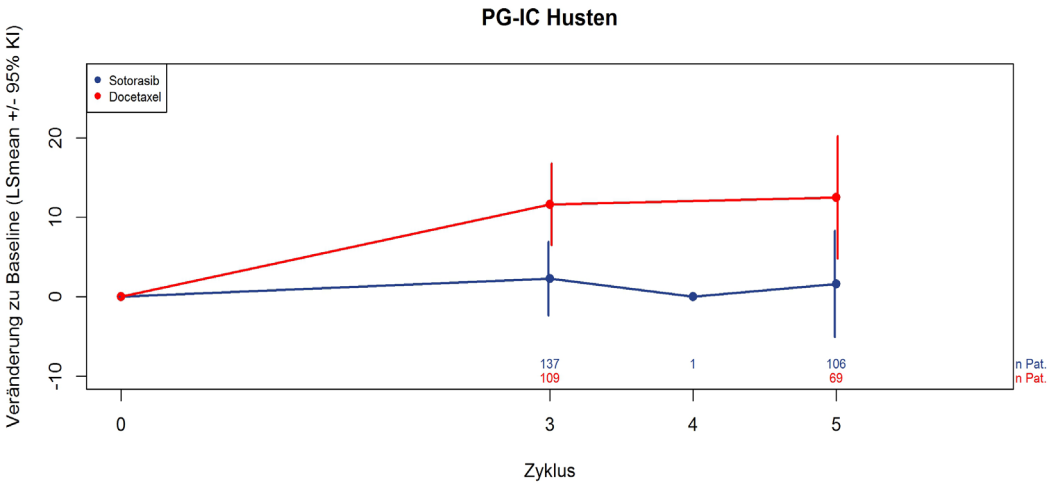

Abbildung 28: Verlaufskurve für den Endpunkt PGI-C Husten, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

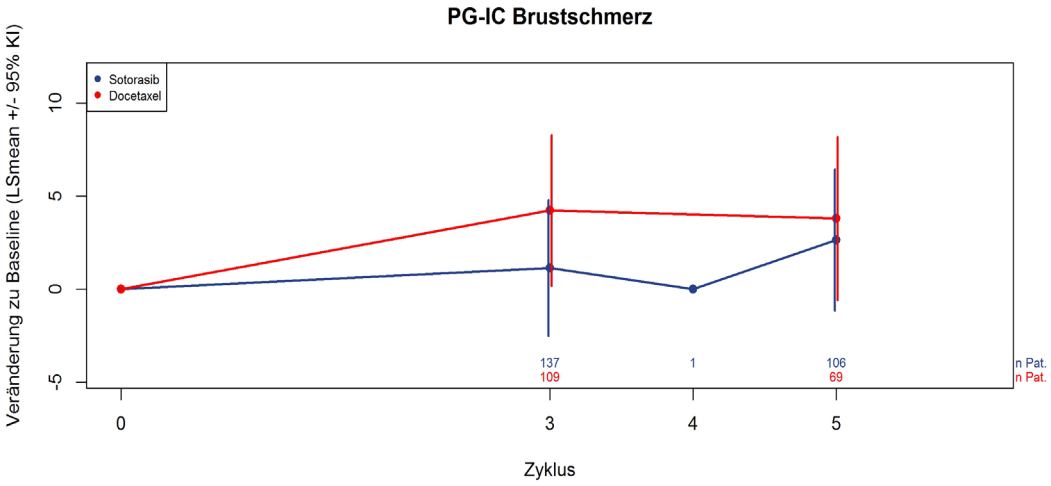

Abbildung 29: Verlaufskurve für den Endpunkt PGI-C Brustschmerz, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

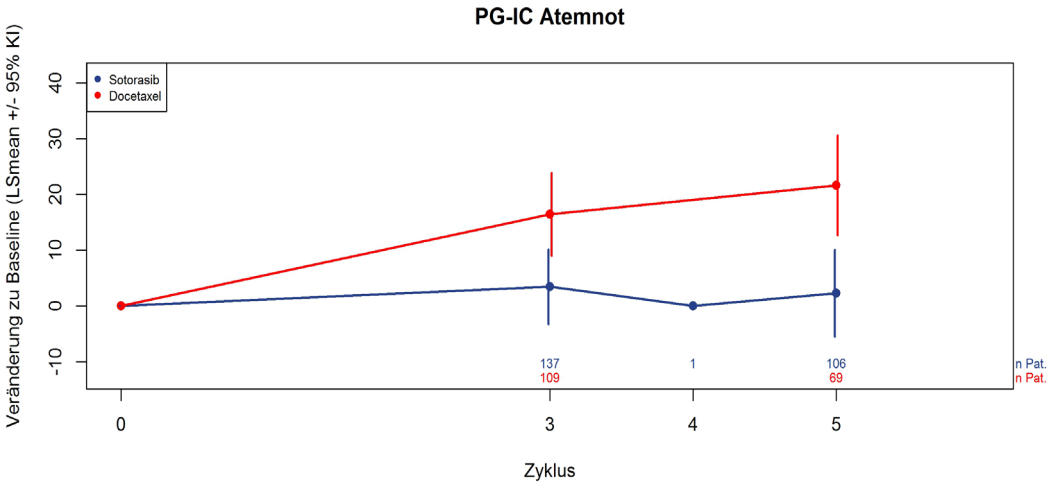

Abbildung 30: Verlaufskurve für den Endpunkt PGI-C Atemnot, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.4.2 Subgruppenanalysen für den Endpunkt PGI-C (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Husten; Alter bei Studienbeginn							
<65 Jahre	4/75 (5,3)	3,5 [3,5; n.b.]	10/59 (16,9)	n.b. [3,3; n.b.]	0,4 [0,1; 1,5]	0,1774	0,2544
≥65 Jahre	1/68 (1,5)	n.b. [n.b.; n.b.]	9/51 (17,6)	4,4 [n.b.; n.b.]	0,1 [0,0; 0,9]	0,0139	
PGI-C Husten; Geschlecht							
Weiblich	5/52 (9,6)	3,5 [n.b.; n.b.]	8/46 (17,4)	n.b. [n.b.; n.b.]	0,4 [0,1; 1,3]	0,1249	n. b.
Männlich	0/91		11/64 (17,2)				
PGI-C Husten; Region 2							
Nordamerika und Europa	5/119 (4,2)	3,5 [3,5; n.b.]	16/94 (17,0)	4,4 [3,3; n.b.]	0,3 [0,1; 0,8]	0,0155	n. b.
Rest der Welt	0/24		3/16 (18,8)				
PGI-C Husten; Region 1							
Nordamerika	0/16		1/13 (7,7)				n. b.
Europa	5/103 (4,9)	3,5 [3,5; n.b.]	15/81 (18,5)	4,4 [3,3; n.b.]	0,3 [0,1; 0,8]	0,0127	
Rest der Welt	0/24		3/16 (18,8)				
PGI-C Husten; ECOG Performance-Status							
0	3/51 (5,9)	n.b. [n.b.; n.b.]	9/49 (18,4)	4,4 [3,3; n.b.]	0,6 [0,2; 2,5]	0,5014	0,1007
1	2/92 (2,2)	3,5 [n.b.; n.b.]	10/61 (16,4)	n.b. [n.b.; n.b.]	0,1 [0,0; 0,6]	0,0011	
PGI-C Husten; Lebermetastasen bei Studienbeginn							
Nein	4/118 (3,4)	n.b. [n.b.; n.b.]	17/93 (18,3)	4,4 [3,3; n.b.]	0,2 [0,1; 0,7]	0,0075	0,7592
Ja	1/25 (4,0)	3,5 [n.b.; n.b.]	2/17 (11,8)	n.b. [n.b.; n.b.]	0,0 [0,0; n.b.]	0,2207	
PGI-C Husten; Knochenmetastasen bei Studienbeginn							
Nein	3/75 (4,0)	3,5 [3,5; n.b.]	15/67 (22,4)	4,4 [3,3; n.b.]	0,3 [0,1; 1,0]	0,0305	0,7643
Ja	2/68 (2,9)	n.b. [n.b.; n.b.]	4/43 (9,3)	n.b. [n.b.; n.b.]	0,1 [0,0; 0,9]	0,0137	
PGI-C Husten; PD-L1-Proteinexpression							
<1%	1/50 (2,0)		8/35 (22,9)				n. a.
≥1% und <50%	0/40		4/39 (10,3)				
≥50%	4/46 (8,7)		5/28 (17,9)				

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Husten; Ethnie-2							
Asiatisch	0/20		4/14 (28,6)				n. b.
Nicht asiatisch	5/122 (4,1)	3,5 [3,5; n.b.]	15/95 (15,8)	4,4 [3,3; n.b.]	0,3 [0,1; 0,8]	0,0122	
PGI-C Husten; Vorgeschichte einer Beteiligung des ZNS							
Nein	4/94 (4,3)	3,5 [n.b.; n.b.]	17/77 (22,1)	4,4 [3,0; 4,4]	0,2 [0,1; 0,6]	0,0024	0,4296
Ja	1/49 (2,0)	n.b. [n.b.; n.b.]	2/33 (6,1)	n.b. [n.b.; n.b.]	0,4 [0,0; 4,2]	0,3946	
PGI-C Husten; Anzahl an vorherigen Therapielinien							
1	2/60 (3,3)	n.b. [n.b.; n.b.]	12/48 (25,0)	n.b. [2,8; n.b.]	0,2 [0,0; 0,7]	0,0050	0,4942
2	2/55 (3,6)	3,5 [3,5; n.b.]	4/46 (8,7)	4,4 [4,4; n.b.]	0,7 [0,1; 4,0]	0,6462	
>2	1/28 (3,6)	n.b. [2,8; n.b.]	3/16 (18,8)	3,3 [n.b.; n.b.]	0,3 [0,0; 3,8]	0,3546	
PGI-C Brustschmerz; Alter bei Studienbeginn							
<65 Jahre	3/75 (4,0)		5/59 (8,5)				n. a.
≥65 Jahre	1/68 (1,5)		2/51 (3,9)				
PGI-C Brustschmerz; Geschlecht							
Weiblich	2/52 (3,8)		2/46 (4,3)				n. a.
Männlich	2/91 (2,2)		5/64 (7,8)				
PGI-C Brustschmerz; Region 2							
Nordamerika und Europa	4/119 (3,4)		5/94 (5,3)				n. a.
Rest der Welt	0/24		2/16 (12,5)				
PGI-C Brustschmerz; Region 1							
Nordamerika	0/16		0/13				n. a.
Europa	4/103 (3,9)		5/81 (6,2)				
Rest der Welt	0/24		2/16 (12,5)				
PGI-C Brustschmerz; ECOG Performance-Status							
0	0/51		2/49 (4,1)				n. a.
1	4/92 (4,3)		5/61 (8,2)				
PGI-C Brustschmerz; Lebermetastasen bei Studienbeginn							
Nein	3/118 (2,5)	n.b. [n.b.; n.b.]	7/93 (7,5)	n.b. [n.b.; n.b.]	0,4 [0,1; 1,7]	0,2212	n. b.
Ja	1/25 (4,0)		0/17				

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Brustschmerz; Knochenmetastasen bei Studienbeginn							
Nein	3/75 (4,0)		4/67 (6,0)				n. a.
Ja	1/68 (1,5)		3/43 (7,0)				
PGI-C Brustschmerz; PD-L1-Proteinexpression							
<1%	1/50 (2,0)		2/35 (5,7)				n. a.
≥1% und <50%	2/40 (5,0)		2/39 (5,1)				
≥50%	1/46 (2,2)		1/28 (3,6)				
PGI-C Brustschmerz; Ethnie-2							
Asiatisch	0/20		2/14 (14,3)				n. a.
Nicht asiatisch	4/122 (3,3)		5/95 (5,3)				
PGI-C Brustschmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	2/94 (2,1)		5/77 (6,5)				n. a.
Ja	2/49 (4,1)		2/33 (6,1)				
PGI-C Brustschmerz; Anzahl an vorherigen Therapielinien							
1	1/60 (1,7)		5/48 (10,4)				n. a.
2	2/55 (3,6)		2/46 (4,3)				
>2	1/28 (3,6)		0/16				
PGI-C Atemnot; Alter bei Studienbeginn							
<65 Jahre	6/75 (8,0)	n.b. [n.b.; n.b.]	18/59 (30,5)	n.b. [2,8; n.b.]	0,3 [0,1; 0,9]	0,0222	0,5754
≥65 Jahre	3/68 (4,4)	n.b. [n.b.; n.b.]	10/51 (19,6)	4,4 [3,0; 4,4]	0,3 [0,1; 1,0]	0,0432	
PGI-C Atemnot; Geschlecht							
Weiblich	7/52 (13,5)	n.b. [n.b.; n.b.]	9/46 (19,6)	n.b. [3,0; n.b.]	0,6 [0,2; 1,8]	0,3561	0,0207
Männlich	2/91 (2,2)	n.b. [n.b.; n.b.]	19/64 (29,7)	4,4 [3,0; 4,4]	0,1 [0,0; 0,4]	<,0001	
PGI-C Atemnot; Region 2							
Nordamerika und Europa	8/119 (6,7)	n.b. [n.b.; n.b.]	24/94 (25,5)	4,4 [3,0; n.b.]	0,3 [0,1; 0,6]	0,0012	0,5905
Rest der Welt	1/24 (4,2)	n.b. [n.b.; n.b.]	4/16 (25,0)	n.b. [1,5; n.b.]	0,0 [0,0; n.b.]	0,0322	
PGI-C Atemnot; Region 1							
Nordamerika	0/16		2/13 (15,4)				n. b.
Europa	8/103 (7,8)	n.b. [n.b.; n.b.]	22/81 (27,2)	4,4 [3,3; n.b.]	0,3 [0,1; 0,7]	0,0022	
Rest der Welt	1/24 (4,2)	n.b. [n.b.; n.b.]	4/16 (25,0)	n.b. [1,5; n.b.]	0,0 [0,0; n.b.]	0,0322	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Atemnot; ECOG Performance-Status							
0	3/51 (5,9)	n.b. [n.b.; n.b.]	17/49 (34,7)	4,4 [2,8; n.b.]	0,2 [0,1; 0,7]	0,0073	0,5539
1	6/92 (6,5)	n.b. [n.b.; n.b.]	11/61 (18,0)	n.b. [3,0; n.b.]	0,4 [0,1; 1,1]	0,0742	
PGI-C Atemnot; Lebermetastasen bei Studienbeginn							
Nein	7/118 (5,9)	n.b. [n.b.; n.b.]	25/93 (26,9)	4,4 [3,0; n.b.]	0,2 [0,1; 0,6]	0,0004	0,5910
Ja	2/25 (8,0)	n.b. [n.b.; n.b.]	3/17 (17,6)	n.b. [1,5; n.b.]	0,2 [0,0; 2,5]	0,1763	
PGI-C Atemnot; Knochenmetastasen bei Studienbeginn							
Nein	6/75 (8,0)	n.b. [n.b.; n.b.]	21/67 (31,3)	4,4 [3,0; n.b.]	0,3 [0,1; 0,6]	0,0020	0,9176
Ja	3/68 (4,4)	n.b. [n.b.; n.b.]	7/43 (16,3)	n.b. [3,0; n.b.]	0,3 [0,1; 1,1]	0,0468	
PGI-C Atemnot; PD-L1-Proteinexpression							
<1%	1/50 (2,0)	n.b. [n.b.; n.b.]	12/35 (34,3)	3,0 [2,8; n.b.]	0,1 [0,0; 0,5]	0,0003	0,1342
≥1% und <50%	2/40 (5,0)	n.b. [n.b.; n.b.]	7/39 (17,9)	4,4 [4,4; n.b.]	0,4 [0,1; 1,9]	0,2166	
≥50%	4/46 (8,7)	n.b. [n.b.; n.b.]	5/28 (17,9)	3,3 [3,0; n.b.]	0,6 [0,1; 2,9]	0,5486	
PGI-C Atemnot; Ethnie-2							
Asiatisch	0/20		3/14 (21,4)				n. b.
Nicht asiatisch	9/122 (7,4)	n.b. [n.b.; n.b.]	25/95 (26,3)	4,4 [3,0; n.b.]	0,3 [0,1; 0,6]	0,0011	
PGI-C Atemnot; Vorgeschichte einer Beteiligung des ZNS							
Nein	7/94 (7,4)	n.b. [n.b.; n.b.]	22/77 (28,6)	4,4 [3,0; 4,4]	0,3 [0,1; 0,6]	0,0010	0,9011
Ja	2/49 (4,1)	n.b. [n.b.; n.b.]	6/33 (18,2)	n.b. [3,0; n.b.]	0,3 [0,1; 1,4]	0,0924	
PGI-C Atemnot; Anzahl an vorherigen Therapielinien							
1	1/60 (1,7)	n.b. [n.b.; n.b.]	12/48 (25,0)	n.b. [3,0; n.b.]	0,1 [0,0; 0,5]	0,0006	0,1226
2	4/55 (7,3)	n.b. [n.b.; n.b.]	13/46 (28,3)	4,4 [3,0; n.b.]	0,3 [0,1; 0,9]	0,0186	
>2	4/28 (14,3)	n.b. [n.b.; n.b.]	3/16 (18,8)	3,3 [2,8; 3,3]	1,6 [0,3; 8,5]	0,6062	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
Die Beobachtungen 4 ("ein bisschen schlechter") und 5 ("viel schlechter") wurden als Verschlechterung gewertet und auf den Wert 100 gesetzt, um die Verschlechterung um 15% abbilden zu können.

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; PGI-C = Patienten-Eindruck der Veränderung; ZNS = Zentrales Nervensystem

2.3.4.3 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt PGI-C (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
PGI-C Husten								
143	12 (8,4)	n.b. [3,5; n.b.]	110	23 (20,9)	4,4 [3,3; n.b.]	0,45 [0,22; 0,92]	0,0283	0,0246
PGI-C Brustschmerz								
143	10 (7,0)	n.b. [n.b.; n.b.]	110	12 (10,9)	n.b. [n.b.; n.b.]	0,71 [0,30; 1,68]	0,4368	0,4347
PGI-C Atemnot								
143	14 (9,8)	n.b. [n.b.; n.b.]	110	31 (28,2)	4,4 [3,0; n.b.]	0,35 [0,19; 0,67]	0,0014	0,0009

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.
Die Beobachtungen 4 ("ein bisschen schlechter") und 5 ("viel schlechter") wurden als Verschlechterung gewertet und auf den Wert 100 gesetzt, um die Verschlechterung um 15% abbilden zu können.

KI = Konfidenzintervall; n.b. = nicht berechenbar; PGI-C = Patienten-Eindruck der Veränderung

2.3.4.4 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt PGI-C (präspezifizierte Analyse inkl. Tod als Ereignis)

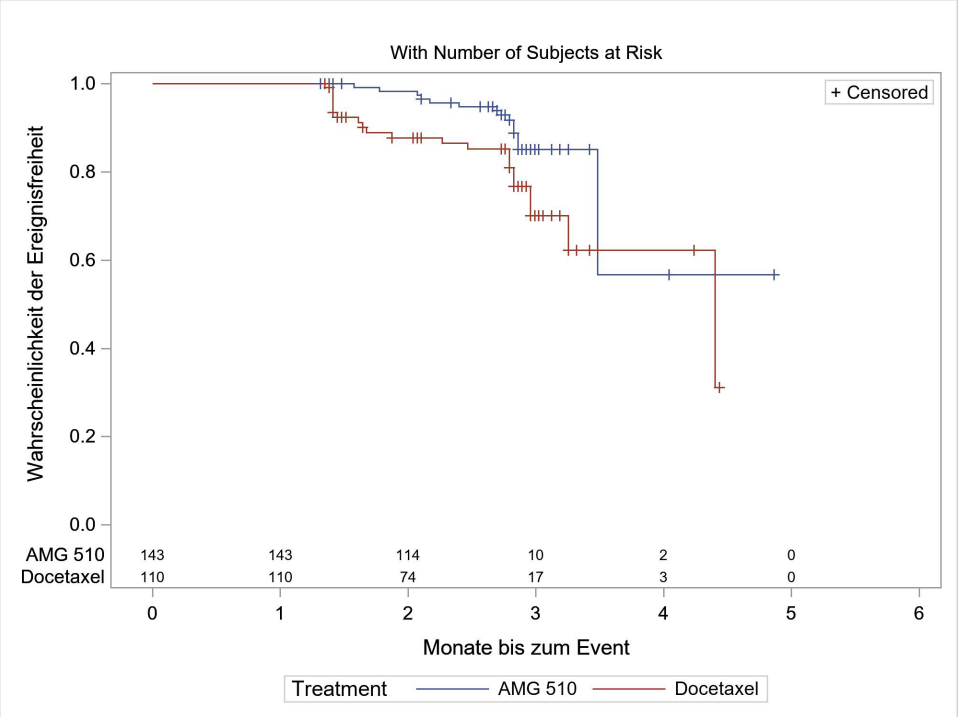

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PGI-C Husten, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

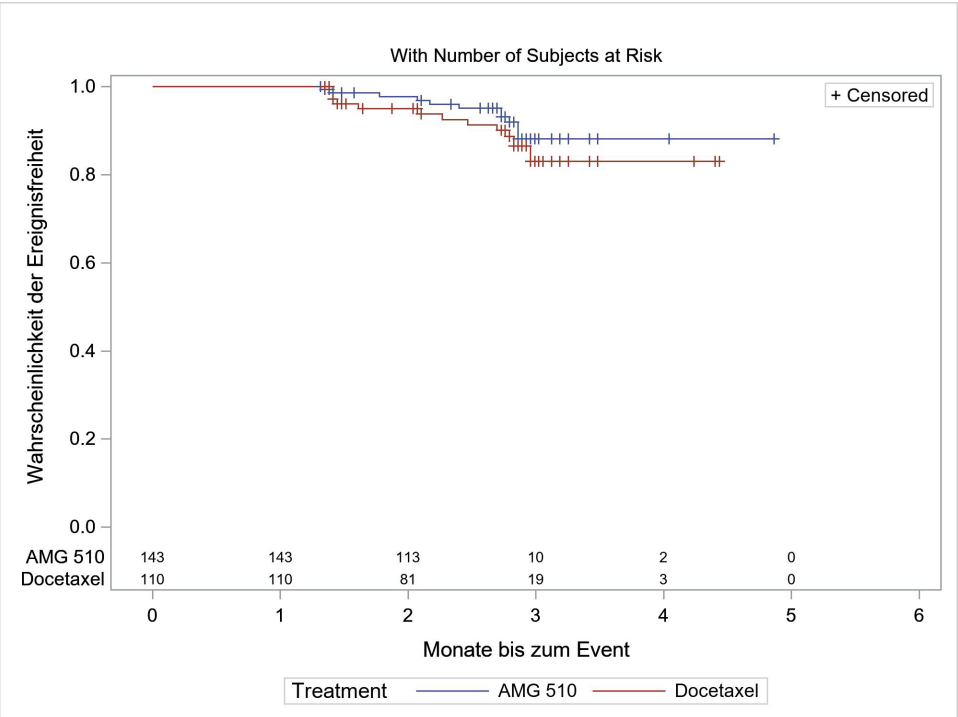

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PGI-C Brustschmerz, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

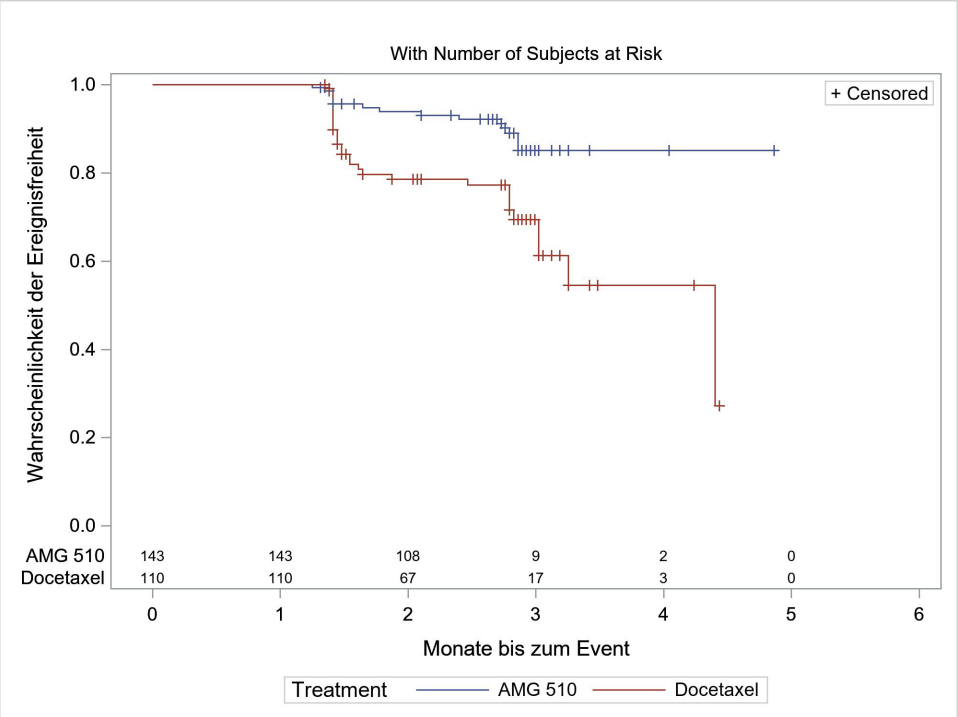

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PGI-C Atemnot, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.4.5 Subgruppenanalysen für den Endpunkt PGI-C (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Husten; Alter bei Studienbeginn							
<65 Jahre	10/75 (13,3)	3,5 [3,5; n.b.]	10/59 (16,9)	n.b. [3,3; n.b.]	0,9 [0,3; 2,4]	0,8343	0,0249
≥65 Jahre	2/68 (2,9)	n.b. [n.b.; n.b.]	13/51 (25,5)	4,4 [3,0; 4,4]	0,1 [0,0; 0,6]	0,0026	
PGI-C Husten; Geschlecht							
Weiblich	8/52 (15,4)	3,5 [2,9; 3,5]	9/46 (19,6)	n.b. [n.b.; n.b.]	0,5 [0,2; 1,4]	0,1541	0,3188
Männlich	4/91 (4,4)	n.b. [n.b.; n.b.]	14/64 (21,9)	4,4 [3,0; 4,4]	0,2 [0,1; 0,8]	0,0124	
PGI-C Husten; Region 2							
Nordamerika und Europa	10/119 (8,4)	3,5 [3,5; n.b.]	20/94 (21,3)	4,4 [3,3; n.b.]	0,4 [0,2; 1,0]	0,0402	0,6339
Rest der Welt	2/24 (8,3)	n.b. [2,9; n.b.]	3/16 (18,8)	n.b. [3,0; n.b.]	0,8 [0,1; 6,1]	0,8245	
PGI-C Husten; Region 1							
Nordamerika	0/16		1/13 (7,7)				n. b.
Europa	10/103 (9,7)	3,5 [3,5; n.b.]	19/81 (23,5)	4,4 [3,0; n.b.]	0,4 [0,2; 0,9]	0,0316	
Rest der Welt	2/24 (8,3)	n.b. [2,9; n.b.]	3/16 (18,8)	n.b. [3,0; n.b.]	0,8 [0,1; 6,1]	0,8245	
PGI-C Husten; ECOG Performance-Status							
0	5/51 (9,8)	n.b. [n.b.; n.b.]	11/49 (22,4)	4,4 [3,3; n.b.]	0,8 [0,3; 2,4]	0,6684	0,2513
1	7/92 (7,6)	3,5 [n.b.; n.b.]	12/61 (19,7)	n.b. [3,0; n.b.]	0,3 [0,1; 0,8]	0,0168	
PGI-C Husten; Lebermetastasen bei Studienbeginn							
Nein	9/118 (7,6)	n.b. [n.b.; n.b.]	18/93 (19,4)	4,4 [3,3; n.b.]	0,5 [0,2; 1,1]	0,0868	0,2502
Ja	3/25 (12,0)	3,5 [2,9; 3,5]	5/17 (29,4)	n.b. [1,6; n.b.]	0,1 [0,0; 1,3]	0,0538	
PGI-C Husten; Knochenmetastasen bei Studienbeginn							
Nein	5/75 (6,7)	3,5 [3,5; n.b.]	16/67 (23,9)	4,4 [3,0; n.b.]	0,4 [0,1; 1,1]	0,0696	0,9929
Ja	7/68 (10,3)	n.b. [n.b.; n.b.]	7/43 (16,3)	n.b. [n.b.; n.b.]	0,3 [0,1; 1,0]	0,0445	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Husten; PD-L1-Proteinexpression							
<1%	4/50 (8,0)	n.b. [n.b.; n.b.]	9/35 (25,7)	n.b. [2,8; n.b.]	0,3 [0,1; 1,0]	0,0397	0,5034
≥1% und <50%	3/40 (7,5)	n.b. [2,9; n.b.]	7/39 (17,9)	4,4 [4,4; n.b.]	0,4 [0,1; 2,0]	0,2391	
≥50%	5/46 (10,9)	3,5 [3,5; n.b.]	5/28 (17,9)	3,3 [3,3; n.b.]	0,6 [0,1; 2,7]	0,4676	
PGI-C Husten; Ethnie-2							
Asiatisch	2/20 (10,0)	n.b. [2,9; n.b.]	4/14 (28,6)	n.b. [1,4; n.b.]	0,5 [0,1; 3,4]	0,5093	0,9880
Nicht asiatisch	10/122 (8,2)	3,5 [3,5; n.b.]	18/95 (18,9)	4,4 [3,3; n.b.]	0,5 [0,2; 1,0]	0,0526	
PGI-C Husten; Vorgeschichte einer Beteiligung des ZNS							
Nein	8/94 (8,5)	3,5 [n.b.; n.b.]	20/77 (26,0)	3,3 [3,0; 4,4]	0,3 [0,1; 0,8]	0,0074	0,1124
Ja	4/49 (8,2)	n.b. [n.b.; n.b.]	3/33 (9,1)	n.b. [n.b.; n.b.]	1,0 [0,2; 4,8]	0,9772	
PGI-C Husten; Anzahl an vorherigen Therapielinien							
1	5/60 (8,3)	n.b. [n.b.; n.b.]	14/48 (29,2)	3,0 [2,8; n.b.]	0,3 [0,1; 0,9]	0,0227	0,1011
2	6/55 (10,9)	3,5 [3,5; n.b.]	5/46 (10,9)	4,4 [4,4; n.b.]	1,3 [0,4; 4,6]	0,7165	
>2	1/28 (3,6)	n.b. [2,8; n.b.]	4/16 (25,0)	3,3 [1,6; 3,3]	0,2 [0,0; 2,2]	0,1631	
PGI-C Brustschmerz; Alter bei Studienbeginn							
<65 Jahre	8/75 (10,7)	n.b. [n.b.; n.b.]	6/59 (10,2)	n.b. [n.b.; n.b.]	1,0 [0,3; 3,1]	0,9657	0,1585
≥65 Jahre	2/68 (2,9)	n.b. [n.b.; n.b.]	6/51 (11,8)	n.b. [n.b.; n.b.]	0,3 [0,1; 1,8]	0,1800	
PGI-C Brustschmerz; Geschlecht							
Weiblich	4/52 (7,7)	n.b. [n.b.; n.b.]	4/46 (8,7)	n.b. [n.b.; n.b.]	0,5 [0,1; 2,2]	0,3271	0,8161
Männlich	6/91 (6,6)	n.b. [n.b.; n.b.]	8/64 (12,5)	n.b. [n.b.; n.b.]	0,6 [0,2; 1,8]	0,3498	
PGI-C Brustschmerz; Region 2							
Nordamerika und Europa	8/119 (6,7)	n.b. [n.b.; n.b.]	10/94 (10,6)	n.b. [n.b.; n.b.]	0,6 [0,3; 1,6]	0,3459	0,4229
Rest der Welt	2/24 (8,3)	n.b. [2,9; n.b.]	2/16 (12,5)	n.b. [3,0; n.b.]	2,2 [0,2; 25,9]	0,5156	
PGI-C Brustschmerz; Region 1							
Nordamerika	0/16		0/13				n. b.
Europa	8/103 (7,8)	n.b. [n.b.; n.b.]	10/81 (12,3)	n.b. [n.b.; n.b.]	0,6 [0,2; 1,6]	0,3171	
Rest der Welt	2/24 (8,3)	n.b. [2,9; n.b.]	2/16 (12,5)	n.b. [3,0; n.b.]	2,2 [0,2; 25,9]	0,5156	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Brustschmerz; ECOG Performance-Status							
0	2/51 (3,9)	n.b. [n.b.; n.b.]	4/49 (8,2)	n.b. [n.b.; n.b.]	0,6 [0,1; 3,5]	0,5829	0,7358
1	8/92 (8,7)	n.b. [n.b.; n.b.]	8/61 (13,1)	n.b. [n.b.; n.b.]	0,8 [0,3; 2,5]	0,7446	
PGI-C Brustschmerz; Lebermetastasen bei Studienbeginn							
Nein	7/118 (5,9)	n.b. [n.b.; n.b.]	9/93 (9,7)	n.b. [n.b.; n.b.]	0,7 [0,3; 2,0]	0,5169	0,5898
Ja	3/25 (12,0)	n.b. [2,9; n.b.]	3/17 (17,6)	n.b. [2,3; n.b.]	0,4 [0,1; 2,9]	0,3819	
PGI-C Brustschmerz; Knochenmetastasen bei Studienbeginn							
Nein	4/75 (5,3)	n.b. [n.b.; n.b.]	6/67 (9,0)	n.b. [n.b.; n.b.]	0,6 [0,2; 2,4]	0,4808	0,7488
Ja	6/68 (8,8)	n.b. [n.b.; n.b.]	6/43 (14,0)	n.b. [n.b.; n.b.]	0,5 [0,1; 1,7]	0,2584	
PGI-C Brustschmerz; PD-L1-Proteinexpression							
<1%	3/50 (6,0)	n.b. [n.b.; n.b.]	3/35 (8,6)	n.b. [n.b.; n.b.]	0,8 [0,2; 3,9]	0,7682	0,9301
≥1% und <50%	5/40 (12,5)	n.b. [2,9; n.b.]	6/39 (15,4)	n.b. [n.b.; n.b.]	0,9 [0,2; 3,2]	0,8368	
≥50%	2/46 (4,3)	n.b. [n.b.; n.b.]	1/28 (3,6)	n.b. [n.b.; n.b.]	1,4 [0,1; 17,2]	0,7924	
PGI-C Brustschmerz; Ethnie-2							
Asiatisch	2/20 (10,0)	n.b. [2,9; n.b.]	2/14 (14,3)	n.b. [3,0; n.b.]	2,2 [0,2; 25,9]	0,5156	0,7933
Nicht asiatisch	8/122 (6,6)	n.b. [n.b.; n.b.]	9/95 (9,5)	n.b. [n.b.; n.b.]	0,7 [0,3; 1,8]	0,4512	
PGI-C Brustschmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	6/94 (6,4)	n.b. [n.b.; n.b.]	9/77 (11,7)	n.b. [n.b.; n.b.]	0,6 [0,2; 1,6]	0,2734	0,4650
Ja	4/49 (8,2)	n.b. [n.b.; n.b.]	3/33 (9,1)	n.b. [n.b.; n.b.]	1,2 [0,3; 5,5]	0,8375	
PGI-C Brustschmerz; Anzahl an vorherigen Therapielinien							
1	4/60 (6,7)	n.b. [n.b.; n.b.]	7/48 (14,6)	n.b. [3,0; n.b.]	0,6 [0,2; 2,0]	0,3802	0,4400
2	5/55 (9,1)	n.b. [n.b.; n.b.]	3/46 (6,5)	n.b. [n.b.; n.b.]	1,4 [0,3; 5,7]	0,6723	
>2	1/28 (3,6)	n.b. [n.b.; n.b.]	2/16 (12,5)	n.b. [2,7; n.b.]	0,3 [0,0; 3,8]	0,3588	
PGI-C Atemnot; Alter bei Studienbeginn							
<65 Jahre	10/75 (13,3)	n.b. [n.b.; n.b.]	18/59 (30,5)	n.b. [2,8; n.b.]	0,5 [0,2; 1,1]	0,0651	0,2118
≥65 Jahre	4/68 (5,9)	n.b. [n.b.; n.b.]	13/51 (25,5)	4,4 [3,0; 4,4]	0,3 [0,1; 0,8]	0,0158	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Atemnot; Geschlecht							
Weiblich	9/52 (17,3)	n.b. [2,9; n.b.]	10/46 (21,7)	n.b. [3,0; n.b.]	0,6 [0,2; 1,6]	0,2988	0,0466
Männlich	5/91 (5,5)	n.b. [n.b.; n.b.]	21/64 (32,8)	3,3 [2,8; 4,4]	0,2 [0,1; 0,5]	0,0003	
PGI-C Atemnot; Region 2							
Nordamerika und Europa	11/119 (9,2)	n.b. [n.b.; n.b.]	27/94 (28,7)	4,4 [3,0; n.b.]	0,3 [0,2; 0,7]	0,0021	0,8357
Rest der Welt	3/24 (12,5)	n.b. [2,9; n.b.]	4/16 (25,0)	n.b. [1,5; n.b.]	0,4 [0,1; 2,0]	0,2264	
PGI-C Atemnot; Region 1							
Nordamerika	0/16		2/13 (15,4)				n. b.
Europa	11/103 (10,7)	n.b. [n.b.; n.b.]	25/81 (30,9)	4,4 [2,8; n.b.]	0,4 [0,2; 0,7]	0,0033	
Rest der Welt	3/24 (12,5)	n.b. [2,9; n.b.]	4/16 (25,0)	n.b. [1,5; n.b.]	0,4 [0,1; 2,0]	0,2264	
PGI-C Atemnot; ECOG Performance-Status							
0	4/51 (7,8)	n.b. [n.b.; n.b.]	18/49 (36,7)	4,4 [2,8; n.b.]	0,3 [0,1; 0,8]	0,0136	0,4206
1	10/92 (10,9)	n.b. [n.b.; n.b.]	13/61 (21,3)	n.b. [3,0; n.b.]	0,6 [0,2; 1,3]	0,1835	
PGI-C Atemnot; Lebermetastasen bei Studienbeginn							
Nein	11/118 (9,3)	n.b. [n.b.; n.b.]	26/93 (28,0)	4,4 [3,0; n.b.]	0,4 [0,2; 0,7]	0,0029	0,8909
Ja	3/25 (12,0)	n.b. [2,9; n.b.]	5/17 (29,4)	n.b. [1,6; n.b.]	0,2 [0,0; 1,6]	0,0839	
PGI-C Atemnot; Knochenmetastasen bei Studienbeginn							
Nein	8/75 (10,7)	n.b. [n.b.; n.b.]	21/67 (31,3)	4,4 [3,0; n.b.]	0,3 [0,1; 0,7]	0,0056	0,9483
Ja	6/68 (8,8)	n.b. [n.b.; n.b.]	10/43 (23,3)	n.b. [2,8; n.b.]	0,3 [0,1; 0,9]	0,0255	
PGI-C Atemnot; PD-L1-Proteinexpression							
<1%	3/50 (6,0)	n.b. [n.b.; n.b.]	12/35 (34,3)	3,0 [2,8; n.b.]	0,2 [0,0; 0,6]	0,0021	0,2019
≥1% und <50%	4/40 (10,0)	n.b. [2,9; n.b.]	10/39 (25,6)	4,4 [2,8; n.b.]	0,4 [0,1; 1,4]	0,1441	
≥50%	5/46 (10,9)	n.b. [n.b.; n.b.]	5/28 (17,9)	3,3 [3,0; n.b.]	0,8 [0,2; 3,3]	0,7100	
PGI-C Atemnot; Ethnie-2							
Asiatisch	2/20 (10,0)	n.b. [2,9; n.b.]	3/14 (21,4)	n.b. [1,5; n.b.]	0,5 [0,1; 2,8]	0,3832	0,5933
Nicht asiatisch	12/122 (9,8)	n.b. [n.b.; n.b.]	27/95 (28,4)	4,4 [3,0; n.b.]	0,4 [0,2; 0,7]	0,0026	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PGI-C Atemnot; Vorgeschichte einer Beteiligung des ZNS							
Nein	10/94 (10,6)	n.b. [n.b.; n.b.]	24/77 (31,2)	3,3 [3,0; 4,4]	0,3 [0,2; 0,7]	0,0020	0,6471
Ja	4/49 (8,2)	n.b. [n.b.; n.b.]	7/33 (21,2)	n.b. [3,0; n.b.]	0,4 [0,1; 1,5]	0,1751	
PGI-C Atemnot; Anzahl an vorherigen Therapielinien							
1	3/60 (5,0)	n.b. [n.b.; n.b.]	13/48 (27,1)	n.b. [2,8; n.b.]	0,2 [0,1; 0,6]	0,0025	0,3543
2	7/55 (12,7)	n.b. [n.b.; n.b.]	14/46 (30,4)	4,4 [3,0; n.b.]	0,4 [0,2; 1,0]	0,0537	
>2	4/28 (14,3)	n.b. [n.b.; n.b.]	4/16 (25,0)	3,3 [2,8; 3,3]	1,1 [0,2; 4,8]	0,9367	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
Die Beobachtungen 4 ("ein bisschen schlechter") und 5 ("viel schlechter") wurden als Verschlechterung gewertet und auf den Wert 100 gesetzt, um die Verschlechterung um 15% abbilden zu können.

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; PGI-C = Patienten-Eindruck der Veränderung; ZNS = Zentrales Nervensystem

2.3.5 BPI-SF

2.3.5.1 Verlaufskurve für den Endpunkt BPI-SF

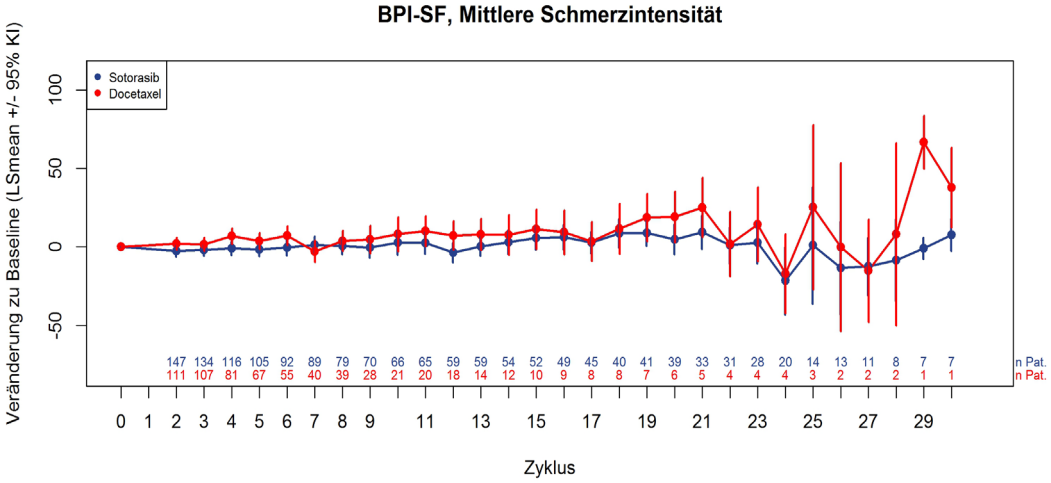

Abbildung 47: Verlaufskurve für den Endpunkt BPI-SF, Mittlere Schmerzintensität, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

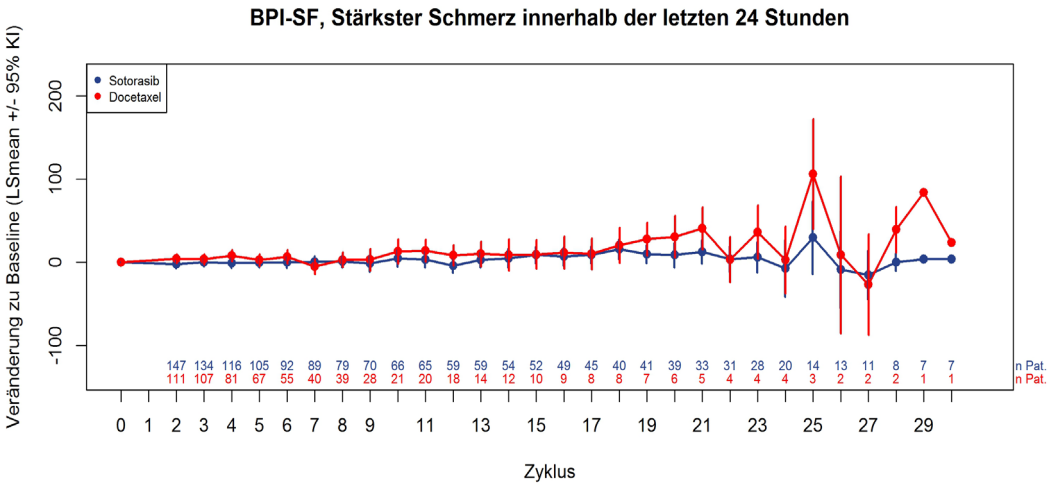

Abbildung 48: Verlaufskurve für den Endpunkt BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

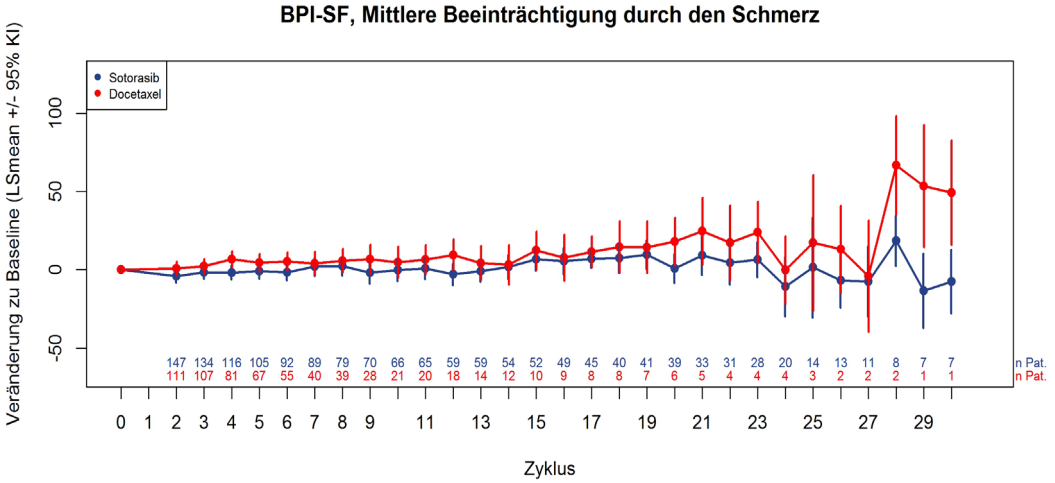

Abbildung 49: Verlaufskurve für den Endpunkt BPI-SF, Mittlere Beeinträchtigung durch den Schmerz, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.5.2 Subgruppenanalysen für den Endpunkt BPI-SF (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Schmerzintensität; Alter bei Studienbeginn							
<65 Jahre	43/85 (50,6)	7,3 [4,2; 9,8]	37/69 (53,6)	2,8 [2,2; 10,6]	0,8 [0,5; 1,3]	0,3675	0,4242
≥65 Jahre	44/78 (56,4)	4,8 [3,4; 6,4]	28/59 (47,5)	4,3 [2,8; n.b.]	1,0 [0,6; 1,6]	0,8569	
BPI-SF, Mittlere Schmerzintensität; Geschlecht							
Weiblich	34/60 (56,7)	4,9 [2,1; 7,7]	27/51 (52,9)	4,6 [2,2; 15,9]	1,0 [0,6; 1,7]	0,9878	0,3119
Männlich	53/103 (51,5)	5,6 [3,6; 9,7]	38/77 (49,4)	2,8 [2,2; 8,7]	0,7 [0,4; 1,1]	0,1191	
BPI-SF, Mittlere Schmerzintensität; Region 2							
Nordamerika und Europa	72/138 (52,2)	5,6 [3,5; 9,8]	55/109 (50,5)	3,7 [2,7; 8,7]	0,9 [0,7; 1,4]	0,7501	0,6615
Rest der Welt	15/25 (60,0)	4,8 [2,8; 9,7]	10/19 (52,6)	2,8 [1,4; n.b.]	0,6 [0,2; 1,6]	0,3363	
BPI-SF, Mittlere Schmerzintensität; Region 1							
Nordamerika	9/19 (47,4)	10,4 [2,1; n.b.]	9/16 (56,2)	3,7 [2,7; n.b.]	2,0 [0,6; 6,3]	0,2541	0,6722
Europa	63/119 (52,9)	5,6 [3,5; 9,7]	46/93 (49,5)	4,3 [2,2; 8,7]	0,8 [0,6; 1,3]	0,4185	
Rest der Welt	15/25 (60,0)	4,8 [2,8; 9,7]	10/19 (52,6)	2,8 [1,4; n.b.]	0,6 [0,2; 1,6]	0,3363	
BPI-SF, Mittlere Schmerzintensität; ECOG Performance-Status							
0	30/57 (52,6)	7,3 [4,2; 11,7]	29/52 (55,8)	3,5 [2,3; 8,7]	0,7 [0,4; 1,2]	0,1909	0,4220
1	57/106 (53,8)	4,2 [3,1; 7,7]	36/76 (47,4)	3,0 [2,2; 15,9]	1,0 [0,6; 1,5]	0,8642	
BPI-SF, Mittlere Schmerzintensität; Lebermetastasen bei Studienbeginn							
Nein	72/135 (53,3)	5,6 [4,2; 9,7]	55/107 (51,4)	3,5 [2,2; 8,7]	0,8 [0,6; 1,2]	0,3776	0,7319
Ja	15/28 (53,6)	4,2 [2,0; 14,5]	10/21 (47,6)	3,7 [2,3; 10,6]	0,8 [0,3; 2,3]	0,6272	
BPI-SF, Mittlere Schmerzintensität; Knochenmetastasen bei Studienbeginn							
Nein	49/86 (57,0)	5,4 [3,5; 9,8]	39/77 (50,6)	3,5 [2,2; 7,6]	0,9 [0,6; 1,4]	0,7201	0,9047
Ja	38/77 (49,4)	5,6 [3,4; 9,7]	26/51 (51,0)	3,7 [2,2; 10,6]	0,8 [0,5; 1,3]	0,3460	
BPI-SF, Mittlere Schmerzintensität; PD-L1-Proteinexpression							
<1%	32/54 (59,3)	4,2 [2,8; 9,7]	23/41 (56,1)	3,5 [2,2; 15,9]	0,9 [0,5; 1,6]	0,7653	0,8064
≥1% und <50%	20/44 (45,5)	7,7 [2,8; n.b.]	20/49 (40,8)	4,3 [2,2; 17,5]	0,9 [0,5; 1,9]	0,8233	
≥50%	29/58 (50,0)	4,9 [3,6; 11,7]	16/30 (53,3)	3,3 [1,4; n.b.]	0,7 [0,3; 1,4]	0,2709	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Schmerzintensität; Ethnie-2							
Asiatisch	12/21 (57,1)	4,2 [2,1; 9,7]	10/18 (55,6)	2,8 [1,4; n.b.]	0,8 [0,3; 1,8]	0,5374	0,7110
Nicht asiatisch	75/141 (53,2)	5,0 [3,5; 9,7]	54/109 (49,5)	3,7 [2,8; 8,7]	0,9 [0,6; 1,3]	0,6655	
BPI-SF, Mittlere Schmerzintensität; Vorgeschichte einer Beteiligung des ZNS							
Nein	56/108 (51,9)	4,9 [3,5; 9,8]	45/88 (51,1)	3,5 [2,3; 8,7]	0,9 [0,6; 1,3]	0,5424	0,8987
Ja	31/55 (56,4)	5,6 [2,8; 9,7]	20/40 (50,0)	3,0 [2,2; 10,6]	0,9 [0,5; 1,6]	0,6717	
BPI-SF, Mittlere Schmerzintensität; Anzahl an vorherigen Therapielinien							
1	36/71 (50,7)	3,6 [2,8; 8,3]	27/58 (46,6)	3,7 [2,2; 7,6]	1,0 [0,6; 1,6]	0,8996	0,3989
2	33/63 (52,4)	9,7 [4,5; 11,8]	29/51 (56,9)	3,0 [1,4; 17,5]	0,6 [0,4; 1,1]	0,0944	
>2	18/29 (62,1)	3,5 [2,1; 7,3]	9/19 (47,4)	8,7 [2,2; n.b.]	1,6 [0,7; 3,8]	0,3060	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Alter bei Studienbeginn							
<65 Jahre	55/85 (64,7)	2,8 [1,4; 3,5]	49/69 (71,0)	2,0 [1,4; 2,8]	0,7 [0,5; 1,1]	0,1056	0,9710
≥65 Jahre	58/78 (74,4)	2,1 [1,4; 4,1]	45/59 (76,3)	1,4 [1,3; 2,1]	0,7 [0,5; 1,2]	0,1889	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Geschlecht							
Weiblich	42/60 (70,0)	2,1 [1,4; 3,5]	36/51 (70,6)	1,6 [0,8; 3,0]	0,9 [0,6; 1,5]	0,6528	0,3718
Männlich	71/103 (68,9)	2,4 [1,4; 4,2]	58/77 (75,3)	1,5 [1,4; 2,2]	0,7 [0,5; 1,0]	0,0498	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Region 2							
Nordamerika und Europa	91/138 (65,9)	2,7 [1,5; 3,6]	78/109 (71,6)	2,0 [1,4; 2,8]	0,8 [0,6; 1,1]	0,2378	0,4943
Rest der Welt	22/25 (88,0)	1,4 [1,4; 2,8]	16/19 (84,2)	1,4 [0,7; 1,6]	0,6 [0,3; 1,5]	0,2867	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Region 1							
Nordamerika	9/19 (47,4)	10,4 [0,7; n.b.]	12/16 (75,0)	2,4 [0,7; 4,4]	1,2 [0,4; 3,3]	0,7418	0,7590
Europa	82/119 (68,9)	2,7 [1,4; 3,5]	66/93 (71,0)	1,6 [1,4; 2,8]	0,8 [0,6; 1,1]	0,1799	
Rest der Welt	22/25 (88,0)	1,4 [1,4; 2,8]	16/19 (84,2)	1,4 [0,7; 1,6]	0,6 [0,3; 1,5]	0,2867	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; ECOG Performance-Status							
0	42/57 (73,7)	2,8 [1,4; 4,9]	44/52 (84,6)	1,4 [0,8; 2,8]	0,6 [0,4; 0,9]	0,0261	0,2372
1	71/106 (67,0)	2,1 [1,4; 3,5]	50/76 (65,8)	1,6 [1,4; 2,2]	0,9 [0,6; 1,3]	0,4453	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Lebermetastasen bei Studienbeginn							
Nein	98/135 (72,6)	2,1 [1,4; 2,8]	79/107 (73,8)	1,9 [1,4; 2,8]	0,8 [0,6; 1,1]	0,2466	0,3071
Ja	15/28 (53,6)	3,5 [1,4; 15,9]	15/21 (71,4)	0,9 [0,7; 2,7]	0,6 [0,2; 1,7]	0,3318	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Knochenmetastasen bei Studienbeginn							
Nein	65/86 (75,6)	2,1 [1,4; 2,8]	55/77 (71,4)	2,1 [1,4; 2,8]	0,9 [0,6; 1,4]	0,6933	0,1024
Ja	48/77 (62,3)	2,8 [2,0; 4,5]	39/51 (76,5)	0,8 [0,7; 2,0]	0,5 [0,3; 0,8]	0,0039	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; PD-L1-Proteinexpression							
<1%	40/54 (74,1)	2,4 [1,3; 2,9]	33/41 (80,5)	1,5 [0,7; 2,7]	0,8 [0,5; 1,3]	0,2827	0,6001
≥1% und <50%	26/44 (59,1)	2,1 [1,4; 8,3]	30/49 (61,2)	2,1 [1,6; 3,0]	0,8 [0,4; 1,4]	0,4104	
≥50%	40/58 (69,0)	2,1 [1,4; 4,5]	24/30 (80,0)	1,4 [0,8; 2,1]	0,6 [0,4; 1,1]	0,1160	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Ethnie-2							
Asiatisch	17/21 (81,0)	1,4 [1,4; 2,8]	16/18 (88,9)	0,9 [0,7; 1,6]	0,5 [0,2; 1,1]	0,0780	0,1976
Nicht asiatisch	95/141 (67,4)	2,7 [1,5; 3,5]	77/109 (70,6)	2,0 [1,4; 2,8]	0,8 [0,6; 1,1]	0,1941	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Vorgeschichte einer Beteiligung des ZNS							
Nein	70/108 (64,8)	2,2 [1,4; 4,9]	67/88 (76,1)	1,5 [1,4; 2,4]	0,7 [0,5; 1,0]	0,0677	0,5765
Ja	43/55 (78,2)	2,1 [1,4; 3,5]	27/40 (67,5)	1,5 [1,0; 2,8]	0,8 [0,5; 1,3]	0,4104	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Anzahl an vorherigen Therapielinien							
1	43/71 (60,6)	2,1 [1,4; 3,6]	43/58 (74,1)	1,5 [1,4; 2,1]	0,7 [0,4; 1,0]	0,0640	0,4687
2	46/63 (73,0)	4,1 [1,5; 5,4]	37/51 (72,5)	2,8 [0,8; 4,2]	0,8 [0,5; 1,2]	0,2605	
>2	24/29 (82,8)	1,4 [0,7; 2,8]	14/19 (73,7)	1,5 [0,8; 2,8]	1,1 [0,6; 2,3]	0,7375	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Alter bei Studienbeginn							
<65 Jahre	49/85 (57,6)	4,2 [2,8; 8,8]	33/69 (47,8)	3,4 [2,2; n.b.]	1,0 [0,6; 1,5]	0,8744	0,1887
≥65 Jahre	34/78 (43,6)	9,4 [4,2; n.b.]	27/59 (45,8)	5,0 [2,8; n.b.]	0,5 [0,3; 1,0]	0,0372	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Geschlecht							
Weiblich	31/60 (51,7)	4,2 [2,4; 15,9]	26/51 (51,0)	3,7 [2,1; n.b.]	0,9 [0,5; 1,5]	0,6210	0,7908
Männlich	52/103 (50,5)	7,7 [4,2; 10,1]	34/77 (44,2)	5,1 [2,8; 10,0]	0,7 [0,4; 1,1]	0,1634	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Region 2							
Nordamerika und Europa	69/138 (50,0)	8,4 [4,2; 10,4]	53/109 (48,6)	4,2 [2,8; 7,3]	0,8 [0,6; 1,2]	0,2914	0,9252
Rest der Welt	14/25 (56,0)	4,2 [3,5; 8,0]	7/19 (36,8)	n.b. [1,4; n.b.]	0,8 [0,3; 2,2]	0,6625	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Region 1							
Nordamerika	7/19 (36,8)	12,2 [2,1; n.b.]	9/16 (56,2)	5,8 [2,7; n.b.]	1,0 [0,3; 3,2]	0,9575	0,9728
Europa	62/119 (52,1)	7,7 [4,2; 10,1]	44/93 (47,3)	4,2 [2,4; 7,3]	0,8 [0,5; 1,1]	0,1761	
Rest der Welt	14/25 (56,0)	4,2 [3,5; 8,0]	7/19 (36,8)	n.b. [1,4; n.b.]	0,8 [0,3; 2,2]	0,6625	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; ECOG Performance-Status							
0	31/57 (54,4)	10,1 [4,5; 13,8]	23/52 (44,2)	7,3 [2,8; n.b.]	0,8 [0,5; 1,5]	0,5331	0,5835
1	52/106 (49,1)	4,2 [3,5; 8,8]	37/76 (48,7)	3,4 [2,2; 5,8]	0,7 [0,4; 1,1]	0,0786	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Lebermetastasen bei Studienbeginn							
Nein	67/135 (49,6)	7,7 [4,2; 10,4]	48/107 (44,9)	5,1 [3,0; 10,0]	0,8 [0,6; 1,2]	0,3408	0,7997
Ja	16/28 (57,1)	2,8 [1,4; 15,9]	12/21 (57,1)	2,7 [1,4; 5,8]	0,5 [0,2; 1,4]	0,2103	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Knochenmetastasen bei Studienbeginn							
Nein	45/86 (52,3)	7,7 [4,1; 12,5]	36/77 (46,8)	5,1 [2,8; 10,0]	0,9 [0,6; 1,5]	0,6664	0,6405
Ja	38/77 (49,4)	5,1 [3,6; 10,1]	24/51 (47,1)	3,3 [2,1; n.b.]	0,6 [0,4; 1,1]	0,1303	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; PD-L1-Proteinexpression							
<1%	30/54 (55,6)	8,0 [3,7; 13,8]	25/41 (61,0)	3,4 [2,1; 5,6]	0,5 [0,3; 0,9]	0,0246	0,3174
≥1% und <50%	22/44 (50,0)	8,4 [2,8; 14,5]	16/49 (32,7)	5,8 [2,8; n.b.]	0,9 [0,5; 1,9]	0,8865	
≥50%	28/58 (48,3)	4,5 [3,6; 10,1]	13/30 (43,3)	7,3 [2,8; n.b.]	0,7 [0,3; 1,5]	0,4030	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Ethnie-2							
Asiatisch	13/21 (61,9)	4,2 [2,8; 8,0]	7/18 (38,9)	n.b. [1,5; n.b.]	1,0 [0,4; 2,7]	0,9794	0,3770
Nicht asiatisch	69/141 (48,9)	8,4 [4,2; 11,0]	52/109 (47,7)	4,3 [2,8; 7,3]	0,8 [0,5; 1,1]	0,2158	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	53/108 (49,1)	8,4 [3,8; 12,2]	40/88 (45,5)	5,1 [2,2; n.b.]	0,8 [0,5; 1,3]	0,3633	0,7457
Ja	30/55 (54,5)	4,9 [3,6; 9,7]	20/40 (50,0)	3,7 [2,7; n.b.]	0,8 [0,4; 1,4]	0,3501	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Anzahl an vorherigen Therapielinien							
1	35/71 (49,3)	5,7 [2,9; 10,1]	27/58 (46,6)	3,7 [2,2; 10,0]	0,9 [0,5; 1,5]	0,5840	0,9830
2	31/63 (49,2)	9,4 [4,2; 12,5]	23/51 (45,1)	5,1 [3,0; n.b.]	0,8 [0,5; 1,4]	0,3993	
>2	17/29 (58,6)	3,8 [2,3; 8,0]	10/19 (52,6)	2,7 [1,4; n.b.]	0,7 [0,3; 1,6]	0,4192	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
Die mittlere Schmerzintensität wurde als Mittelwert der Fragen 3 bis 6 berechnet.
Die mittlere Beeinträchtigung durch den Schmerz wurde als Mittelwert der Fragen 9A-G berechnet.

Die Auswertung erfolgte auf Grundlage der ITT-Population.
BPI-SF = Brief Pain Inventory (Short Form); KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; ZNS = Zentrales Nervensystem

2.3.5.3 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt BPI-SF (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**N**	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**Hazard Ratio [95% KI]**	**p(Cox)[1]**	**p(logrank)[2]**
BPI-SF, Mittlere Schmerzintensität								
165	106 (64,2)	4,2 [3,3; 5,6]	139	83 (59,7)	2,8 [2,2; 3,7]	0,86 [0,64; 1,16]	0,3167	0,3163
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden								
165	131 (79,4)	2,1 [1,4; 2,8]	139	109 (78,4)	1,4 [1,3; 1,9]	0,76 [0,58; 0,98]	0,0371	0,0365
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz								
165	101 (61,2)	4,2 [3,5; 7,5]	139	79 (56,8)	3,0 [2,2; 5,0]	0,76 [0,56; 1,03]	0,0729	0,0721

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.
Die mittlere Schmerzintensität wurde als Mittelwert der Fragen 3 bis 6 berechnet.
Die mittlere Beeinträchtigung durch den Schmerz wurde als Mittelwert der Fragen 9A-G berechnet.

BPI-SF = Brief Pain Inventory (Short Form); KI = Konfidenzintervall; n.b. = nicht berechenbar

2.3.5.4 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt BPI-SF (präspezifizierte Analyse inkl. Tod als Ereignis)

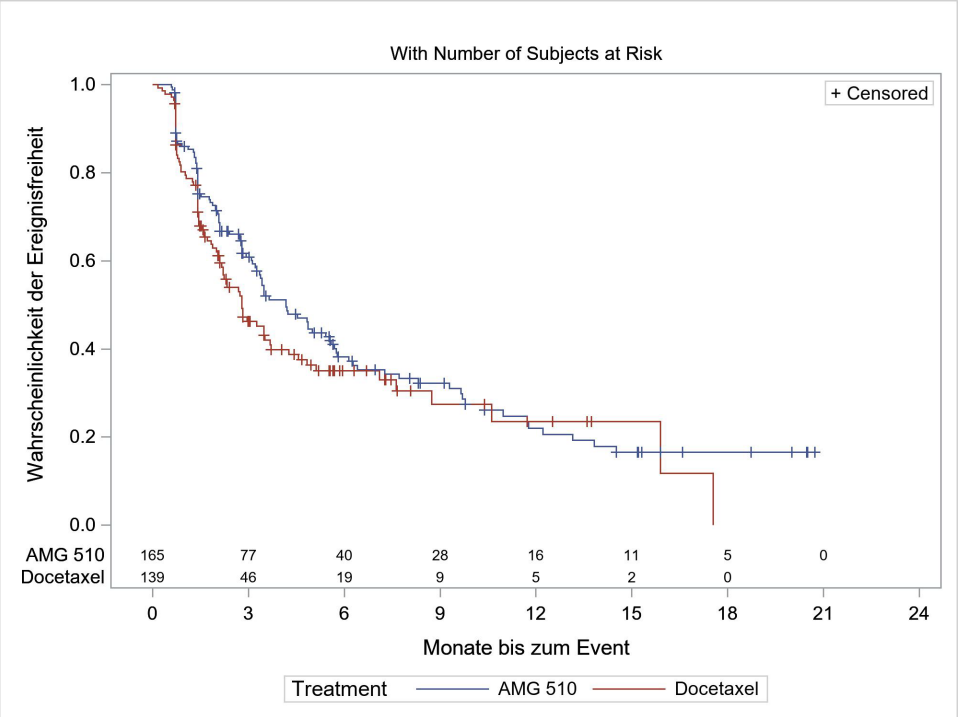

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "BPI-SF Mittlere Schmerzintensität, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

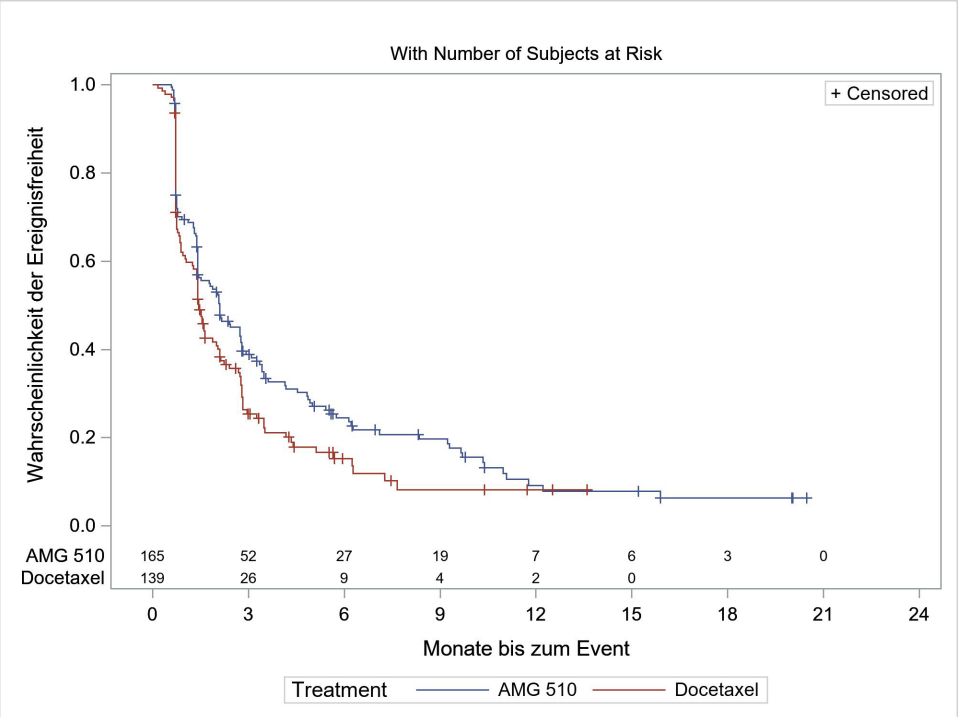

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "BPI-SF Stärkster Schmerz innerhalb der letzten 24 Stunden, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

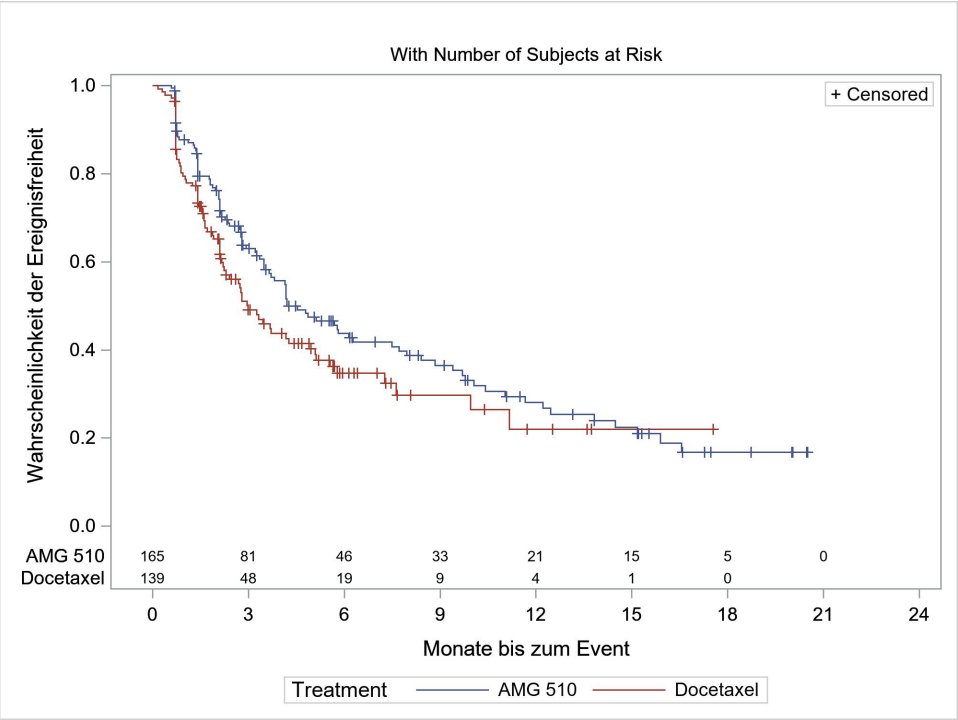

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "BPI-SF Mittlere Beeinträchtigung durch den Schmerz, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

2.3.5.5 Subgruppenanalysen für den Endpunkt BPI-SF (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Schmerzintensität; Alter bei Studienbeginn							
<65 Jahre	56/87 (64,4)	4,2 [2,8; 7,7]	51/80 (63,8)	2,2 [1,8; 3,3]	0,8 [0,5; 1,2]	0,2038	0,2983
≥65 Jahre	50/78 (64,1)	4,2 [3,1; 5,6]	32/59 (54,2)	3,7 [2,2; 7,1]	1,0 [0,6; 1,6]	0,9596	
BPI-SF, Mittlere Schmerzintensität; Geschlecht							
Weiblich	38/60 (63,3)	3,5 [2,1; 6,4]	37/58 (63,8)	2,7 [1,4; 7,1]	0,8 [0,5; 1,3]	0,3784	0,8972
Männlich	68/105 (64,8)	4,2 [3,2; 5,8]	46/81 (56,8)	2,8 [2,2; 4,3]	0,8 [0,5; 1,1]	0,1801	
BPI-SF, Mittlere Schmerzintensität; Region 2							
Nordamerika und Europa	89/140 (63,6)	3,5 [3,1; 5,6]	71/118 (60,2)	2,8 [2,2; 4,3]	0,9 [0,6; 1,2]	0,4768	0,7868
Rest der Welt	17/25 (68,0)	4,8 [2,1; 7,3]	12/21 (57,1)	1,9 [1,3; n.b.]	0,7 [0,3; 1,8]	0,4918	
BPI-SF, Mittlere Schmerzintensität; Region 1							
Nordamerika	11/19 (57,9)	6,1 [2,1; 12,2]	9/16 (56,3)	3,7 [2,7; n.b.]	2,1 [0,7; 6,5]	0,1981	0,4406
Europa	78/121 (64,5)	3,5 [2,9; 5,6]	62/102 (60,8)	2,7 [2,1; 4,3]	0,8 [0,6; 1,1]	0,1942	
Rest der Welt	17/25 (68,0)	4,8 [2,1; 7,3]	12/21 (57,1)	1,9 [1,3; n.b.]	0,7 [0,3; 1,8]	0,4918	
BPI-SF, Mittlere Schmerzintensität; ECOG Performance-Status							
0	34/58 (58,6)	5,7 [3,5; 11,0]	30/52 (57,7)	3,5 [2,3; 8,7]	0,8 [0,4; 1,3]	0,3048	0,9605
1	72/107 (67,3)	3,4 [2,7; 4,8]	53/87 (60,9)	2,3 [1,6; 3,0]	0,8 [0,6; 1,2]	0,3514	
BPI-SF, Mittlere Schmerzintensität; Lebermetastasen bei Studienbeginn							
Nein	84/135 (62,2)	4,8 [3,2; 5,8]	69/115 (60,0)	2,8 [2,1; 4,3]	0,8 [0,6; 1,1]	0,1878	0,6196
Ja	22/30 (73,3)	3,4 [1,4; 5,0]	14/24 (58,3)	2,7 [1,4; 10,6]	0,8 [0,3; 1,9]	0,6409	
BPI-SF, Mittlere Schmerzintensität; Knochenmetastasen bei Studienbeginn							
Nein	57/86 (66,3)	4,8 [2,9; 6,3]	50/84 (59,5)	2,7 [2,0; 4,8]	0,9 [0,6; 1,3]	0,4744	0,9205
Ja	49/79 (62,0)	3,6 [2,8; 5,7]	33/55 (60,0)	2,8 [1,6; 4,6]	0,8 [0,5; 1,3]	0,3108	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Schmerzintensität; PD-L1-Proteinexpression							
<1%	41/54 (75,9)	3,4 [2,7; 5,8]	27/44 (61,4)	2,8 [1,6; 7,6]	1,0 [0,6; 1,7]	0,9904	0,6153
≥1% und <50%	27/45 (60,0)	3,5 [2,0; 9,3]	30/55 (54,5)	2,7 [1,9; 10,6]	0,9 [0,5; 1,6]	0,6541	
≥50%	32/59 (54,2)	4,9 [3,4; 9,7]	18/31 (58,1)	3,3 [1,4; n.b.]	0,7 [0,3; 1,3]	0,2160	
BPI-SF, Mittlere Schmerzintensität; Ethnie-2							
Asiatisch	14/21 (66,7)	4,2 [2,0; 9,3]	10/18 (55,6)	2,8 [1,4; n.b.]	0,9 [0,4; 2,1]	0,8044	0,8667
Nicht asiatisch	92/143 (64,3)	4,2 [3,2; 5,6]	72/120 (60,0)	2,8 [2,1; 4,3]	0,9 [0,6; 1,2]	0,3527	
BPI-SF, Mittlere Schmerzintensität; Vorgeschichte einer Beteiligung des ZNS							
Nein	71/109 (65,1)	4,2 [3,1; 5,7]	54/92 (58,7)	3,3 [2,1; 7,1]	0,9 [0,6; 1,3]	0,6958	0,3055
Ja	35/56 (62,5)	5,4 [2,1; 8,3]	29/47 (61,7)	2,7 [1,4; 3,7]	0,7 [0,4; 1,2]	0,2058	
BPI-SF, Mittlere Schmerzintensität; Anzahl an vorherigen Therapielinien							
1	47/72 (65,3)	3,2 [2,1; 4,9]	34/62 (54,8)	2,8 [2,1; 7,1]	1,0 [0,7; 1,6]	0,8947	0,4496
2	40/64 (62,5)	5,6 [4,2; 11,0]	36/56 (64,3)	2,8 [1,4; 4,8]	0,6 [0,4; 1,0]	0,0612	
>2	19/29 (65,5)	3,5 [2,1; 4,9]	13/21 (61,9)	2,7 [1,6; 10,6]	1,1 [0,5; 2,3]	0,8045	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Alter bei Studienbeginn							
<65 Jahre	67/87 (77,0)	2,1 [1,4; 2,8]	62/80 (77,5)	1,4 [0,9; 2,2]	0,7 [0,5; 1,0]	0,0599	0,9127
≥65 Jahre	64/78 (82,1)	2,1 [1,4; 3,3]	47/59 (79,7)	1,4 [1,3; 2,0]	0,8 [0,5; 1,1]	0,1812	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Geschlecht							
Weiblich	47/60 (78,3)	2,0 [1,3; 3,1]	45/58 (77,6)	1,4 [0,8; 2,1]	0,8 [0,5; 1,3]	0,3352	0,6398
Männlich	84/105 (80,0)	2,1 [1,4; 2,9]	64/81 (79,0)	1,5 [1,3; 2,1]	0,7 [0,5; 1,0]	0,0586	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Region 2							
Nordamerika und Europa	107/140 (76,4)	2,1 [1,4; 2,9]	91/118 (77,1)	1,5 [1,4; 2,1]	0,8 [0,6; 1,1]	0,1734	0,3880
Rest der Welt	24/25 (96,0)	1,4 [1,4; 2,8]	18/21 (85,7)	1,3 [0,8; 1,5]	0,7 [0,3; 1,4]	0,2848	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Region 1							
Nordamerika	11/19 (57,9)	6,1 [0,7; n.b.]	12/16 (75,0)	2,4 [0,7; 4,4]	1,2 [0,4; 3,3]	0,6954	0,7125
Europa	96/121 (79,3)	2,1 [1,4; 2,8]	79/102 (77,5)	1,4 [0,9; 2,1]	0,8 [0,6; 1,1]	0,1053	
Rest der Welt	24/25 (96,0)	1,4 [1,4; 2,8]	18/21 (85,7)	1,3 [0,8; 1,5]	0,7 [0,3; 1,4]	0,2848	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; ECOG Performance-Status							
0	46/58 (79,3)	2,7 [1,4; 3,6]	44/52 (84,6)	1,4 [0,8; 2,8]	0,7 [0,4; 1,0]	0,0643	0,5043
1	85/107 (79,4)	2,0 [1,4; 2,7]	65/87 (74,7)	1,4 [1,1; 1,9]	0,8 [0,6; 1,1]	0,1797	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Lebermetastasen bei Studienbeginn							
Nein	108/135 (80,0)	2,1 [1,4; 2,8]	90/115 (78,3)	1,5 [1,4; 2,2]	0,8 [0,6; 1,1]	0,1367	0,5113
Ja	23/30 (76,7)	2,1 [0,9; 3,5]	19/24 (79,2)	0,9 [0,7; 1,6]	0,7 [0,3; 1,5]	0,3427	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Knochenmetastasen bei Studienbeginn							
Nein	72/86 (83,7)	1,8 [1,3; 2,7]	64/84 (76,2)	1,6 [1,4; 2,7]	0,9 [0,6; 1,3]	0,5414	0,0984
Ja	59/79 (74,7)	2,4 [1,4; 3,4]	45/55 (81,8)	0,8 [0,7; 1,6]	0,5 [0,3; 0,8]	0,0020	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; PD-L1-Proteinexpression							
<1%	47/54 (87,0)	2,1 [1,3; 2,8]	36/44 (81,8)	1,4 [0,7; 2,2]	0,8 [0,5; 1,3]	0,3365	0,5197
≥1% und <50%	34/45 (75,6)	1,9 [1,3; 3,5]	39/55 (70,9)	2,0 [1,4; 2,8]	0,8 [0,5; 1,4]	0,5006	
≥50%	43/59 (72,9)	2,1 [1,4; 3,6]	26/31 (83,9)	1,4 [0,8; 2,1]	0,6 [0,4; 1,1]	0,0891	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Ethnie-2							
Asiatisch	19/21 (90,5)	1,4 [1,4; 2,4]	16/18 (88,9)	0,9 [0,7; 1,6]	0,5 [0,2; 1,1]	0,0964	0,2803
Nicht asiatisch	111/143 (77,6)	2,1 [1,4; 2,8]	92/120 (76,7)	1,5 [1,4; 2,1]	0,8 [0,6; 1,1]	0,1183	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Vorgeschichte einer Beteiligung des ZNS							
Nein	84/109 (77,1)	2,1 [1,4; 3,1]	74/92 (80,4)	1,5 [1,2; 2,1]	0,8 [0,5; 1,0]	0,0875	0,9791
Ja	47/56 (83,9)	2,0 [1,4; 2,8]	35/47 (74,5)	1,4 [0,8; 2,1]	0,7 [0,4; 1,1]	0,1569	
BPI-SF, Stärkster Schmerz innerhalb der letzten 24 Stunden; Anzahl an vorherigen Therapielinien							
1	54/72 (75,0)	2,0 [1,4; 2,8]	48/62 (77,4)	1,4 [1,2; 2,0]	0,7 [0,5; 1,1]	0,0908	0,8156
2	52/64 (81,3)	2,7 [1,4; 4,9]	43/56 (76,8)	1,4 [0,8; 3,5]	0,8 [0,5; 1,2]	0,2115	
>2	25/29 (86,2)	1,4 [0,7; 2,8]	18/21 (85,7)	1,5 [0,8; 2,7]	0,9 [0,5; 1,8]	0,8299	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Alter bei Studienbeginn							
<65 Jahre	60/87 (69,0)	3,4 [2,4; 4,9]	49/80 (61,3)	2,7 [2,1; 3,4]	0,8 [0,6; 1,2]	0,3750	0,3586
≥65 Jahre	41/78 (52,6)	6,3 [4,1; 11,7]	30/59 (50,8)	4,3 [2,1; 10,0]	0,6 [0,3; 1,0]	0,0366	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Geschlecht							
Weiblich	33/60 (55,0)	3,5 [2,1; 13,8]	37/58 (63,8)	2,1 [1,6; 4,2]	0,6 [0,4; 1,0]	0,0561	0,3951
Männlich	68/105 (64,8)	4,8 [3,8; 7,7]	42/81 (51,9)	3,7 [2,7; 7,6]	0,8 [0,5; 1,2]	0,2501	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Region 2							
Nordamerika und Europa	86/140 (61,4)	4,5 [3,4; 8,4]	70/118 (59,3)	3,0 [2,2; 4,3]	0,8 [0,5; 1,1]	0,1030	0,8698
Rest der Welt	15/25 (60,0)	4,2 [3,5; 8,0]	9/21 (42,9)	n.b. [1,1; n.b.]	0,8 [0,3; 2,1]	0,6394	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Region 1							
Nordamerika	9/19 (47,4)	6,1 [2,1; n.b.]	9/16 (56,3)	5,8 [2,7; n.b.]	1,1 [0,4; 3,4]	0,8133	0,7179
Europa	77/121 (63,6)	4,2 [3,2; 8,4]	61/102 (59,8)	2,8 [2,1; 4,2]	0,7 [0,5; 1,0]	0,0401	
Rest der Welt	15/25 (60,0)	4,2 [3,5; 8,0]	9/21 (42,9)	n.b. [1,1; n.b.]	0,8 [0,3; 2,1]	0,6394	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; ECOG Performance-Status							
0	35/58 (60,3)	8,0 [4,2; 12,2]	25/52 (48,1)	7,3 [2,8; n.b.]	0,9 [0,5; 1,5]	0,5731	0,2382
1	66/107 (61,7)	3,7 [2,8; 5,1]	54/87 (62,1)	2,3 [1,6; 3,7]	0,6 [0,4; 0,9]	0,0096	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Lebermetastasen bei Studienbeginn							
Nein	79/135 (58,5)	5,1 [4,1; 8,8]	61/115 (53,0)	3,7 [2,4; 7,3]	0,8 [0,5; 1,1]	0,1454	0,6891
Ja	22/30 (73,3)	2,8 [1,4; 5,8]	18/24 (75,0)	1,6 [1,0; 3,0]	0,5 [0,2; 1,1]	0,0715	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Knochenmetastasen bei Studienbeginn							
Nein	53/86 (61,6)	4,8 [3,3; 9,7]	47/84 (56,0)	3,4 [2,2; 7,3]	0,8 [0,5; 1,2]	0,3175	0,6176
Ja	48/79 (60,8)	4,2 [3,2; 6,1]	32/55 (58,2)	2,8 [1,9; 3,7]	0,6 [0,4; 1,0]	0,0487	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; PD-L1-Proteinexpression							
<1%	39/54 (72,2)	4,2 [2,9; 9,4]	29/44 (65,9)	2,3 [1,6; 5,1]	0,6 [0,3; 1,0]	0,0396	0,6591
≥1% und <50%	27/45 (60,0)	4,8 [2,7; 9,8]	26/55 (47,3)	3,0 [2,2; n.b.]	0,8 [0,4; 1,4]	0,4375	
≥50%	32/59 (54,2)	4,2 [3,5; 7,5]	17/31 (54,8)	5,1 [1,9; 11,2]	0,7 [0,4; 1,3]	0,2742	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Ethnie-2							
Asiatisch	14/21 (66,7)	4,2 [2,8; 8,0]	7/18 (38,9)	n.b. [1,5; n.b.]	1,1 [0,4; 2,8]	0,8889	0,2079
Nicht asiatisch	86/143 (60,1)	4,5 [3,4; 8,4]	71/120 (59,2)	3,0 [2,2; 4,3]	0,7 [0,5; 1,0]	0,0546	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Vorgeschichte einer Beteiligung des ZNS							
Nein	65/109 (59,6)	4,5 [3,2; 8,4]	51/92 (55,4)	3,3 [2,1; 7,3]	0,8 [0,6; 1,2]	0,2613	0,4833
Ja	36/56 (64,3)	4,2 [3,5; 8,0]	28/47 (59,6)	2,8 [2,2; 4,3]	0,6 [0,4; 1,1]	0,1006	
BPI-SF, Mittlere Beeinträchtigung durch den Schmerz; Anzahl an vorherigen Therapielinien							
1	43/72 (59,7)	4,2 [2,4; 8,8]	34/62 (54,8)	2,8 [2,1; 7,6]	0,9 [0,6; 1,4]	0,5630	0,6843
2	40/64 (62,5)	5,8 [4,2; 11,0]	30/56 (53,6)	4,3 [2,8; 7,3]	0,8 [0,5; 1,2]	0,2797	
>2	18/29 (62,1)	3,8 [2,3; 8,0]	15/21 (71,4)	1,9 [0,8; 3,3]	0,5 [0,2; 1,1]	0,0742	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
Die mittlere Schmerzintensität wurde als Mittelwert der Fragen 3 bis 6 berechnet.
Die mittlere Beeinträchtigung durch den Schmerz wurde als Mittelwert der Fragen 9A-G berechnet.

Die Auswertung erfolgte auf Grundlage der ITT-Population.
BPI-SF = Brief Pain Inventory (Short Form); KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; ZNS = Zentrales Nervensystem

3 Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

3.1 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**N**	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**Hazard Ratio [95% KI]**	**p(Cox)[1]**	**p(logrank)[2]**
QLQ-C30 Globaler Gesundheitsstatus								
160	90 (56,2)	4,2 [3,0; 6,2]	130	78 (60,0)	2,3 [1,8; 3,5]	0,68 [0,50; 0,94]	0,0197	0,0190
QLQ-C30 Physisches Funktionsniveau								
160	95 (59,4)	3,6 [2,8; 6,1]	130	86 (66,2)	2,3 [1,6; 3,5]	0,64 [0,47; 0,88]	0,0052	0,0049
QLQ-C30 Rollen-Funktionsniveau								
160	95 (59,4)	3,5 [2,8; 6,9]	130	86 (66,2)	2,1 [1,5; 2,8]	0,62 [0,46; 0,85]	0,0027	0,0025
QLQ-C30 Emotionales Funktionsniveau								
160	69 (43,1)	8,4 [5,1; 18,0]	130	54 (41,5)	5,8 [4,2; n.b.]	0,79 [0,55; 1,15]	0,2202	0,2193
QLQ-C30 Kognitives Funktionsniveau								
160	79 (49,4)	5,6 [3,5; 9,4]	130	72 (55,4)	2,8 [2,1; 5,0]	0,66 [0,47; 0,92]	0,0155	0,0148
QLQ-C30 Soziales Funktionsniveau								
160	93 (58,1)	4,9 [3,4; 8,3]	130	84 (64,6)	2,1 [1,4; 3,0]	0,57 [0,41; 0,78]	0,0004	0,0003

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

3.2 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30

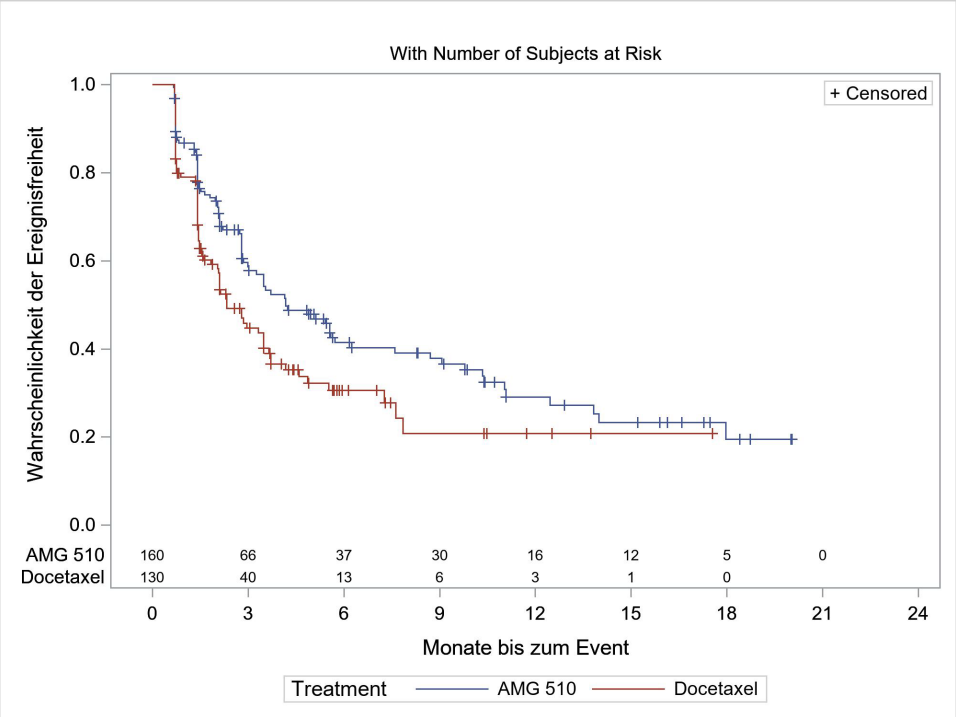

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Globaler Gesundheitsstatus, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

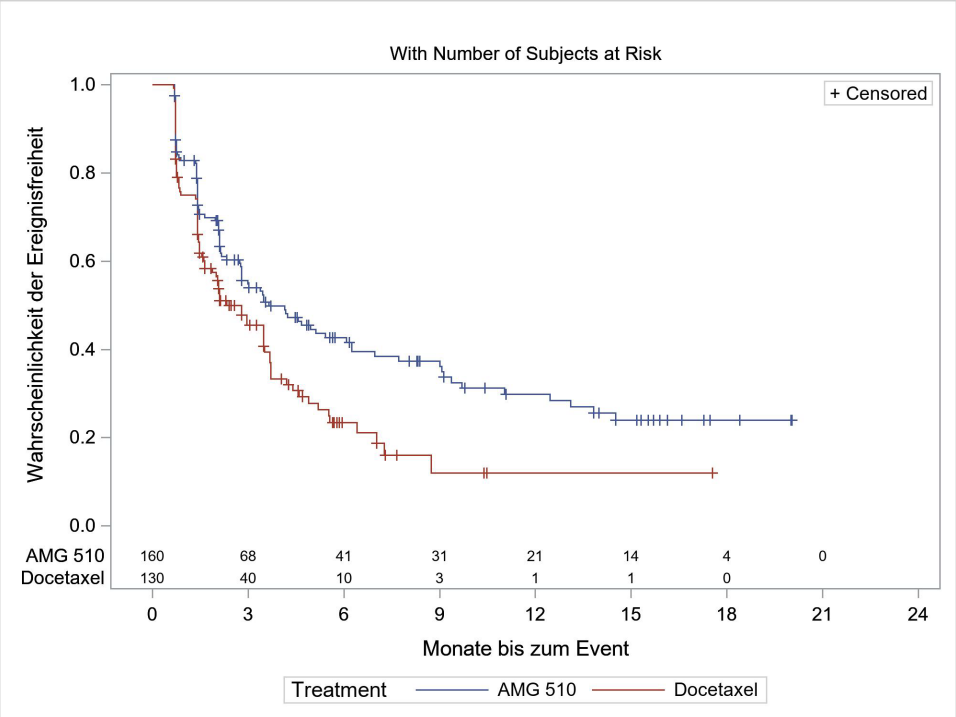

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Physisches Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

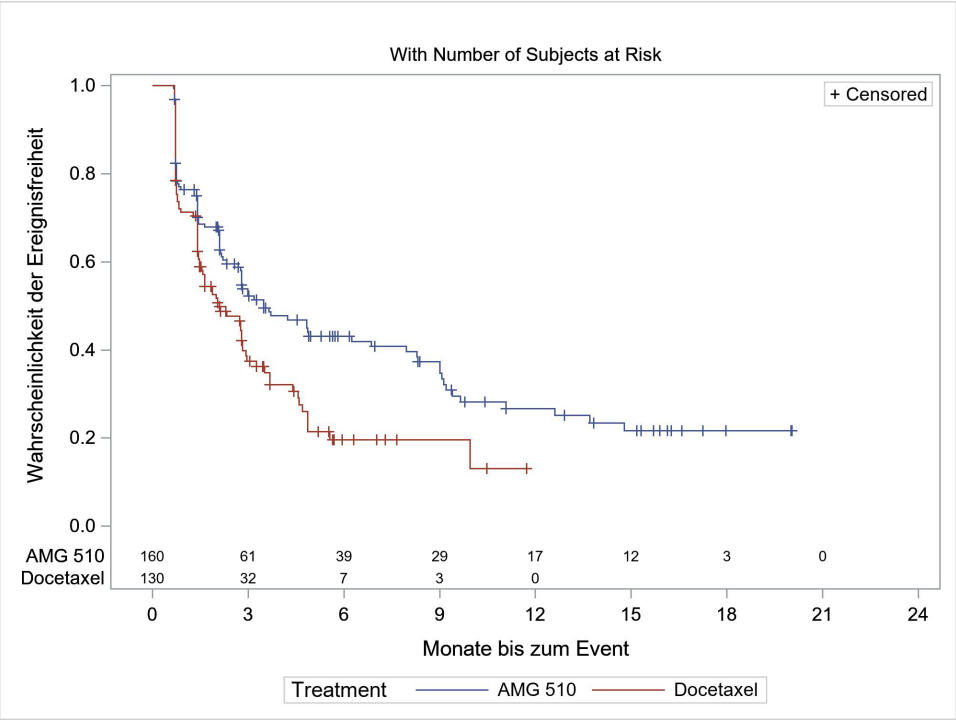

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Rollen-Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

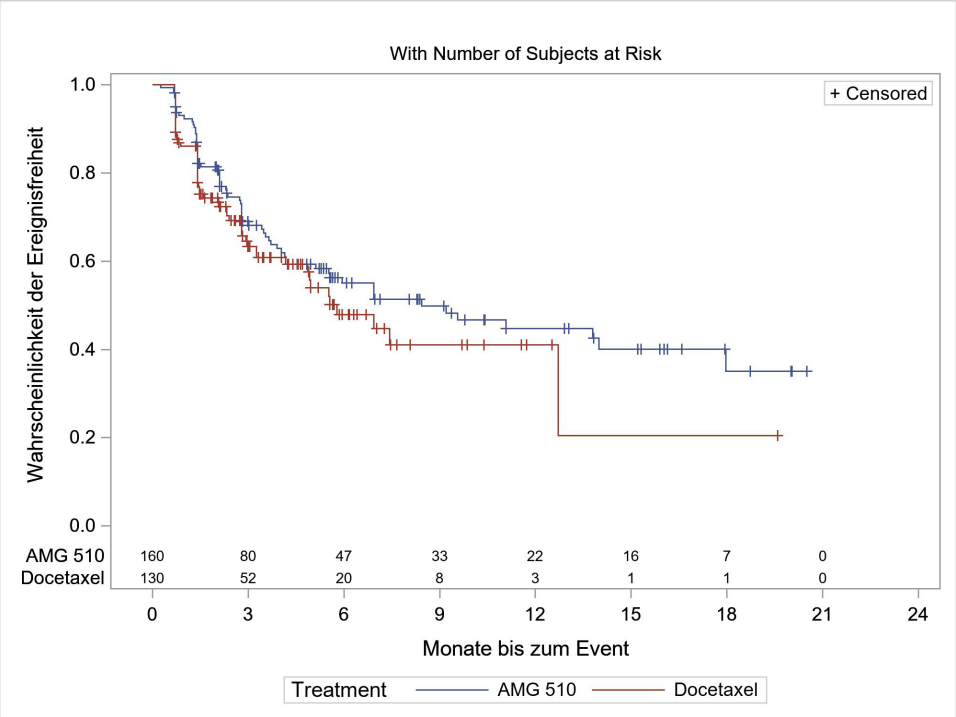

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Emotionales Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

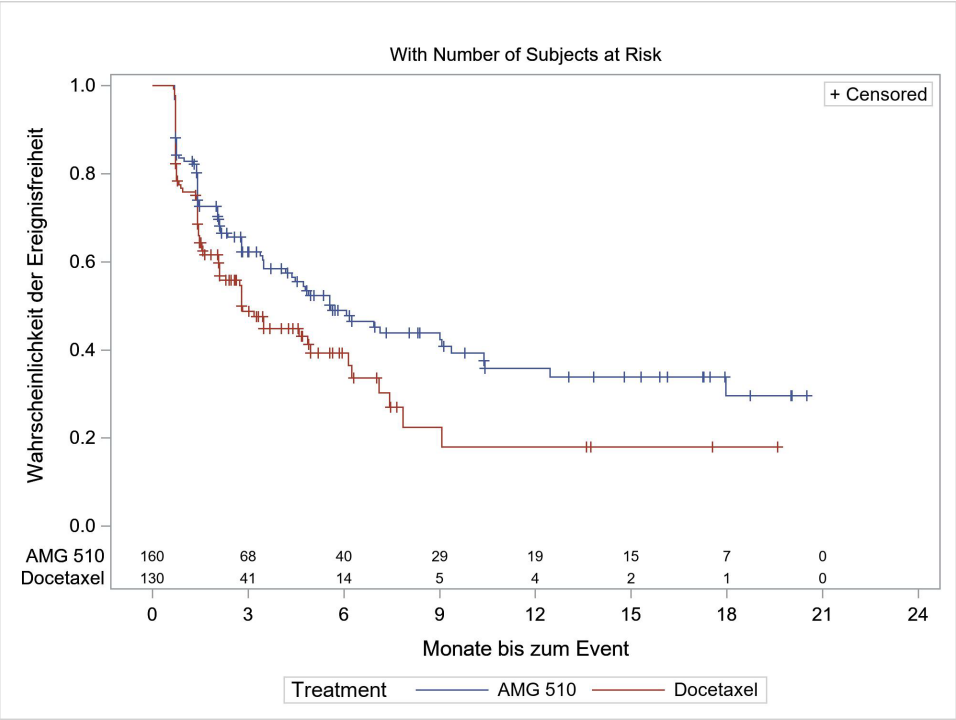

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Kognitives Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

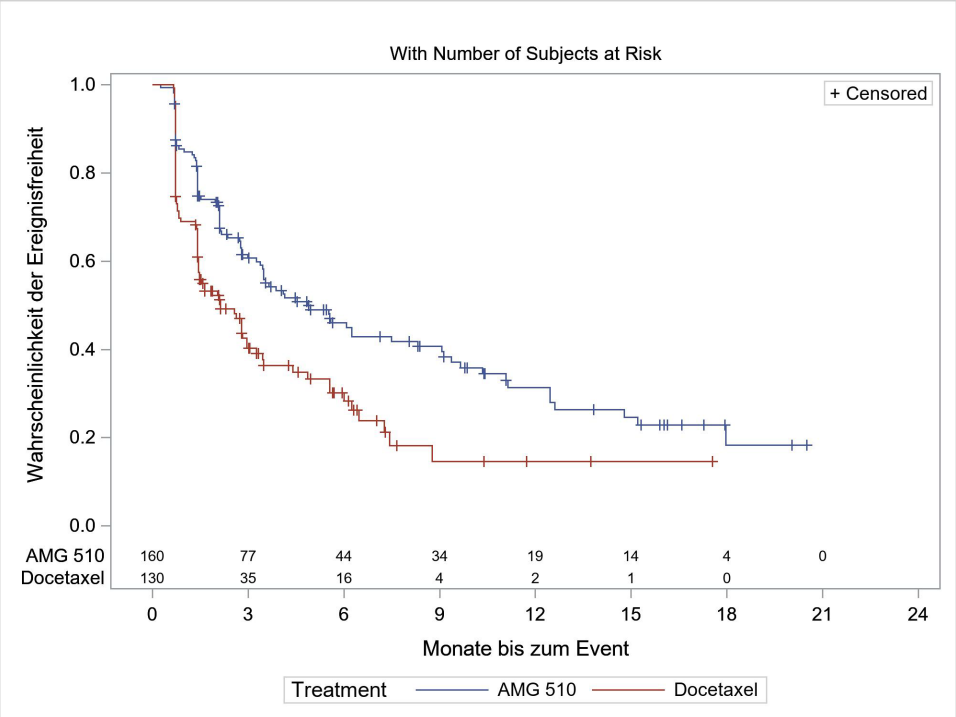

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Soziales Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

3.3 Verlaufskurven für den Endpunkt EORTC QLQ-C30

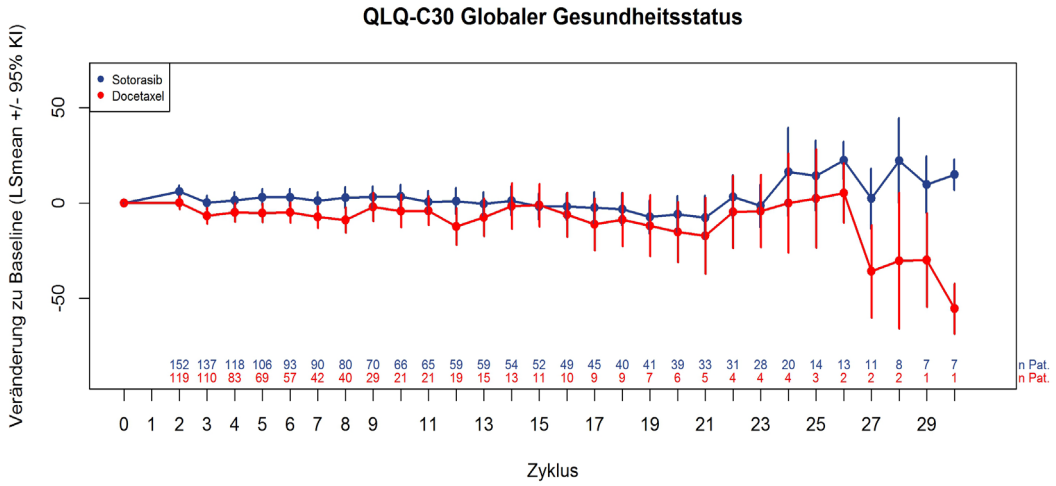

Abbildung 1: Verlaufskurve für den Endpunkt QLQ-C30 Globaler Gesundheitsstatus, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

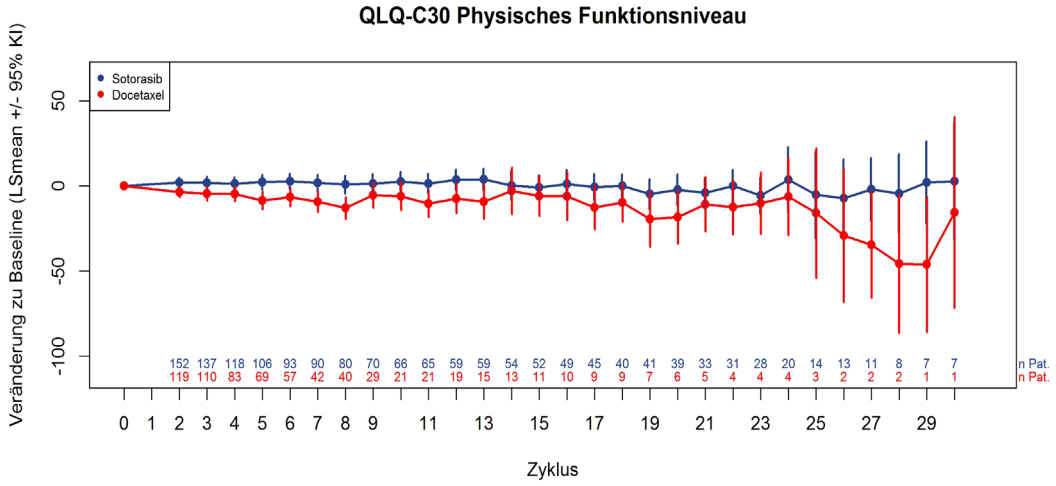

Abbildung 10: Verlaufskurve für den Endpunkt QLQ-C30 Physisches Funktionsniveau, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

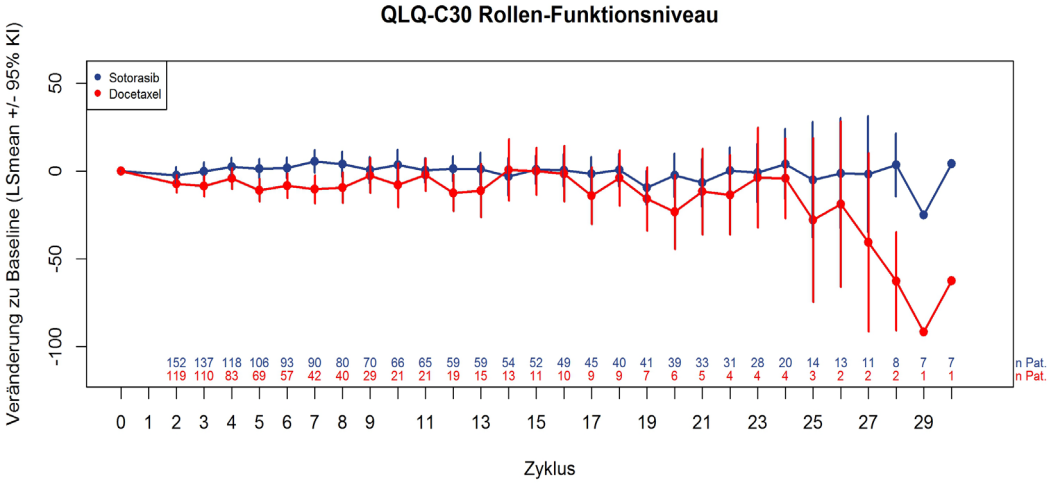

Abbildung 11: Verlaufskurve für den Endpunkt QLQ-C30 Rollen-Funktionsniveau, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

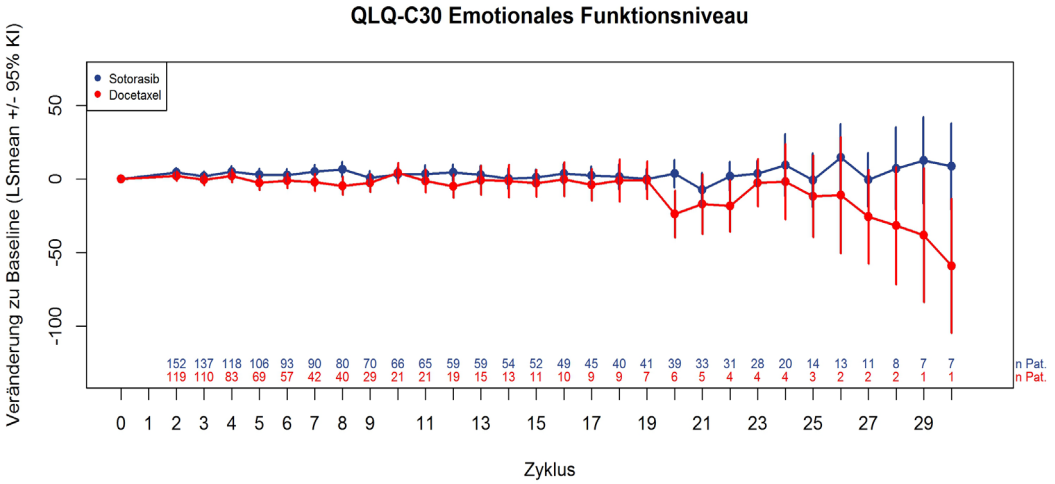

Abbildung 12: Verlaufskurve für den Endpunkt QLQ-C30 Emotionales Funktionsniveau, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

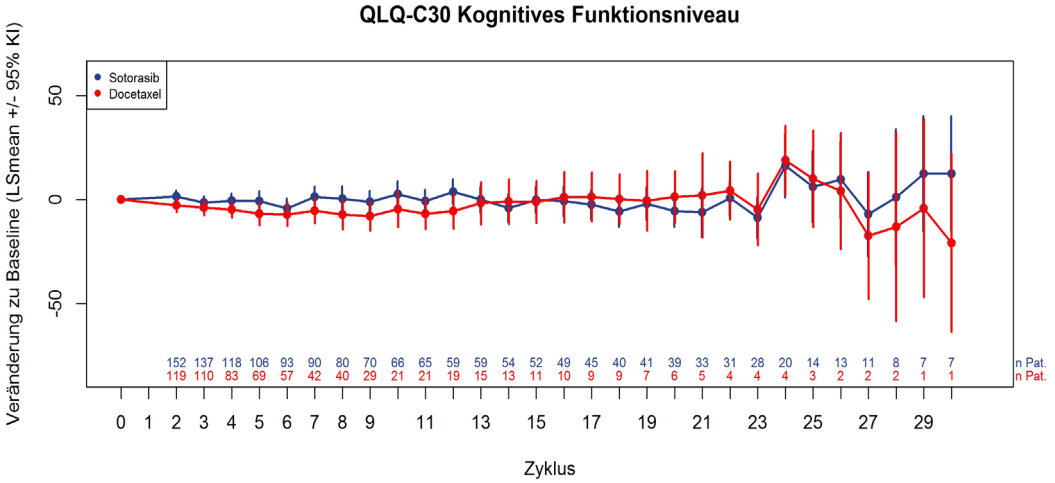

Abbildung 13: Verlaufskurve für den Endpunkt QLQ-C30 Kognitives Funktionsniveau, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

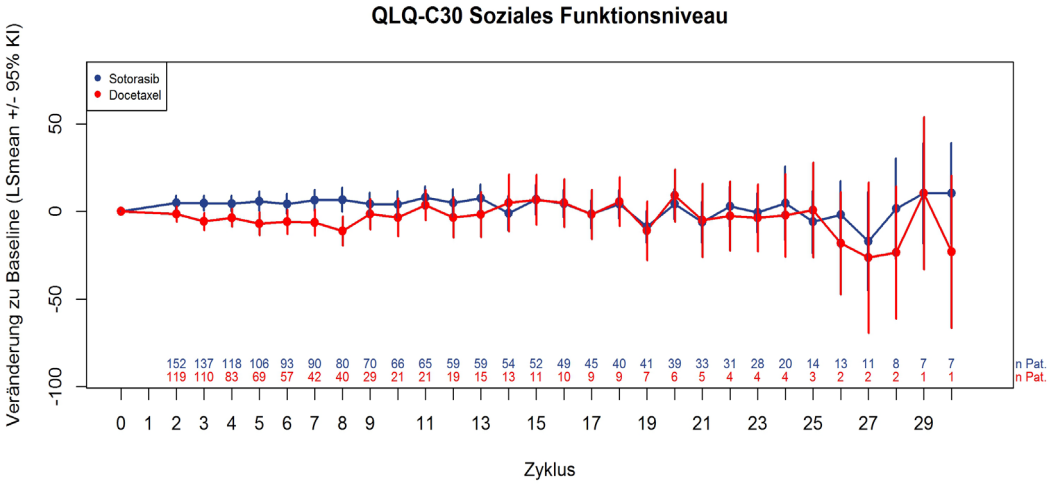

Abbildung 14: Verlaufskurve für den Endpunkt QLQ-C30 Soziales Funktionsniveau, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

3.4 Subgruppenanalysen für den Endpunkt EORTC QLQ-C30 (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Globaler Gesundheitsstatus; Alter bei Studienbeginn							
<65 Jahre	49/84 (58,3)	3,0 [2,1; 8,7]	39/70 (55,7)	2,3 [2,0; 5,5]	1,0 [0,6; 1,5]	0,8379	0,1729
≥65 Jahre	41/76 (53,9)	5,1 [3,5; 9,8]	39/60 (65,0)	2,8 [1,4; 3,5]	0,5 [0,3; 0,9]	0,0097	
QLQ-C30 Globaler Gesundheitsstatus; Geschlecht							
Weiblich	40/58 (69,0)	2,8 [1,5; 3,5]	29/53 (54,7)	3,5 [1,4; 7,9]	1,3 [0,8; 2,2]	0,3291	0,0028
Männlich	50/102 (49,0)	5,7 [4,2; 11,0]	49/77 (63,6)	2,1 [1,5; 3,5]	0,4 [0,3; 0,7]	0,0002	
QLQ-C30 Globaler Gesundheitsstatus; Region 2							
Nordamerika und Europa	77/135 (57,0)	4,2 [2,8; 6,2]	67/111 (60,4)	2,3 [1,5; 3,7]	0,7 [0,5; 1,0]	0,0515	0,8448
Rest der Welt	13/25 (52,0)	5,4 [3,5; 12,5]	11/19 (57,9)	2,8 [1,5; n.b.]	0,5 [0,2; 1,4]	0,1531	
QLQ-C30 Globaler Gesundheitsstatus; Region 1							
Nordamerika	4/17 (23,5)	n.b. [3,3; n.b.]	8/16 (50,0)	7,6 [3,0; n.b.]	0,6 [0,1; 2,5]	0,4750	0,8859
Europa	73/118 (61,9)	3,5 [2,8; 5,6]	59/95 (62,1)	2,1 [1,4; 3,3]	0,7 [0,5; 1,0]	0,0495	
Rest der Welt	13/25 (52,0)	5,4 [3,5; 12,5]	11/19 (57,9)	2,8 [1,5; n.b.]	0,5 [0,2; 1,4]	0,1531	
QLQ-C30 Globaler Gesundheitsstatus; ECOG Performance-Status							
0	35/56 (62,5)	4,2 [2,7; 10,3]	32/52 (61,5)	2,3 [1,4; 4,6]	0,7 [0,4; 1,3]	0,2800	0,8071
1	55/104 (52,9)	4,2 [2,8; 5,7]	46/78 (59,0)	2,3 [1,6; 3,6]	0,6 [0,4; 1,0]	0,0343	
QLQ-C30 Globaler Gesundheitsstatus; Lebermetastasen bei Studienbeginn							
Nein	72/133 (54,1)	5,1 [3,5; 8,7]	67/108 (62,0)	2,3 [1,8; 3,5]	0,6 [0,4; 0,9]	0,0048	0,1324
Ja	18/27 (66,7)	2,8 [1,4; 5,7]	11/22 (50,0)	4,9 [1,4; 7,9]	0,7 [0,3; 1,9]	0,4931	
QLQ-C30 Globaler Gesundheitsstatus; Knochenmetastasen bei Studienbeginn							
Nein	46/86 (53,5)	5,6 [3,0; 11,0]	45/78 (57,7)	3,5 [1,6; 4,6]	0,6 [0,4; 1,0]	0,0303	0,6009
Ja	44/74 (59,5)	3,5 [2,1; 5,6]	33/52 (63,5)	2,1 [1,4; 3,3]	0,7 [0,5; 1,2]	0,2435	
QLQ-C30 Globaler Gesundheitsstatus; PD-L1-Proteinexpression							
<1%	29/53 (54,7)	5,6 [2,8; 11,1]	25/43 (58,1)	2,1 [1,4; 3,7]	0,5 [0,3; 0,9]	0,0219	0,3907
≥1% und <50%	22/43 (51,2)	4,2 [2,1; n.b.]	23/50 (46,0)	4,6 [2,1; n.b.]	1,0 [0,5; 1,9]	0,9338	
≥50%	33/57 (57,9)	3,5 [2,8; 5,7]	24/29 (82,8)	2,1 [1,4; 2,8]	0,5 [0,3; 0,9]	0,0270	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Globaler Gesundheitsstatus; Ethnie-2							
Asiatisch	10/21 (47,6)	11,0 [4,1; n.b.]	12/18 (66,7)	2,1 [1,4; 3,5]	0,5 [0,2; 1,2]	0,1109	0,4634
Nicht asiatisch	79/138 (57,2)	3,5 [2,8; 5,7]	65/111 (58,6)	2,9 [1,8; 3,7]	0,7 [0,5; 1,0]	0,0698	
QLQ-C30 Globaler Gesundheitsstatus; Vorgeschichte einer Beteiligung des ZNS							
Nein	55/106 (51,9)	3,7 [2,8; 9,8]	56/91 (61,5)	2,3 [1,4; 3,6]	0,7 [0,5; 1,0]	0,0464	0,5591
Ja	35/54 (64,8)	5,4 [2,9; 9,1]	22/39 (56,4)	2,8 [1,8; 7,9]	0,6 [0,3; 1,1]	0,1186	
QLQ-C30 Globaler Gesundheitsstatus; Anzahl an vorherigen Therapielinien							
1	29/70 (41,4)	10,4 [2,8; n.b.]	34/60 (56,7)	2,8 [1,5; 3,7]	0,6 [0,3; 1,0]	0,0302	0,3317
2	40/62 (64,5)	4,9 [3,0; 5,7]	34/50 (68,0)	2,1 [1,4; 3,5]	0,7 [0,4; 1,1]	0,0985	
>2	21/28 (75,0)	2,8 [2,1; 4,1]	10/20 (50,0)	5,5 [1,4; n.b.]	1,2 [0,6; 2,7]	0,6054	
QLQ-C30 Physisches Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	35/84 (41,7)	10,4 [5,6; 13,8]	35/70 (50,0)	4,6 [2,8; 6,7]	0,6 [0,4; 1,0]	0,0470	0,1702
≥65 Jahre	33/76 (43,4)	8,3 [4,6; n.b.]	33/60 (55,0)	3,7 [2,1; 7,6]	0,4 [0,2; 0,7]	0,0009	
QLQ-C30 Physisches Funktionsniveau; Geschlecht							
Weiblich	28/58 (48,3)	8,3 [3,4; n.b.]	27/53 (50,9)	3,7 [1,9; 7,3]	0,7 [0,4; 1,3]	0,2788	0,1185
Männlich	40/102 (39,2)	11,0 [5,9; n.b.]	41/77 (53,2)	4,4 [2,8; 5,5]	0,4 [0,2; 0,6]	<,0001	
QLQ-C30 Physisches Funktionsniveau; Region 2							
Nordamerika und Europa	56/135 (41,5)	10,4 [5,2; 13,8]	62/111 (55,9)	3,7 [2,8; 4,9]	0,5 [0,4; 0,8]	0,0008	0,5460
Rest der Welt	12/25 (48,0)	5,9 [3,6; n.b.]	6/19 (31,6)	n.b. [1,4; n.b.]	0,8 [0,3; 2,3]	0,6325	
QLQ-C30 Physisches Funktionsniveau; Region 1							
Nordamerika	5/17 (29,4)	n.b. [3,4; n.b.]	11/16 (68,8)	3,7 [2,0; 10,0]	0,4 [0,1; 1,5]	0,1517	0,6060
Europa	51/118 (43,2)	9,8 [5,1; 13,1]	51/95 (53,7)	4,6 [2,8; 5,0]	0,5 [0,4; 0,8]	0,0029	
Rest der Welt	12/25 (48,0)	5,9 [3,6; n.b.]	6/19 (31,6)	n.b. [1,4; n.b.]	0,8 [0,3; 2,3]	0,6325	
QLQ-C30 Physisches Funktionsniveau; ECOG Performance-Status							
0	27/56 (48,2)	11,0 [5,4; n.b.]	29/52 (55,8)	4,6 [3,3; 7,3]	0,6 [0,3; 1,1]	0,0822	0,4555
1	41/104 (39,4)	9,1 [4,7; n.b.]	39/78 (50,0)	3,7 [2,1; 6,7]	0,5 [0,3; 0,7]	0,0011	
QLQ-C30 Physisches Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	55/133 (41,4)	11,0 [5,6; 13,8]	57/108 (52,8)	4,6 [3,3; 5,6]	0,5 [0,3; 0,7]	0,0003	0,5323
Ja	13/27 (48,1)	5,0 [3,0; n.b.]	11/22 (50,0)	3,7 [1,4; n.b.]	0,6 [0,2; 1,8]	0,3239	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Physisches Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	40/86 (46,5)	12,5 [4,7; 13,8]	45/78 (57,7)	4,4 [2,3; 5,0]	0,5 [0,3; 0,8]	0,0016	0,8501
Ja	28/74 (37,8)	9,1 [5,0; n.b.]	23/52 (44,2)	4,6 [3,0; 8,7]	0,5 [0,2; 0,9]	0,0163	
QLQ-C30 Physisches Funktionsniveau; PD-L1-Proteinexpression							
<1%	22/53 (41,5)	10,4 [5,0; n.b.]	23/43 (53,5)	3,7 [1,5; n.b.]	0,3 [0,2; 0,6]	0,0007	0,2016
≥1% und <50%	22/43 (51,2)	9,8 [3,4; 13,1]	21/50 (42,0)	4,6 [3,0; 5,5]	0,8 [0,4; 1,6]	0,5167	
≥50%	22/57 (38,6)	6,1 [4,3; n.b.]	19/29 (65,5)	4,9 [1,6; 6,7]	0,4 [0,2; 0,9]	0,0135	
QLQ-C30 Physisches Funktionsniveau; Ethnie-2							
Asiatisch	11/21 (52,4)	5,9 [3,0; 13,1]	8/18 (44,4)	n.b. [0,7; n.b.]	0,6 [0,2; 1,6]	0,2845	0,4616
Nicht asiatisch	56/138 (40,6)	11,0 [5,6; n.b.]	59/111 (53,2)	4,4 [3,3; 5,0]	0,5 [0,3; 0,7]	0,0004	
QLQ-C30 Physisches Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	42/106 (39,6)	12,5 [5,0; n.b.]	51/91 (56,0)	3,7 [2,8; 5,5]	0,4 [0,3; 0,7]	0,0001	0,4049
Ja	26/54 (48,1)	6,1 [4,2; 13,1]	17/39 (43,6)	4,9 [2,8; n.b.]	0,6 [0,3; 1,1]	0,0871	
QLQ-C30 Physisches Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	24/70 (34,3)	10,4 [8,3; n.b.]	28/60 (46,7)	4,9 [2,0; n.b.]	0,5 [0,3; 0,9]	0,0187	0,8077
2	28/62 (45,2)	12,5 [5,4; 13,8]	29/50 (58,0)	3,7 [2,8; 6,7]	0,4 [0,2; 0,8]	0,0024	
>2	16/28 (57,1)	4,6 [3,5; 5,9]	11/20 (55,0)	3,7 [1,6; 8,7]	0,7 [0,3; 1,6]	0,3684	
QLQ-C30 Rollen-Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	48/84 (57,1)	2,8 [1,4; 9,0]	46/70 (65,7)	2,1 [1,5; 3,3]	0,7 [0,5; 1,2]	0,1929	0,2022
≥65 Jahre	47/76 (61,8)	4,8 [2,8; 8,3]	40/60 (66,7)	2,8 [1,4; 3,0]	0,5 [0,3; 0,8]	0,0037	
QLQ-C30 Rollen-Funktionsniveau; Geschlecht							
Weiblich	36/58 (62,1)	2,7 [1,4; 3,5]	35/53 (66,0)	1,6 [1,4; 3,5]	0,7 [0,4; 1,1]	0,1277	0,6971
Männlich	59/102 (57,8)	4,9 [3,0; 9,0]	51/77 (66,2)	2,8 [1,5; 3,0]	0,6 [0,4; 0,9]	0,0065	
QLQ-C30 Rollen-Funktionsniveau; Region 2							
Nordamerika und Europa	75/135 (55,6)	4,2 [2,7; 9,0]	75/111 (67,6)	2,1 [1,5; 2,8]	0,6 [0,4; 0,8]	0,0015	0,4414
Rest der Welt	20/25 (80,0)	2,8 [0,8; 4,8]	11/19 (57,9)	1,9 [0,8; n.b.]	0,9 [0,4; 2,1]	0,8171	
QLQ-C30 Rollen-Funktionsniveau; Region 1							
Nordamerika	9/17 (52,9)	3,7 [0,7; n.b.]	10/16 (62,5)	2,8 [0,7; 10,0]	0,7 [0,2; 2,2]	0,5915	0,6071
Europa	66/118 (55,9)	4,2 [2,7; 9,0]	65/95 (68,4)	2,1 [1,5; 2,8]	0,5 [0,4; 0,8]	0,0013	
Rest der Welt	20/25 (80,0)	2,8 [0,8; 4,8]	11/19 (57,9)	1,9 [0,8; n.b.]	0,9 [0,4; 2,1]	0,8171	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Rollen-Funktionsniveau; ECOG Performance-Status							
0	35/56 (62,5)	6,2 [2,3; 9,7]	34/52 (65,4)	2,8 [1,4; 3,7]	0,5 [0,3; 0,9]	0,0176	0,9828
1	60/104 (57,7)	3,2 [2,1; 4,9]	52/78 (66,7)	1,9 [1,4; 2,8]	0,7 [0,4; 1,0]	0,0378	
QLQ-C30 Rollen-Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	78/133 (58,6)	3,5 [2,7; 8,3]	72/108 (66,7)	2,3 [1,5; 2,9]	0,6 [0,4; 0,8]	0,0032	0,8746
Ja	17/27 (63,0)	3,6 [1,4; 9,1]	14/22 (63,6)	1,6 [0,8; 4,9]	0,6 [0,2; 1,5]	0,2787	
QLQ-C30 Rollen-Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	58/86 (67,4)	3,2 [2,2; 8,3]	53/78 (67,9)	2,0 [1,5; 2,9]	0,6 [0,4; 1,0]	0,0275	0,5859
Ja	37/74 (50,0)	4,2 [2,1; n.b.]	33/52 (63,5)	2,7 [1,4; 3,7]	0,6 [0,4; 1,0]	0,0702	
QLQ-C30 Rollen-Funktionsniveau; PD-L1-Proteinexpression							
<1%	32/53 (60,4)	4,2 [2,1; 9,1]	31/43 (72,1)	1,5 [0,8; 2,8]	0,5 [0,3; 0,9]	0,0226	0,2640
≥1% und <50%	29/43 (67,4)	2,1 [0,8; 6,9]	28/50 (56,0)	2,8 [1,6; 4,6]	0,8 [0,5; 1,5]	0,5111	
≥50%	29/57 (50,9)	3,6 [2,7; 13,7]	21/29 (72,4)	3,3 [1,4; 4,9]	0,4 [0,2; 0,8]	0,0106	
QLQ-C30 Rollen-Funktionsniveau; Ethnie-2							
Asiatisch	16/21 (76,2)	2,8 [0,7; 4,9]	9/18 (50,0)	4,9 [0,8; n.b.]	1,3 [0,6; 3,1]	0,5409	0,0496
Nicht asiatisch	79/138 (57,2)	3,7 [2,8; 8,3]	76/111 (68,5)	2,1 [1,5; 2,8]	0,6 [0,4; 0,8]	0,0007	
QLQ-C30 Rollen-Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	60/106 (56,6)	3,7 [2,3; 8,3]	66/91 (72,5)	1,9 [1,4; 2,8]	0,5 [0,3; 0,7]	0,0002	0,0839
Ja	35/54 (64,8)	3,0 [1,4; 9,1]	20/39 (51,3)	3,0 [1,6; 5,6]	1,0 [0,5; 1,7]	0,9011	
QLQ-C30 Rollen-Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	35/70 (50,0)	3,6 [2,1; 9,2]	37/60 (61,7)	2,3 [1,5; 2,8]	0,7 [0,5; 1,2]	0,1988	0,4516
2	37/62 (59,7)	8,0 [2,8; 9,4]	35/50 (70,0)	1,5 [1,4; 3,7]	0,5 [0,3; 0,8]	0,0019	
>2	23/28 (82,1)	2,2 [1,4; 4,2]	14/20 (70,0)	2,9 [0,7; 3,3]	0,8 [0,4; 1,6]	0,4999	
QLQ-C30 Emotionales Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	43/84 (51,2)	4,2 [2,8; 13,8]	28/70 (40,0)	6,9 [4,2; n.b.]	1,3 [0,8; 2,1]	0,3712	0,0155
≥65 Jahre	26/76 (34,2)	14,0 [6,9; n.b.]	26/60 (43,3)	5,0 [2,3; n.b.]	0,6 [0,3; 1,0]	0,0577	
QLQ-C30 Emotionales Funktionsniveau; Geschlecht							
Weiblich	27/58 (46,6)	6,9 [2,8; n.b.]	19/53 (35,8)	7,4 [4,9; n.b.]	1,1 [0,6; 2,0]	0,8724	0,1078
Männlich	42/102 (41,2)	9,6 [4,2; n.b.]	35/77 (45,5)	5,0 [2,8; n.b.]	0,6 [0,4; 1,0]	0,0431	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Emotionales Funktionsniveau; Region 2							
Nordamerika und Europa	59/135 (43,7)	6,9 [4,2; n.b.]	48/111 (43,2)	5,6 [4,2; 12,7]	0,8 [0,6; 1,3]	0,4008	0,6564
Rest der Welt	10/25 (40,0)	9,6 [3,6; n.b.]	6/19 (31,6)	n.b. [2,8; n.b.]	0,6 [0,2; 2,3]	0,4487	
QLQ-C30 Emotionales Funktionsniveau; Region 1							
Nordamerika	4/17 (23,5)	n.b. [3,7; n.b.]	5/16 (31,2)	n.b. [5,6; n.b.]	2,4 [0,4; 13,5]	0,3109	0,9293
Europa	55/118 (46,6)	5,9 [3,5; 18,0]	43/95 (45,3)	5,0 [3,0; 12,7]	0,8 [0,6; 1,3]	0,4180	
Rest der Welt	10/25 (40,0)	9,6 [3,6; n.b.]	6/19 (31,6)	n.b. [2,8; n.b.]	0,6 [0,2; 2,3]	0,4487	
QLQ-C30 Emotionales Funktionsniveau; ECOG Performance-Status							
0	26/56 (46,4)	9,2 [4,0; n.b.]	30/52 (57,7)	4,2 [2,1; 7,4]	0,5 [0,3; 0,9]	0,0150	0,0291
1	43/104 (41,3)	8,4 [4,1; 18,0]	24/78 (30,8)	n.b. [4,9; n.b.]	1,2 [0,7; 2,1]	0,4534	
QLQ-C30 Emotionales Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	58/133 (43,6)	8,4 [5,1; 18,0]	43/108 (39,8)	6,9 [4,9; n.b.]	0,8 [0,5; 1,2]	0,2908	0,8110
Ja	11/27 (40,7)	11,1 [2,8; 11,1]	11/22 (50,0)	2,8 [1,4; n.b.]	0,6 [0,2; 1,8]	0,3734	
QLQ-C30 Emotionales Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	41/86 (47,7)	8,4 [4,1; 18,0]	29/78 (37,2)	7,4 [4,9; 12,7]	0,9 [0,5; 1,5]	0,6897	0,1603
Ja	28/74 (37,8)	11,1 [3,6; n.b.]	25/52 (48,1)	3,3 [2,3; n.b.]	0,5 [0,3; 1,0]	0,0355	
QLQ-C30 Emotionales Funktionsniveau; PD-L1-Proteinexpression							
<1%	24/53 (45,3)	11,1 [2,8; n.b.]	16/43 (37,2)	7,4 [4,9; n.b.]	1,1 [0,6; 2,3]	0,6879	0,2292
≥1% und <50%	22/43 (51,2)	6,9 [2,3; 13,8]	18/50 (36,0)	12,7 [5,5; 12,7]	1,0 [0,5; 1,9]	0,9359	
≥50%	20/57 (35,1)	18,0 [3,6; n.b.]	15/29 (51,7)	4,9 [2,3; n.b.]	0,5 [0,2; 1,1]	0,0866	
QLQ-C30 Emotionales Funktionsniveau; Ethnie-2							
Asiatisch	9/21 (42,9)	9,6 [2,1; n.b.]	7/18 (38,9)	n.b. [1,6; n.b.]	0,7 [0,2; 2,2]	0,5486	0,9377
Nicht asiatisch	60/138 (43,5)	8,4 [4,2; 18,0]	46/111 (41,4)	5,6 [4,2; n.b.]	0,8 [0,6; 1,2]	0,3309	
QLQ-C30 Emotionales Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	38/106 (35,8)	9,2 [5,5; n.b.]	38/91 (41,8)	5,6 [3,0; n.b.]	0,7 [0,4; 1,1]	0,1159	0,3295
Ja	31/54 (57,4)	5,1 [2,8; 13,8]	16/39 (41,0)	5,8 [2,8; n.b.]	1,0 [0,5; 1,9]	0,9575	
QLQ-C30 Emotionales Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	30/70 (42,9)	6,9 [3,6; 13,8]	21/60 (35,0)	7,4 [2,8; n.b.]	1,0 [0,6; 1,8]	0,9554	0,4761
2	21/62 (33,9)	n.b. [6,9; n.b.]	22/50 (44,0)	6,9 [3,3; 12,7]	0,6 [0,3; 1,2]	0,1404	
>2	18/28 (64,3)	4,1 [2,8; 14,0]	11/20 (55,0)	3,3 [1,4; 5,8]	0,6 [0,3; 1,3]	0,2093	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Kognitives Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	44/84 (52,4)	5,6 [2,8; 9,4]	38/70 (54,3)	2,8 [2,1; 7,4]	0,8 [0,5; 1,2]	0,2444	0,4682
≥65 Jahre	35/76 (46,1)	5,6 [3,4; n.b.]	34/60 (56,7)	3,2 [1,4; 6,2]	0,6 [0,3; 1,0]	0,0362	
QLQ-C30 Kognitives Funktionsniveau; Geschlecht							
Weiblich	31/58 (53,4)	4,5 [2,8; 12,5]	28/53 (52,8)	3,2 [1,4; 7,9]	0,9 [0,5; 1,5]	0,6014	0,3574
Männlich	48/102 (47,1)	6,1 [3,4; 10,4]	44/77 (57,1)	2,7 [1,5; 4,9]	0,5 [0,3; 0,8]	0,0051	
QLQ-C30 Kognitives Funktionsniveau; Region 2							
Nordamerika und Europa	65/135 (48,1)	6,9 [3,5; 10,4]	61/111 (55,0)	3,2 [2,1; 6,1]	0,7 [0,5; 1,0]	0,0413	0,9736
Rest der Welt	14/25 (56,0)	4,7 [1,4; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,6 [0,2; 1,6]	0,2975	
QLQ-C30 Kognitives Funktionsniveau; Region 1							
Nordamerika	6/17 (35,3)	12,5 [2,1; n.b.]	11/16 (68,8)	6,1 [1,4; 7,9]	0,3 [0,1; 1,2]	0,0678	0,8861
Europa	59/118 (50,0)	6,2 [3,4; 10,4]	50/95 (52,6)	3,2 [2,1; 5,0]	0,7 [0,5; 1,0]	0,0558	
Rest der Welt	14/25 (56,0)	4,7 [1,4; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,6 [0,2; 1,6]	0,2975	
QLQ-C30 Kognitives Funktionsniveau; ECOG Performance-Status							
0	24/56 (42,9)	9,0 [4,5; n.b.]	33/52 (63,5)	2,8 [1,5; 4,9]	0,4 [0,2; 0,8]	0,0063	0,1623
1	55/104 (52,9)	4,8 [2,8; 7,1]	39/78 (50,0)	2,8 [1,6; 6,2]	0,8 [0,5; 1,2]	0,2407	
QLQ-C30 Kognitives Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	68/133 (51,1)	4,9 [2,8; 9,4]	57/108 (52,8)	3,5 [2,1; 6,2]	0,8 [0,5; 1,1]	0,2049	0,0666
Ja	11/27 (40,7)	7,1 [3,5; n.b.]	15/22 (68,2)	1,5 [0,9; 2,8]	0,1 [0,0; 0,5]	0,0010	
QLQ-C30 Kognitives Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	47/86 (54,7)	4,7 [2,1; 12,5]	41/78 (52,6)	4,9 [2,1; 6,2]	0,8 [0,5; 1,3]	0,4761	0,1028
Ja	32/74 (43,2)	7,1 [4,5; 10,4]	31/52 (59,6)	2,1 [1,4; 4,6]	0,5 [0,3; 0,9]	0,0154	
QLQ-C30 Kognitives Funktionsniveau; PD-L1-Proteinexpression							
<1%	23/53 (43,4)	9,1 [2,4; n.b.]	29/43 (67,4)	2,8 [1,4; 3,5]	0,5 [0,3; 0,8]	0,0071	0,2447
≥1% und <50%	23/43 (53,5)	5,6 [3,5; 12,5]	23/50 (46,0)	6,1 [2,1; 9,1]	0,6 [0,3; 1,2]	0,1538	
≥50%	28/57 (49,1)	5,6 [2,8; 18,0]	14/29 (48,3)	6,2 [0,8; n.b.]	0,9 [0,4; 1,9]	0,8104	
QLQ-C30 Kognitives Funktionsniveau; Ethnie-2							
Asiatisch	12/21 (57,1)	4,7 [1,4; 6,1]	13/18 (72,2)	1,4 [0,7; 2,8]	0,5 [0,2; 1,3]	0,1505	0,5996
Nicht asiatisch	67/138 (48,6)	6,2 [3,5; 10,4]	58/111 (52,3)	3,5 [2,3; 6,2]	0,7 [0,5; 1,0]	0,0645	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Kognitives Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	46/106 (43,4)	9,0 [3,5; n.b.]	52/91 (57,1)	2,8 [1,6; 5,0]	0,6 [0,4; 0,9]	0,0099	0,1580
Ja	33/54 (61,1)	4,7 [2,1; 6,2]	20/39 (51,3)	3,5 [1,5; 7,9]	0,8 [0,4; 1,4]	0,4078	
QLQ-C30 Kognitives Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	31/70 (44,3)	9,0 [2,8; n.b.]	33/60 (55,0)	2,8 [1,4; 7,1]	0,6 [0,3; 1,0]	0,0295	0,1683
2	27/62 (43,5)	10,4 [4,9; n.b.]	28/50 (56,0)	3,5 [2,1; 9,1]	0,5 [0,3; 0,9]	0,0284	
>2	21/28 (75,0)	2,1 [1,4; 4,2]	11/20 (55,0)	2,7 [1,4; n.b.]	1,3 [0,6; 2,7]	0,5319	
QLQ-C30 Soziales Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	48/84 (57,1)	5,6 [3,0; 9,4]	50/70 (71,4)	1,4 [1,4; 2,6]	0,5 [0,3; 0,8]	0,0019	0,2565
≥65 Jahre	45/76 (59,2)	4,1 [2,8; 7,5]	34/60 (56,7)	3,5 [1,6; 6,0]	0,8 [0,5; 1,3]	0,3557	
QLQ-C30 Soziales Funktionsniveau; Geschlecht							
Weiblich	35/58 (60,3)	3,5 [2,0; 12,5]	36/53 (67,9)	2,1 [0,8; 4,9]	0,6 [0,4; 1,0]	0,0635	0,6548
Männlich	58/102 (56,9)	5,5 [3,5; 7,5]	48/77 (62,3)	2,1 [1,4; 3,5]	0,5 [0,3; 0,7]	0,0006	
QLQ-C30 Soziales Funktionsniveau; Region 2							
Nordamerika und Europa	73/135 (54,1)	6,2 [3,5; 10,3]	75/111 (67,6)	2,1 [1,4; 3,0]	0,5 [0,4; 0,7]	<,0001	0,0387
Rest der Welt	20/25 (80,0)	2,8 [1,4; 4,9]	9/19 (47,4)	6,0 [1,4; n.b.]	1,2 [0,5; 2,9]	0,6918	
QLQ-C30 Soziales Funktionsniveau; Region 1							
Nordamerika	7/17 (41,2)	n.b. [2,1; n.b.]	10/16 (62,5)	3,0 [0,8; n.b.]	0,5 [0,2; 1,7]	0,2657	0,1121
Europa	66/118 (55,9)	5,6 [3,5; 9,7]	65/95 (68,4)	2,1 [1,4; 2,8]	0,5 [0,3; 0,7]	0,0002	
Rest der Welt	20/25 (80,0)	2,8 [1,4; 4,9]	9/19 (47,4)	6,0 [1,4; n.b.]	1,2 [0,5; 2,9]	0,6918	
QLQ-C30 Soziales Funktionsniveau; ECOG Performance-Status							
0	32/56 (57,1)	7,5 [4,1; 12,5]	34/52 (65,4)	1,5 [1,4; 5,6]	0,4 [0,2; 0,7]	0,0010	0,3941
1	61/104 (58,7)	3,5 [2,4; 6,1]	50/78 (64,1)	2,1 [1,4; 3,0]	0,6 [0,4; 1,0]	0,0275	
QLQ-C30 Soziales Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	76/133 (57,1)	5,6 [3,5; 9,4]	68/108 (63,0)	2,6 [1,5; 3,5]	0,6 [0,4; 0,8]	0,0013	0,9566
Ja	17/27 (63,0)	3,5 [2,1; 9,1]	16/22 (72,7)	1,4 [0,7; 2,8]	0,3 [0,1; 0,9]	0,0246	
QLQ-C30 Soziales Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	52/86 (60,5)	5,6 [2,8; 11,1]	45/78 (57,7)	2,8 [1,6; 6,2]	0,7 [0,4; 1,1]	0,0870	0,0396
Ja	41/74 (55,4)	4,1 [3,0; 9,1]	39/52 (75,0)	1,4 [0,8; 2,1]	0,3 [0,2; 0,6]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Soziales Funktionsniveau; PD-L1-Proteinexpression							
<1%	29/53 (54,7)	5,6 [3,9; 12,5]	29/43 (67,4)	2,6 [1,4; 5,6]	0,4 [0,2; 0,7]	0,0017	0,5448
≥1% und <50%	25/43 (58,1)	3,0 [2,1; 9,1]	30/50 (60,0)	2,0 [1,4; 3,4]	0,6 [0,3; 1,1]	0,0713	
≥50%	36/57 (63,2)	3,6 [2,1; 7,5]	20/29 (69,0)	2,1 [0,7; 6,2]	0,7 [0,4; 1,3]	0,3126	
QLQ-C30 Soziales Funktionsniveau; Ethnie-2							
Asiatisch	18/21 (85,7)	2,1 [1,4; 4,1]	9/18 (50,0)	6,0 [0,8; n.b.]	1,3 [0,5; 3,2]	0,5403	0,0019
Nicht asiatisch	74/138 (53,6)	6,2 [3,5; 10,3]	74/111 (66,7)	2,1 [1,4; 3,0]	0,5 [0,4; 0,7]	<,0001	
QLQ-C30 Soziales Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	55/106 (51,9)	5,0 [3,4; 11,1]	61/91 (67,0)	2,1 [1,4; 2,8]	0,5 [0,4; 0,8]	0,0005	0,3785
Ja	38/54 (70,4)	4,1 [2,8; 9,1]	23/39 (59,0)	3,0 [1,4; 7,4]	0,6 [0,4; 1,1]	0,1275	
QLQ-C30 Soziales Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	37/70 (52,9)	4,9 [2,8; 9,1]	38/60 (63,3)	2,6 [1,4; 5,6]	0,6 [0,4; 0,9]	0,0201	0,8865
2	36/62 (58,1)	6,1 [2,8; 11,1]	34/50 (68,0)	2,1 [1,4; 3,4]	0,5 [0,3; 0,8]	0,0051	
>2	20/28 (71,4)	3,5 [1,4; 6,2]	12/20 (60,0)	1,4 [0,7; n.b.]	0,8 [0,4; 1,6]	0,4905	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-C30 = Quality of Life Questionnaire Core 30; ZNS = Zentrales Nervensystem

3.5 Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-C30 Globaler Gesundheitsstatus								
160	103 (64,4)	3,5 [2,8; 5,6]	130	82 (63,1)	2,3 [1,7; 3,5]	0,74 [0,54; 1,00]	0,0493	0,0485
QLQ-C30 Physisches Funktionsniveau								
160	110 (68,8)	3,4 [2,4; 4,7]	130	90 (69,2)	2,3 [1,6; 3,5]	0,70 [0,52; 0,94]	0,0177	0,0172
QLQ-C30 Rollen-Funktionsniveau								
160	107 (66,9)	3,0 [2,2; 4,8]	130	89 (68,5)	2,1 [1,5; 2,8]	0,66 [0,49; 0,89]	0,0059	0,0055
QLQ-C30 Emotionales Funktionsniveau								
160	88 (55,0)	5,8 [3,6; 8,4]	130	60 (46,2)	5,1 [3,0; 7,4]	0,88 [0,63; 1,24]	0,4666	0,4663
QLQ-C30 Kognitives Funktionsniveau								
160	92 (57,5)	4,5 [3,2; 6,1]	130	77 (59,2)	2,8 [2,1; 4,6]	0,71 [0,52; 0,98]	0,0354	0,0347
QLQ-C30 Soziales Funktionsniveau								
160	106 (66,2)	3,6 [2,8; 5,8]	130	87 (66,9)	2,1 [1,4; 2,8]	0,61 [0,45; 0,83]	0,0014	0,0012

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

3.6 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 10 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

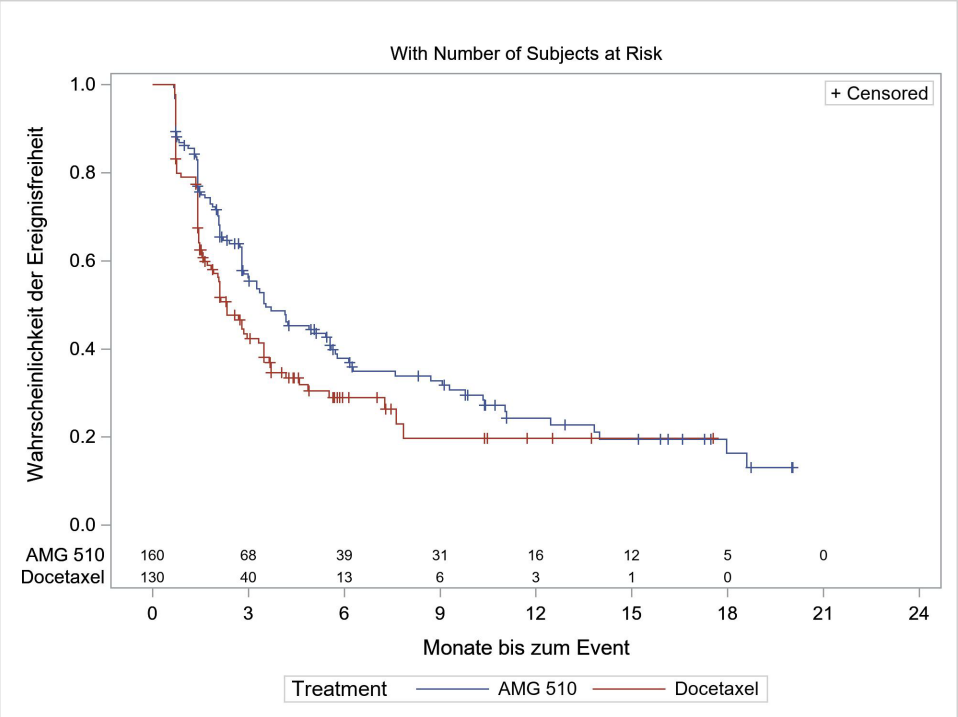

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Globaler Gesundheitsstatus, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

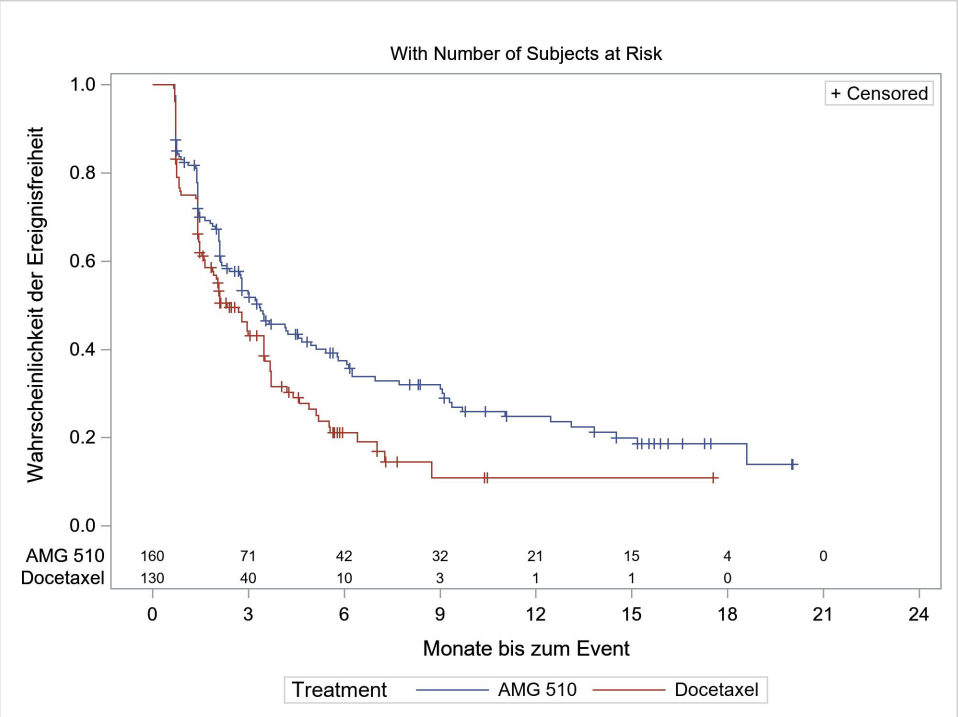

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Physisches Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

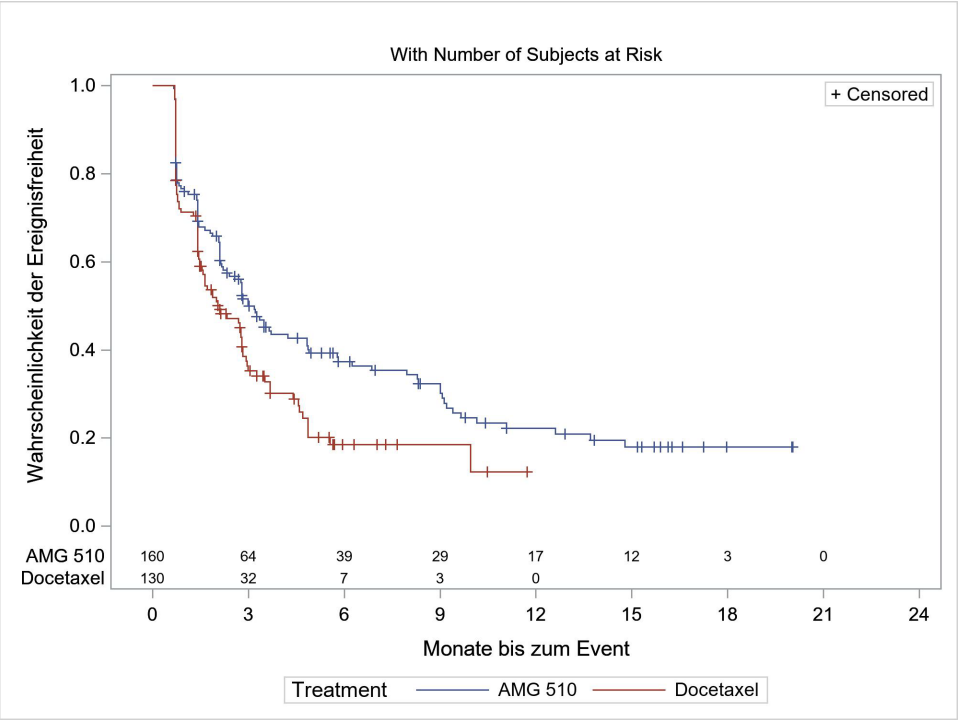

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Rollen-Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

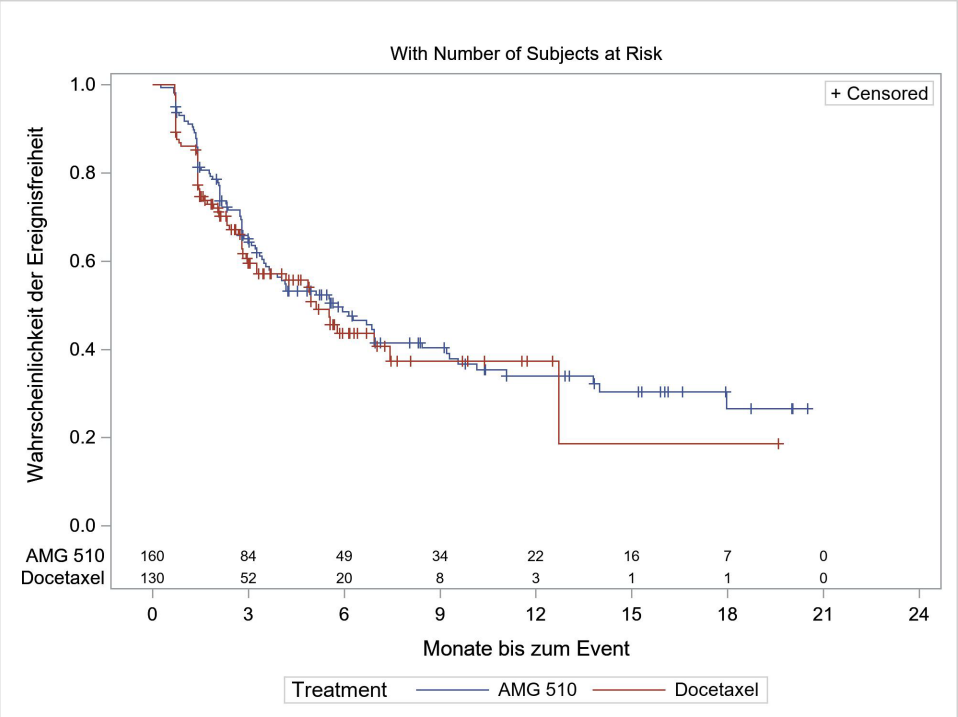

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Emotionales Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

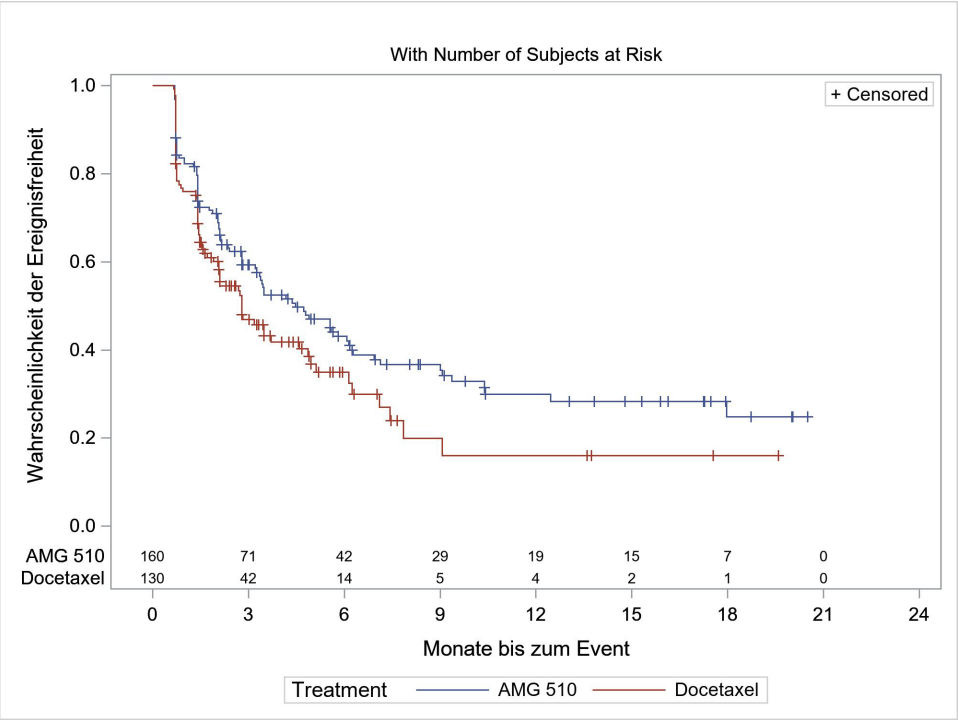

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Kognitives Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

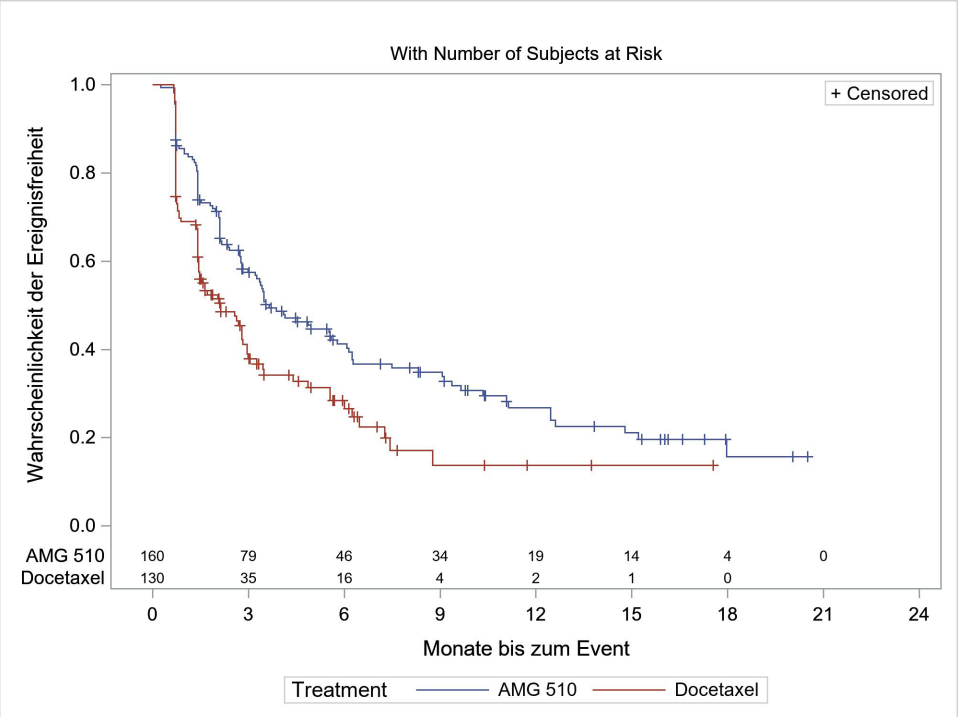

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Soziales Funktionsniveau, Zeit bis zur Verschlechterung um ≥10 Punkte" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

3.7 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
QLQ-C30 Globaler Gesundheitsstatus								
160	103 (64,4)	3,5 [2,8; 5,6]	130	82 (63,1)	2,3 [1,7; 3,5]	0,74 [0,54; 1,00]	0,0493	0,0485
QLQ-C30 Physisches Funktionsniveau								
160	85 (53,1)	6,1 [4,7; 10,4]	130	73 (56,2)	3,7 [2,8; 4,9]	0,58 [0,42; 0,81]	0,0012	0,0010
QLQ-C30 Rollen-Funktionsniveau								
160	107 (66,9)	3,0 [2,2; 4,8]	130	89 (68,5)	2,1 [1,5; 2,8]	0,66 [0,49; 0,89]	0,0059	0,0055
QLQ-C30 Emotionales Funktionsniveau								
160	88 (55,0)	5,8 [3,6; 8,4]	130	60 (46,2)	5,1 [3,0; 7,4]	0,88 [0,63; 1,24]	0,4666	0,4663
QLQ-C30 Kognitives Funktionsniveau								
160	92 (57,5)	4,5 [3,2; 6,1]	130	77 (59,2)	2,8 [2,1; 4,6]	0,71 [0,52; 0,98]	0,0354	0,0347
QLQ-C30 Soziales Funktionsniveau								
160	106 (66,2)	3,6 [2,8; 5,8]	130	87 (66,9)	2,1 [1,4; 2,8]	0,61 [0,45; 0,83]	0,0014	0,0012

1) p-Wert des Cox-Modells
2) p-Wert des Logrank-Tests
Die Auswertung erfolgte auf Grundlage der ITT-Population.

KI = Konfidenzintervall; QLQ-C30 = Quality of Life Questionnaire Core 30

3.8 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt EORTC QLQ-C30 (präspezifizierte Analyse inkl. Tod als Ereignis)

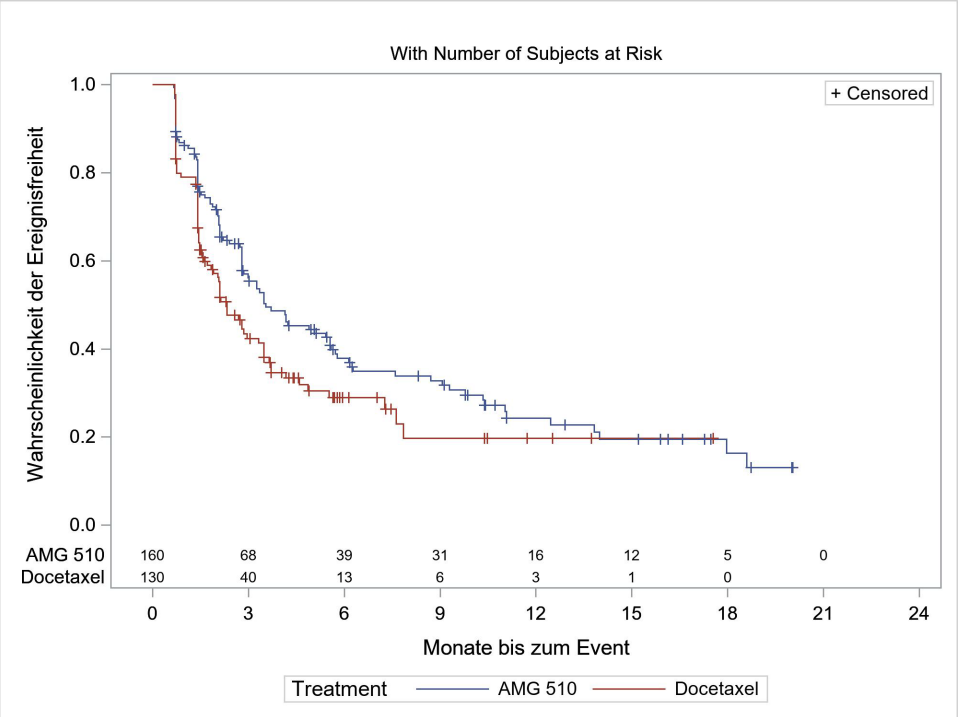

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Globaler Gesundheitsstatus, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

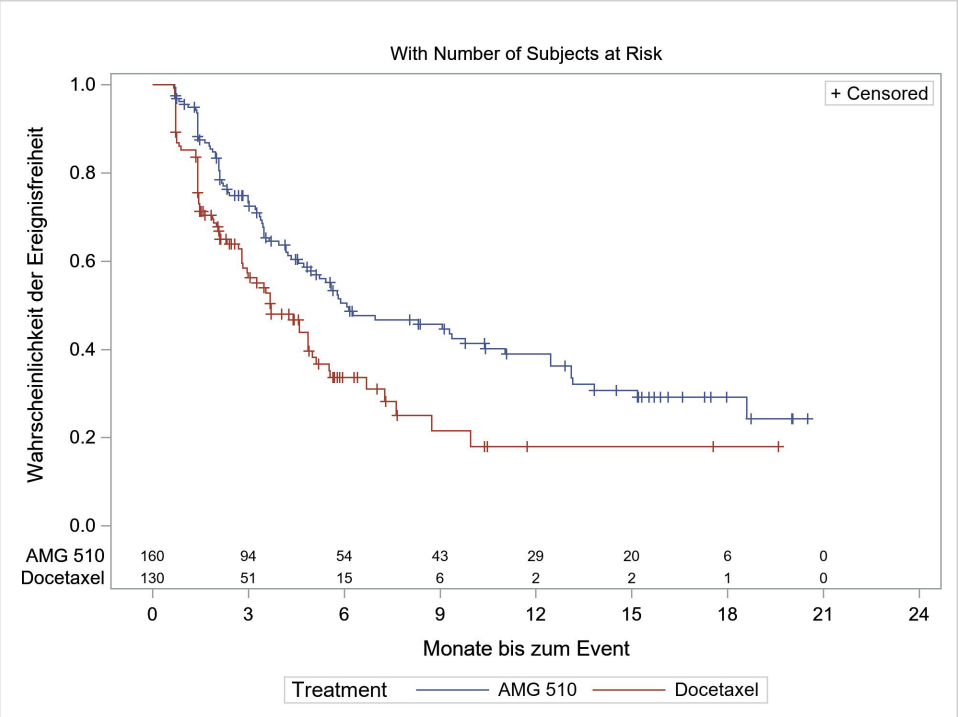

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Physisches Funktionsniveau, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

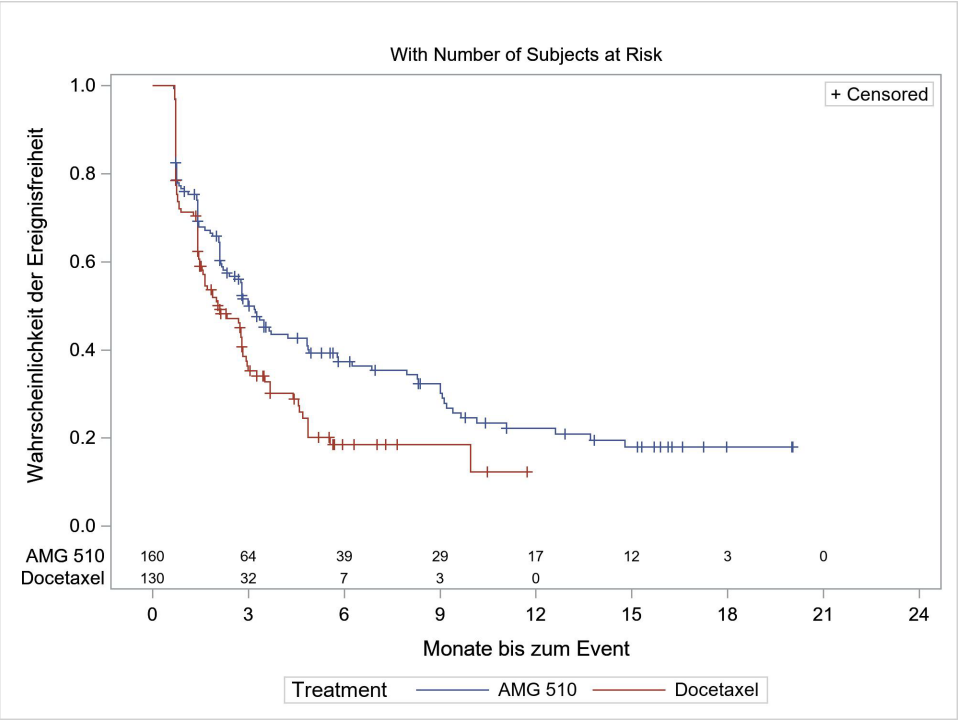

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Rollen-Funktionsniveau, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

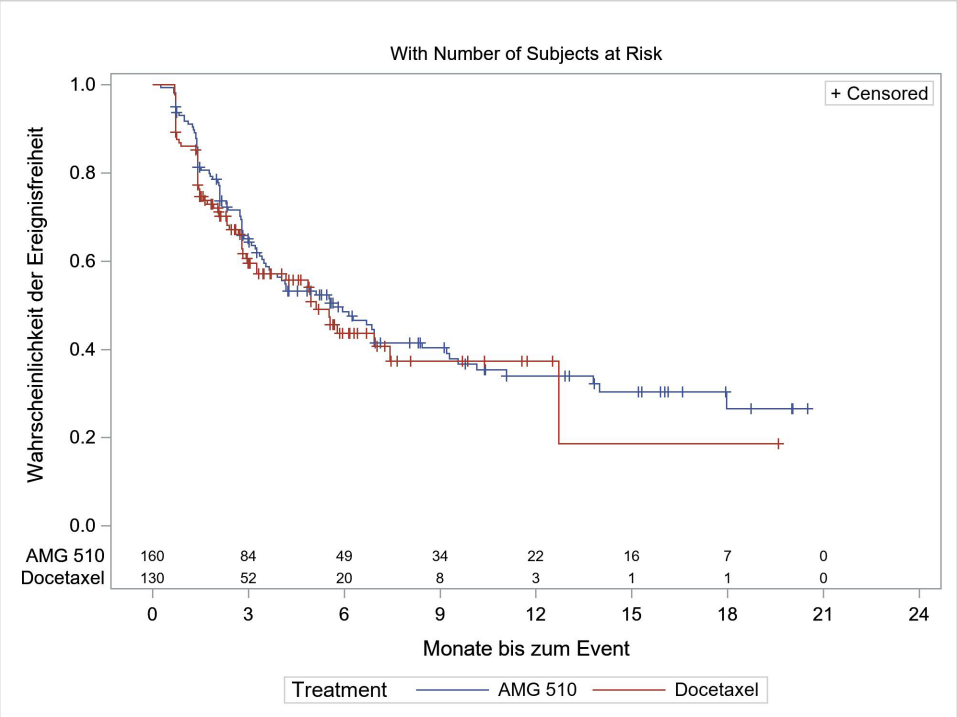

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Emotionales Funktionsniveau, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

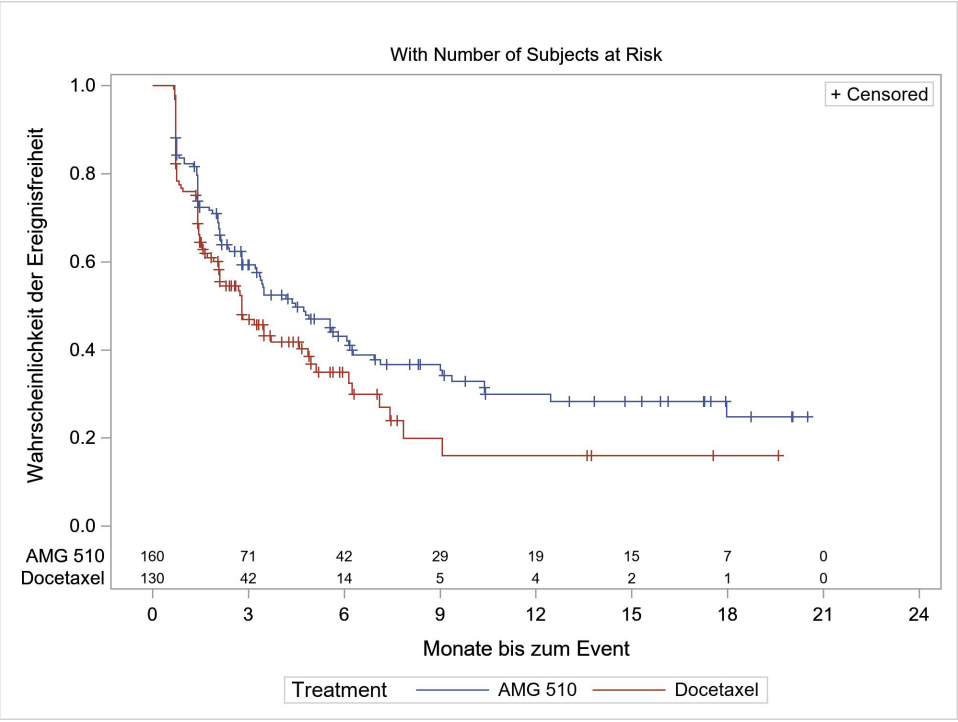

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Kognitives Funktionsniveau, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

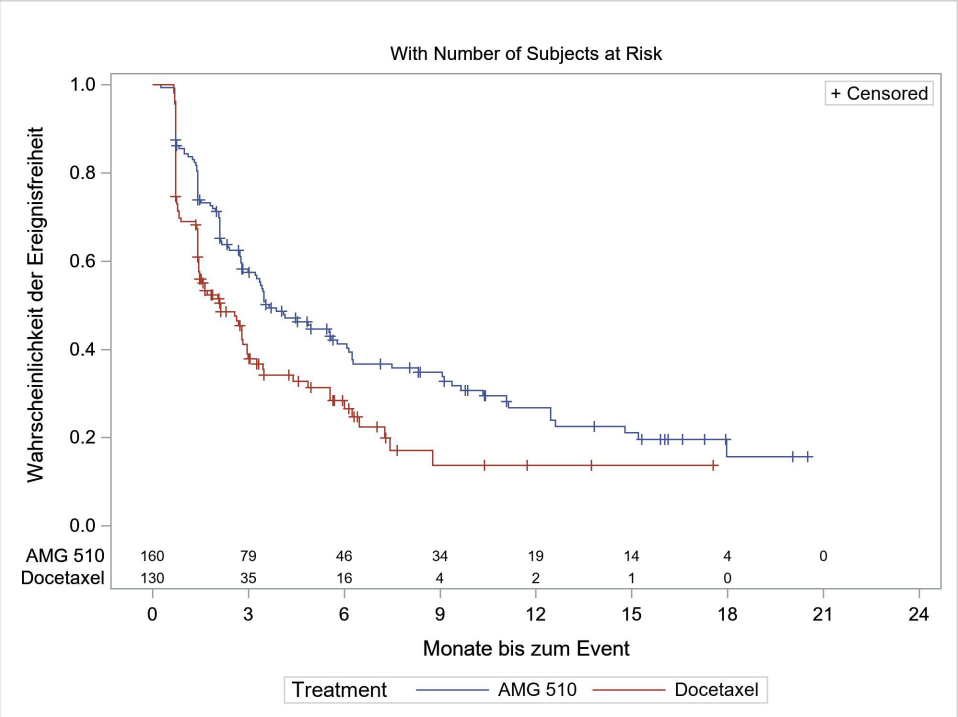

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "QLQ-C30 Soziales Funktionsniveau, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

3.9 Subgruppenanalysen für den Endpunkt EORTC QLQ-C30 (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Globaler Gesundheitsstatus; Alter bei Studienbeginn							
<65 Jahre	58/84 (69,0)	2,8 [2,1; 4,2]	42/70 (60,0)	2,3 [1,8; 4,9]	1,0 [0,7; 1,6]	0,8645	0,1281
≥65 Jahre	45/76 (59,2)	5,1 [3,5; 6,3]	40/60 (66,7)	2,1 [1,4; 3,5]	0,5 [0,3; 0,9]	0,0161	
QLQ-C30 Globaler Gesundheitsstatus; Geschlecht							
Weiblich	43/58 (74,1)	2,1 [1,4; 3,3]	33/53 (62,3)	2,3 [1,4; 4,9]	1,2 [0,8; 2,0]	0,4098	0,0126
Männlich	60/102 (58,8)	5,6 [3,7; 7,6]	49/77 (63,6)	2,1 [1,5; 3,5]	0,5 [0,3; 0,8]	0,0014	
QLQ-C30 Globaler Gesundheitsstatus; Region 2							
Nordamerika und Europa	89/135 (65,9)	3,3 [2,8; 5,6]	70/111 (63,1)	2,3 [1,5; 3,5]	0,8 [0,6; 1,1]	0,1114	0,7135
Rest der Welt	14/25 (56,0)	5,4 [3,5; 12,5]	12/19 (63,2)	2,1 [1,5; 3,5]	0,5 [0,2; 1,3]	0,1607	
QLQ-C30 Globaler Gesundheitsstatus; Region 1							
Nordamerika	6/17 (35,3)	n.b. [3,3; n.b.]	8/16 (50,0)	7,6 [3,0; n.b.]	0,8 [0,2; 2,9]	0,6877	0,9750
Europa	83/118 (70,3)	3,0 [2,4; 4,2]	62/95 (65,3)	2,1 [1,4; 2,7]	0,7 [0,5; 1,0]	0,0881	
Rest der Welt	14/25 (56,0)	5,4 [3,5; 12,5]	12/19 (63,2)	2,1 [1,5; 3,5]	0,5 [0,2; 1,3]	0,1607	
QLQ-C30 Globaler Gesundheitsstatus; ECOG Performance-Status							
0	38/56 (67,9)	4,2 [2,7; 8,7]	32/52 (61,5)	2,3 [1,4; 4,6]	0,8 [0,5; 1,3]	0,3688	0,7652
1	65/104 (62,5)	3,5 [2,8; 5,6]	50/78 (64,1)	2,3 [1,6; 3,0]	0,7 [0,5; 1,0]	0,0530	
QLQ-C30 Globaler Gesundheitsstatus; Lebermetastasen bei Studienbeginn							
Nein	82/133 (61,7)	4,2 [2,9; 6,2]	70/108 (64,8)	2,1 [1,6; 3,5]	0,7 [0,5; 0,9]	0,0148	0,1590
Ja	21/27 (77,8)	3,0 [1,4; 4,2]	12/22 (54,5)	2,8 [1,4; 7,9]	0,7 [0,3; 1,9]	0,4848	
QLQ-C30 Globaler Gesundheitsstatus; Knochenmetastasen bei Studienbeginn							
Nein	54/86 (62,8)	5,4 [2,9; 9,3]	47/78 (60,3)	2,7 [1,7; 4,6]	0,7 [0,5; 1,1]	0,0870	0,8228
Ja	49/74 (66,2)	3,3 [2,1; 4,9]	35/52 (67,3)	2,1 [1,4; 3,0]	0,7 [0,5; 1,2]	0,2151	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Globaler Gesundheitsstatus; PD-L1-Proteinexpression							
<1%	37/53 (69,8)	4,2 [2,4; 7,6]	26/43 (60,5)	2,1 [1,4; 3,7]	0,6 [0,4; 1,1]	0,0851	0,3220
≥1% und <50%	26/43 (60,5)	4,2 [1,9; 10,4]	25/50 (50,0)	3,3 [2,0; 7,9]	1,0 [0,6; 1,9]	0,9277	
≥50%	34/57 (59,6)	3,5 [2,8; 5,7]	25/29 (86,2)	2,1 [1,4; 2,8]	0,5 [0,3; 0,9]	0,0234	
QLQ-C30 Globaler Gesundheitsstatus; Ethnie-2							
Asiatisch	11/21 (52,4)	9,3 [4,1; 12,5]	13/18 (72,2)	2,0 [1,4; 3,5]	0,5 [0,2; 1,2]	0,1164	0,3734
Nicht asiatisch	91/138 (65,9)	3,4 [2,8; 5,6]	68/111 (61,3)	2,3 [1,8; 3,6]	0,8 [0,6; 1,1]	0,1518	
QLQ-C30 Globaler Gesundheitsstatus; Vorgeschichte einer Beteiligung des ZNS							
Nein	65/106 (61,3)	3,4 [2,8; 5,6]	60/91 (65,9)	2,1 [1,4; 3,3]	0,7 [0,5; 1,1]	0,0904	0,5866
Ja	38/54 (70,4)	5,1 [2,8; 8,7]	22/39 (56,4)	2,8 [1,8; 7,9]	0,7 [0,4; 1,2]	0,1844	
QLQ-C30 Globaler Gesundheitsstatus; Anzahl an vorherigen Therapielinien							
1	38/70 (54,3)	6,1 [2,1; 11,0]	36/60 (60,0)	2,3 [1,5; 3,6]	0,7 [0,4; 1,1]	0,0938	0,6510
2	44/62 (71,0)	4,2 [3,0; 5,6]	34/50 (68,0)	2,1 [1,4; 3,5]	0,7 [0,5; 1,2]	0,1939	
>2	21/28 (75,0)	2,8 [2,1; 4,1]	12/20 (60,0)	2,3 [1,4; 7,9]	1,1 [0,5; 2,2]	0,8847	
QLQ-C30 Physisches Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	46/84 (54,8)	5,9 [3,5; 12,5]	40/70 (57,1)	3,7 [2,8; 5,1]	0,7 [0,4; 1,1]	0,1165	0,1566
≥65 Jahre	39/76 (51,3)	6,1 [4,3; 11,0]	33/60 (55,0)	3,7 [2,1; 7,6]	0,4 [0,3; 0,8]	0,0029	
QLQ-C30 Physisches Funktionsniveau; Geschlecht							
Weiblich	31/58 (53,4)	4,2 [2,4; 13,8]	30/53 (56,6)	3,7 [1,6; 5,6]	0,7 [0,4; 1,3]	0,2690	0,3005
Männlich	54/102 (52,9)	6,3 [5,4; 12,5]	43/77 (55,8)	4,4 [2,8; 5,1]	0,5 [0,3; 0,7]	0,0005	
QLQ-C30 Physisches Funktionsniveau; Region 2							
Nordamerika und Europa	71/135 (52,6)	6,3 [4,6; 12,5]	66/111 (59,5)	3,7 [2,8; 4,9]	0,6 [0,4; 0,8]	0,0037	0,5973
Rest der Welt	14/25 (56,0)	5,6 [3,4; 13,1]	7/19 (36,8)	n.b. [1,3; n.b.]	0,8 [0,3; 2,1]	0,6392	
QLQ-C30 Physisches Funktionsniveau; Region 1							
Nordamerika	7/17 (41,2)	12,5 [2,1; n.b.]	11/16 (68,8)	3,7 [2,0; 10,0]	0,5 [0,1; 1,7]	0,2615	0,6773
Europa	64/118 (54,2)	5,8 [4,2; 10,4]	55/95 (57,9)	3,7 [2,7; 4,9]	0,6 [0,4; 0,9]	0,0110	
Rest der Welt	14/25 (56,0)	5,6 [3,4; 13,1]	7/19 (36,8)	n.b. [1,3; n.b.]	0,8 [0,3; 2,1]	0,6392	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Physisches Funktionsniveau; ECOG Performance-Status							
0	30/56 (53,6)	9,4 [4,2; 13,8]	30/52 (57,7)	4,6 [3,3; 5,5]	0,6 [0,4; 1,1]	0,0960	0,6731
1	55/104 (52,9)	5,6 [4,2; 9,3]	43/78 (55,1)	3,0 [2,0; 5,6]	0,5 [0,4; 0,8]	0,0051	
QLQ-C30 Physisches Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	68/133 (51,1)	8,3 [5,2; 12,5]	60/108 (55,6)	4,4 [2,8; 5,5]	0,6 [0,4; 0,8]	0,0017	0,5961
Ja	17/27 (63,0)	3,6 [3,0; 6,1]	13/22 (59,1)	2,8 [1,4; 4,9]	0,5 [0,2; 1,4]	0,1732	
QLQ-C30 Physisches Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	49/86 (57,0)	7,0 [4,3; 13,1]	47/78 (60,3)	3,7 [2,3; 5,0]	0,6 [0,4; 0,9]	0,0072	0,9438
Ja	36/74 (48,6)	5,8 [3,6; 10,4]	26/52 (50,0)	3,7 [2,8; 8,7]	0,5 [0,3; 0,9]	0,0201	
QLQ-C30 Physisches Funktionsniveau; PD-L1-Proteinexpression							
<1%	32/53 (60,4)	5,8 [4,2; 13,1]	24/43 (55,8)	3,5 [1,4; n.b.]	0,5 [0,3; 0,9]	0,0140	0,2649
≥1% und <50%	26/43 (60,5)	7,0 [2,1; 12,5]	23/50 (46,0)	4,4 [3,0; 5,5]	0,8 [0,4; 1,6]	0,5801	
≥50%	25/57 (43,9)	5,8 [4,2; 13,1]	21/29 (72,4)	3,7 [1,6; 5,6]	0,5 [0,2; 0,9]	0,0149	
QLQ-C30 Physisches Funktionsniveau; Ethnie-2							
Asiatisch	13/21 (61,9)	5,6 [3,0; 9,3]	9/18 (50,0)	2,8 [0,7; n.b.]	0,6 [0,2; 1,6]	0,3092	0,5011
Nicht asiatisch	71/138 (51,4)	7,0 [4,6; 12,5]	63/111 (56,8)	3,7 [3,0; 4,9]	0,6 [0,4; 0,8]	0,0024	
QLQ-C30 Physisches Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	54/106 (50,9)	6,3 [4,3; 12,5]	55/91 (60,4)	3,7 [2,3; 5,0]	0,5 [0,4; 0,8]	0,0010	0,4937
Ja	31/54 (57,4)	5,9 [3,6; 11,0]	18/39 (46,2)	4,9 [2,8; n.b.]	0,6 [0,3; 1,1]	0,1156	
QLQ-C30 Physisches Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	34/70 (48,6)	9,1 [3,4; 13,1]	29/60 (48,3)	4,9 [1,9; 10,0]	0,7 [0,4; 1,1]	0,1302	0,9424
2	34/62 (54,8)	6,3 [4,7; 13,1]	31/50 (62,0)	3,7 [2,8; 4,9]	0,5 [0,3; 0,8]	0,0053	
>2	17/28 (60,7)	4,6 [3,5; 5,9]	13/20 (65,0)	3,7 [1,6; 5,5]	0,6 [0,3; 1,3]	0,1986	
QLQ-C30 Rollen-Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	58/84 (69,0)	2,4 [1,4; 3,4]	48/70 (68,6)	2,1 [1,5; 2,8]	0,8 [0,5; 1,3]	0,3652	0,1019
≥65 Jahre	49/76 (64,5)	4,2 [2,8; 8,3]	41/60 (68,3)	2,0 [1,4; 3,0]	0,5 [0,3; 0,8]	0,0037	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Rollen-Funktionsniveau; Geschlecht							
Weiblich	40/58 (69,0)	2,3 [1,4; 3,3]	37/53 (69,8)	1,6 [1,4; 2,7]	0,7 [0,4; 1,2]	0,1842	0,7419
Männlich	67/102 (65,7)	3,7 [2,8; 6,9]	52/77 (67,5)	2,8 [1,5; 3,0]	0,6 [0,4; 0,9]	0,0112	
QLQ-C30 Rollen-Funktionsniveau; Region 2							
Nordamerika und Europa	87/135 (64,4)	3,2 [2,2; 5,8]	78/111 (70,3)	2,1 [1,5; 2,8]	0,6 [0,4; 0,9]	0,0043	0,5638
Rest der Welt	20/25 (80,0)	2,8 [0,8; 4,8]	11/19 (57,9)	1,9 [0,8; n.b.]	0,9 [0,4; 2,1]	0,8171	
QLQ-C30 Rollen-Funktionsniveau; Region 1							
Nordamerika	10/17 (58,8)	3,7 [0,7; n.b.]	10/16 (62,5)	2,8 [0,7; 10,0]	0,9 [0,3; 2,6]	0,8079	0,6696
Europa	77/118 (65,3)	3,2 [2,2; 6,2]	68/95 (71,6)	2,1 [1,5; 2,8]	0,6 [0,4; 0,8]	0,0032	
Rest der Welt	20/25 (80,0)	2,8 [0,8; 4,8]	11/19 (57,9)	1,9 [0,8; n.b.]	0,9 [0,4; 2,1]	0,8171	
QLQ-C30 Rollen-Funktionsniveau; ECOG Performance-Status							
0	37/56 (66,1)	4,9 [2,3; 9,7]	35/52 (67,3)	2,8 [1,4; 3,3]	0,5 [0,3; 0,9]	0,0210	0,7636
1	70/104 (67,3)	2,8 [2,1; 3,6]	54/78 (69,2)	1,7 [1,4; 2,8]	0,7 [0,5; 1,0]	0,0755	
QLQ-C30 Rollen-Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	87/133 (65,4)	3,0 [2,2; 5,8]	74/108 (68,5)	2,3 [1,5; 2,8]	0,6 [0,5; 0,9]	0,0098	0,9054
Ja	20/27 (74,1)	3,3 [1,4; 4,8]	15/22 (68,2)	1,6 [0,8; 4,9]	0,6 [0,3; 1,4]	0,2518	
QLQ-C30 Rollen-Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	63/86 (73,3)	3,0 [2,1; 5,8]	55/78 (70,5)	1,9 [1,5; 2,8]	0,7 [0,4; 1,0]	0,0496	0,6252
Ja	44/74 (59,5)	3,2 [2,1; 5,8]	34/52 (65,4)	2,7 [1,4; 3,5]	0,6 [0,4; 1,0]	0,0626	
QLQ-C30 Rollen-Funktionsniveau; PD-L1-Proteinexpression							
<1%	39/53 (73,6)	3,2 [2,1; 5,8]	31/43 (72,1)	1,5 [0,8; 2,8]	0,6 [0,4; 1,0]	0,0516	0,4734
≥1% und <50%	31/43 (72,1)	1,9 [0,8; 3,5]	31/50 (62,0)	2,0 [1,6; 3,0]	0,8 [0,5; 1,4]	0,4523	
≥50%	32/57 (56,1)	3,6 [2,7; 9,0]	21/29 (72,4)	3,3 [1,4; 4,9]	0,5 [0,2; 0,9]	0,0141	
QLQ-C30 Rollen-Funktionsniveau; Ethnie-2							
Asiatisch	16/21 (76,2)	2,8 [0,7; 4,9]	9/18 (50,0)	4,9 [0,8; n.b.]	1,3 [0,6; 3,1]	0,5409	0,0670
Nicht asiatisch	91/138 (65,9)	3,2 [2,2; 4,9]	79/111 (71,2)	2,0 [1,5; 2,8]	0,6 [0,4; 0,8]	0,0019	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Rollen-Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	69/106 (65,1)	3,2 [2,2; 5,8]	68/91 (74,7)	1,9 [1,4; 2,8]	0,5 [0,4; 0,8]	0,0005	0,1001
Ja	38/54 (70,4)	2,8 [1,4; 9,1]	21/39 (53,8)	3,0 [1,6; 5,6]	1,0 [0,6; 1,7]	0,9452	
QLQ-C30 Rollen-Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	43/70 (61,4)	2,8 [2,1; 4,9]	38/60 (63,3)	2,1 [1,5; 2,8]	0,8 [0,5; 1,3]	0,3964	0,4299
2	41/62 (66,1)	4,9 [2,8; 9,0]	36/50 (72,0)	1,5 [1,4; 3,5]	0,5 [0,3; 0,8]	0,0022	
>2	23/28 (82,1)	2,2 [1,4; 4,2]	15/20 (75,0)	2,7 [0,7; 3,3]	0,7 [0,4; 1,5]	0,3982	
QLQ-C30 Emotionales Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	53/84 (63,1)	3,2 [2,4; 5,6]	32/70 (45,7)	5,5 [3,0; 12,7]	1,3 [0,8; 2,1]	0,2545	0,0187
≥65 Jahre	35/76 (46,1)	6,9 [5,8; 14,0]	28/60 (46,7)	4,9 [2,3; n.b.]	0,6 [0,4; 1,1]	0,1336	
QLQ-C30 Emotionales Funktionsniveau; Geschlecht							
Weiblich	34/58 (58,6)	5,1 [2,8; 10,2]	23/53 (43,4)	5,8 [3,0; n.b.]	1,0 [0,6; 1,8]	0,9283	0,0960
Männlich	54/102 (52,9)	6,1 [3,7; 9,3]	37/77 (48,1)	5,0 [2,8; n.b.]	0,7 [0,4; 1,1]	0,0815	
QLQ-C30 Emotionales Funktionsniveau; Region 2							
Nordamerika und Europa	73/135 (54,1)	5,6 [3,4; 8,4]	53/111 (47,7)	5,1 [3,0; 7,4]	0,9 [0,6; 1,3]	0,6366	0,9023
Rest der Welt	15/25 (60,0)	6,9 [2,9; 9,6]	7/19 (36,8)	n.b. [1,3; n.b.]	0,8 [0,3; 2,5]	0,7166	
QLQ-C30 Emotionales Funktionsniveau; Region 1							
Nordamerika	6/17 (35,3)	n.b. [3,7; n.b.]	5/16 (31,3)	n.b. [5,6; n.b.]	2,8 [0,5; 14,9]	0,2122	0,9758
Europa	67/118 (56,8)	4,2 [3,1; 6,9]	48/95 (50,5)	4,9 [2,8; 6,9]	0,9 [0,6; 1,3]	0,5660	
Rest der Welt	15/25 (60,0)	6,9 [2,9; 9,6]	7/19 (36,8)	n.b. [1,3; n.b.]	0,8 [0,3; 2,5]	0,7166	
QLQ-C30 Emotionales Funktionsniveau; ECOG Performance-Status							
0	29/56 (51,8)	6,9 [3,9; n.b.]	30/52 (57,7)	4,2 [2,1; 7,4]	0,5 [0,3; 0,9]	0,0248	0,0256
1	59/104 (56,7)	5,1 [3,2; 6,9]	30/78 (38,5)	5,8 [2,8; n.b.]	1,2 [0,8; 2,0]	0,3450	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Emotionales Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	72/133 (54,1)	6,3 [3,7; 9,3]	48/108 (44,4)	5,5 [3,3; n.b.]	0,9 [0,6; 1,3]	0,4734	0,9505
Ja	16/27 (59,3)	3,6 [2,9; 11,1]	12/22 (54,5)	2,8 [1,4; n.b.]	0,6 [0,2; 1,7]	0,3628	
QLQ-C30 Emotionales Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	49/86 (57,0)	6,9 [3,3; 9,6]	32/78 (41,0)	6,9 [4,9; 12,7]	1,0 [0,6; 1,6]	0,9692	0,2315
Ja	39/74 (52,7)	4,2 [3,4; 6,9]	28/52 (53,8)	2,8 [1,9; 5,8]	0,6 [0,4; 1,1]	0,0757	
QLQ-C30 Emotionales Funktionsniveau; PD-L1-Proteinexpression							
<1%	31/53 (58,5)	4,2 [2,8; 14,0]	17/43 (39,5)	6,9 [3,3; n.b.]	1,4 [0,7; 2,6]	0,3085	0,2025
≥1% und <50%	28/43 (65,1)	5,6 [2,1; 8,4]	21/50 (42,0)	5,8 [2,4; 12,7]	1,0 [0,5; 1,8]	0,9998	
≥50%	26/57 (45,6)	6,7 [3,5; 18,0]	17/29 (58,6)	3,3 [2,3; n.b.]	0,5 [0,3; 1,1]	0,0934	
QLQ-C30 Emotionales Funktionsniveau; Ethnie-2							
Asiatisch	13/21 (61,9)	6,9 [1,8; 9,6]	8/18 (44,4)	2,8 [1,4; n.b.]	0,9 [0,3; 2,3]	0,7455	0,9701
Nicht asiatisch	75/138 (54,3)	5,8 [3,5; 8,4]	51/111 (45,9)	5,1 [3,3; 7,4]	0,9 [0,6; 1,3]	0,5973	
QLQ-C30 Emotionales Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	51/106 (48,1)	6,1 [3,4; 9,3]	43/91 (47,3)	5,0 [2,8; n.b.]	0,8 [0,5; 1,2]	0,2142	0,3612
Ja	37/54 (68,5)	4,2 [2,1; 9,6]	17/39 (43,6)	5,8 [2,8; n.b.]	1,1 [0,6; 2,0]	0,7561	
QLQ-C30 Emotionales Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	41/70 (58,6)	4,2 [2,9; 8,4]	24/60 (40,0)	7,4 [2,8; n.b.]	1,1 [0,7; 1,9]	0,6982	0,4729
2	28/62 (45,2)	9,6 [3,9; n.b.]	23/50 (46,0)	5,1 [3,3; 12,7]	0,8 [0,5; 1,4]	0,4375	
>2	19/28 (67,9)	4,1 [2,8; 6,9]	13/20 (65,0)	3,0 [1,4; 5,8]	0,5 [0,2; 1,1]	0,0978	
QLQ-C30 Kognitives Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	53/84 (63,1)	3,4 [2,2; 6,9]	41/70 (58,6)	2,8 [2,1; 4,9]	0,8 [0,5; 1,3]	0,4184	0,2910
≥65 Jahre	39/76 (51,3)	5,6 [3,4; 6,3]	36/60 (60,0)	2,8 [1,4; 6,1]	0,6 [0,4; 1,0]	0,0387	
QLQ-C30 Kognitives Funktionsniveau; Geschlecht							
Weiblich	34/58 (58,6)	4,4 [2,4; 9,4]	31/53 (58,5)	2,8 [1,6; 7,4]	0,8 [0,5; 1,5]	0,5415	0,5994
Männlich	58/102 (56,9)	4,8 [2,8; 6,2]	46/77 (59,7)	2,7 [1,5; 4,9]	0,6 [0,4; 0,9]	0,0172	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Kognitives Funktionsniveau; Region 2							
Nordamerika und Europa	77/135 (57,0)	4,5 [3,2; 6,9]	66/111 (59,5)	2,8 [2,1; 4,9]	0,7 [0,5; 1,0]	0,0666	0,9068
Rest der Welt	15/25 (60,0)	4,7 [1,4; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,7]	0,3659	
QLQ-C30 Kognitives Funktionsniveau; Region 1							
Nordamerika	8/17 (47,1)	6,1 [1,9; n.b.]	11/16 (68,8)	6,1 [1,4; 7,9]	0,4 [0,1; 1,4]	0,1311	0,9586
Europa	69/118 (58,5)	4,2 [2,8; 6,9]	55/95 (57,9)	2,8 [2,1; 4,6]	0,7 [0,5; 1,0]	0,0712	
Rest der Welt	15/25 (60,0)	4,7 [1,4; 6,1]	11/19 (57,9)	1,5 [0,8; n.b.]	0,7 [0,3; 1,7]	0,3659	
QLQ-C30 Kognitives Funktionsniveau; ECOG Performance-Status							
0	27/56 (48,2)	6,9 [3,4; n.b.]	33/52 (63,5)	2,8 [1,5; 4,9]	0,5 [0,3; 0,9]	0,0133	0,1862
1	65/104 (62,5)	3,4 [2,4; 5,6]	44/78 (56,4)	2,8 [1,6; 5,1]	0,8 [0,5; 1,2]	0,3186	
QLQ-C30 Kognitives Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	75/133 (56,4)	4,5 [2,4; 6,3]	61/108 (56,5)	3,5 [2,1; 5,1]	0,8 [0,6; 1,1]	0,2318	0,1924
Ja	17/27 (63,0)	5,6 [3,3; 9,1]	16/22 (72,7)	1,5 [0,9; 2,8]	0,1 [0,0; 0,5]	0,0007	
QLQ-C30 Kognitives Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	50/86 (58,1)	3,5 [2,1; 6,3]	44/78 (56,4)	3,2 [2,1; 6,1]	0,8 [0,5; 1,3]	0,4174	0,2527
Ja	42/74 (56,8)	5,6 [3,2; 7,1]	33/52 (63,5)	2,1 [1,4; 3,7]	0,6 [0,4; 1,0]	0,0339	
QLQ-C30 Kognitives Funktionsniveau; PD-L1-Proteinexpression							
<1%	30/53 (56,6)	3,4 [2,1; 10,4]	30/43 (69,8)	2,8 [1,4; 3,5]	0,6 [0,3; 1,0]	0,0299	0,4113
≥1% und <50%	26/43 (60,5)	4,9 [2,2; 7,1]	25/50 (50,0)	4,6 [1,7; 7,9]	0,6 [0,3; 1,1]	0,1172	
≥50%	31/57 (54,4)	4,7 [1,8; 9,4]	16/29 (55,2)	4,9 [0,8; n.b.]	0,9 [0,5; 1,8]	0,8548	
QLQ-C30 Kognitives Funktionsniveau; Ethnie-2							
Asiatisch	13/21 (61,9)	4,7 [1,4; 6,1]	13/18 (72,2)	1,4 [0,7; 2,8]	0,6 [0,2; 1,3]	0,1902	0,6006
Nicht asiatisch	79/138 (57,2)	4,5 [2,8; 6,9]	63/111 (56,8)	3,2 [2,1; 5,0]	0,8 [0,5; 1,1]	0,1011	
QLQ-C30 Kognitives Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	56/106 (52,8)	4,8 [3,2; 9,0]	57/91 (62,6)	2,8 [1,6; 3,7]	0,6 [0,4; 0,9]	0,0189	0,1645
Ja	36/54 (66,7)	4,5 [2,1; 6,1]	20/39 (51,3)	3,5 [1,5; 7,9]	0,8 [0,5; 1,5]	0,5352	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Kognitives Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	38/70 (54,3)	4,8 [2,4; 9,1]	35/60 (58,3)	2,8 [1,4; 6,2]	0,7 [0,4; 1,1]	0,0855	0,3448
2	32/62 (51,6)	6,2 [4,4; 18,0]	29/50 (58,0)	3,5 [2,1; 5,1]	0,6 [0,3; 1,0]	0,0505	
>2	22/28 (78,6)	2,1 [1,4; 3,5]	13/20 (65,0)	2,1 [1,4; 7,9]	1,2 [0,6; 2,4]	0,6599	
QLQ-C30 Soziales Funktionsniveau; Alter bei Studienbeginn							
<65 Jahre	58/84 (69,0)	3,5 [2,1; 5,8]	52/70 (74,3)	1,4 [1,4; 2,6]	0,6 [0,4; 0,9]	0,0068	0,4193
≥65 Jahre	48/76 (63,2)	3,9 [2,8; 6,2]	35/60 (58,3)	3,3 [1,6; 6,0]	0,8 [0,5; 1,3]	0,4168	
QLQ-C30 Soziales Funktionsniveau; Geschlecht							
Weiblich	37/58 (63,8)	3,4 [1,5; 12,5]	38/53 (71,7)	2,1 [0,8; 2,8]	0,6 [0,4; 1,0]	0,0503	0,9735
Männlich	69/102 (67,6)	4,1 [3,0; 5,8]	49/77 (63,6)	2,1 [1,4; 3,4]	0,5 [0,4; 0,8]	0,0028	
QLQ-C30 Soziales Funktionsniveau; Region 2							
Nordamerika und Europa	86/135 (63,7)	4,5 [3,2; 6,2]	78/111 (70,3)	1,7 [1,4; 2,8]	0,5 [0,4; 0,8]	0,0002	0,0467
Rest der Welt	20/25 (80,0)	2,8 [1,4; 4,9]	9/19 (47,4)	6,0 [1,4; n.b.]	1,2 [0,5; 2,9]	0,6918	
QLQ-C30 Soziales Funktionsniveau; Region 1							
Nordamerika	9/17 (52,9)	6,1 [1,9; n.b.]	10/16 (62,5)	3,0 [0,8; n.b.]	0,6 [0,2; 1,8]	0,3504	0,1280
Europa	77/118 (65,3)	4,5 [2,8; 6,3]	68/95 (71,6)	1,7 [1,4; 2,8]	0,5 [0,4; 0,8]	0,0005	
Rest der Welt	20/25 (80,0)	2,8 [1,4; 4,9]	9/19 (47,4)	6,0 [1,4; n.b.]	1,2 [0,5; 2,9]	0,6918	
QLQ-C30 Soziales Funktionsniveau; ECOG Performance-Status							
0	34/56 (60,7)	6,2 [3,5; 10,3]	35/52 (67,3)	1,5 [1,4; 5,6]	0,4 [0,3; 0,7]	0,0011	0,2902
1	72/104 (69,2)	3,3 [2,1; 4,1]	52/78 (66,7)	2,1 [1,4; 2,8]	0,7 [0,5; 1,0]	0,0613	
QLQ-C30 Soziales Funktionsniveau; Lebermetastasen bei Studienbeginn							
Nein	86/133 (64,7)	4,1 [2,8; 6,2]	70/108 (64,8)	2,6 [1,5; 3,4]	0,6 [0,4; 0,9]	0,0049	0,7963
Ja	20/27 (74,1)	3,4 [2,1; 6,1]	17/22 (77,3)	1,4 [0,7; 2,8]	0,3 [0,1; 0,9]	0,0212	
QLQ-C30 Soziales Funktionsniveau; Knochenmetastasen bei Studienbeginn							
Nein	58/86 (67,4)	4,1 [2,7; 7,5]	47/78 (60,3)	2,8 [1,7; 6,2]	0,7 [0,5; 1,1]	0,1377	0,0326
Ja	48/74 (64,9)	3,4 [2,4; 5,5]	40/52 (76,9)	1,4 [0,8; 2,1]	0,3 [0,2; 0,6]	<,0001	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
QLQ-C30 Soziales Funktionsniveau; PD-L1-Proteinexpression							
<1%	38/53 (71,7)	5,0 [3,4; 8,3]	29/43 (67,4)	2,6 [1,4; 5,6]	0,5 [0,3; 0,9]	0,0193	0,8761
≥1% und <50%	29/43 (67,4)	2,7 [2,0; 6,2]	33/50 (66,0)	1,7 [1,4; 2,8]	0,6 [0,3; 1,1]	0,0893	
≥50%	36/57 (63,2)	3,6 [2,1; 7,5]	20/29 (69,0)	2,1 [0,7; 6,2]	0,7 [0,4; 1,3]	0,3126	
QLQ-C30 Soziales Funktionsniveau; Ethnie-2							
Asiatisch	18/21 (85,7)	2,1 [1,4; 4,1]	9/18 (50,0)	6,0 [0,8; n.b.]	1,3 [0,5; 3,2]	0,5403	0,0035
Nicht asiatisch	87/138 (63,0)	4,5 [3,3; 6,3]	77/111 (69,4)	2,1 [1,4; 2,8]	0,5 [0,4; 0,8]	0,0002	
QLQ-C30 Soziales Funktionsniveau; Vorgeschichte einer Beteiligung des ZNS							
Nein	66/106 (62,3)	3,5 [2,7; 6,1]	63/91 (69,2)	2,1 [1,4; 2,8]	0,6 [0,4; 0,8]	0,0024	0,5849
Ja	40/54 (74,1)	3,6 [2,7; 8,3]	24/39 (61,5)	3,0 [1,4; 6,0]	0,6 [0,4; 1,1]	0,1182	
QLQ-C30 Soziales Funktionsniveau; Anzahl an vorherigen Therapielinien							
1	45/70 (64,3)	3,4 [2,4; 6,1]	39/60 (65,0)	2,6 [1,4; 5,6]	0,7 [0,4; 1,0]	0,0761	0,8305
2	40/62 (64,5)	5,8 [2,7; 9,7]	35/50 (70,0)	2,1 [1,4; 3,3]	0,5 [0,3; 0,8]	0,0071	
>2	21/28 (75,0)	3,4 [1,4; 6,2]	13/20 (65,0)	1,4 [0,7; 4,9]	0,7 [0,4; 1,5]	0,4024	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; QLQ-C30 = Quality of Life Questionnaire Core 30; ZNS = Zentrales Nervensystem

4 Sicherheit

4.1 Unerwünschte Ereignisse

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first TEAE							
Overall	148/151 (98.0)	0.16 (0.13, 0.20)	166/169 (98.2)	0.72 (0.49, 0.82)		0.540 (0.428, 0.682)	< 0.001
Age - at baseline (years)					0.70		
< 65	83/85 (97.6)	0.16 (0.10, 0.20)	89/91 (97.8)	0.49 (0.26, 0.72)		0.532 (0.393, 0.719)	< 0.001
≥ 65	65/66 (98.5)	0.16 (0.13, 0.23)	77/78 (98.7)	0.90 (0.62, 1.25)		0.558 (0.390, 0.799)	< 0.001

Page 1 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.97		
Male	85/86 (98.8)	0.20 (0.13, 0.23)	106/107 (99.1)	0.72 (0.49, 1.12)		0.545 (0.404, 0.735)	< 0.001
Female	63/65 (96.9)	0.13 (0.10, 0.16)	60/62 (96.8)	0.66 (0.26, 0.79)		0.546 (0.373, 0.799)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.021		
Asian	19/19 (100.0)	0.07 (0.03, 0.13)	21/21 (100.0)	0.46 (0.16, 0.89)		0.222 (0.099, 0.498)	< 0.001
Non-Asian	128/131 (97.7)	0.20 (0.13, 0.23)	144/147 (98.0)	0.72 (0.59, 0.92)		0.577 (0.451, 0.739)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.060		
North America	18/19 (94.7)	0.16 (0.07, 0.23)	20/20 (100.0)	0.25 (0.10, 0.72)		0.673 (0.349, 1.297)	0.23
Europe	108/110 (98.2)	0.20 (0.13, 0.23)	121/124 (97.6)	0.72 (0.62, 0.95)		0.560 (0.429, 0.731)	< 0.001
Rest of world	22/22 (100.0)	0.13 (0.07, 0.16)	25/25 (100.0)	0.72 (0.16, 1.41)		0.272 (0.141, 0.524)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.031		
North America and Europe	126/129 (97.7)	0.16 (0.13, 0.23)	141/144 (97.9)	0.72 (0.43, 0.89)		0.578 (0.451, 0.740)	< 0.001
Rest of world	22/22 (100.0)	0.13 (0.07, 0.16)	25/25 (100.0)	0.72 (0.16, 1.41)		0.272 (0.141, 0.524)	< 0.001
Baseline ECOG status (screening)					0.20		
0	52/53 (98.1)	0.20 (0.10, 0.43)	58/59 (98.3)	0.82 (0.69, 1.08)		0.665 (0.460, 0.961)	0.034
1	96/98 (98.0)	0.13 (0.10, 0.20)	108/110 (98.2)	0.62 (0.30, 0.76)		0.465 (0.335, 0.645)	< 0.001

Page 5 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.72		
1	66/67 (98.5)	0.16 (0.10, 0.23)	74/76 (97.4)	0.66 (0.26, 0.89)		0.567 (0.402, 0.800)	< 0.001
2	59/61 (96.7)	0.16 (0.10, 0.20)	63/64 (98.4)	0.77 (0.43, 1.08)		0.491 (0.330, 0.729)	< 0.001
> 2	23/23 (100.0)	0.16 (0.07, 0.30)	29/29 (100.0)	0.72 (0.23, 1.05)		0.596 (0.339, 1.049)	0.065

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.84		
Yes	48/50 (96.0)	0.16 (0.07, 0.23)	55/57 (96.5)	0.59 (0.26, 0.92)		0.547 (0.370, 0.808)	0.003
No	100/101 (99.0)	0.16 (0.10, 0.20)	111/112 (99.1)	0.72 (0.62, 0.92)		0.538 (0.402, 0.721)	< 0.001
Liver metastasis					0.052		
Yes	28/28 (100.0)	0.15 (0.07, 0.20)	29/30 (96.7)	0.43 (0.20, 1.41)		0.319 (0.185, 0.547)	< 0.001
No	120/123 (97.6)	0.16 (0.13, 0.23)	137/139 (98.6)	0.72 (0.59, 0.92)		0.587 (0.455, 0.758)	< 0.001

Page 7 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.61		
Yes	59/61 (96.7)	0.13 (0.10, 0.20)	79/80 (98.8)	0.64 (0.30, 1.08)		0.585 (0.405, 0.844)	0.003
No	89/90 (98.9)	0.16 (0.10, 0.23)	87/89 (97.8)	0.72 (0.49, 0.92)		0.508 (0.372, 0.694)	< 0.001

Page 8 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

Table 14-6.2.501. Summary of Time to First Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.37		
< 1%	47/47 (100.0)	0.13 (0.10, 0.20)	55/55 (100.0)	0.66 (0.26, 0.79)		0.476 (0.307, 0.740)	< 0.001
≥ 1% and < 50%	59/61 (96.7)	0.20 (0.10, 0.26)	46/46 (100.0)	0.72 (0.23, 1.08)		0.623 (0.425, 0.914)	0.019
≥ 50%	34/34 (100.0)	0.16 (0.07, 0.20)	58/60 (96.7)	0.74 (0.43, 1.25)		0.382 (0.223, 0.652)	< 0.001

Page 9 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-501-teae-sum.rtf (Date Generated: 28SEP22:02:12:01) Source: adam.adsl, adam.adtts

4.2 Schwere UE (CTCAE Grad ≥ 3)

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 TEAE							
Overall	91/151 (60.3)	2.96 (1.38, 4.14)	121/169 (71.6)	3.02 (2.10, 3.94)		0.846 (0.642, 1.116)	0.24
Age - at baseline (years)					0.46		
< 65	49/85 (57.6)	3.68 (0.99, 4.27)	67/91 (73.6)	2.86 (1.64, 3.91)		0.957 (0.659, 1.388)	0.83
≥ 65	42/66 (63.6)	2.50 (1.12, 4.47)	54/78 (69.2)	3.35 (2.50, 6.21)		0.729 (0.483, 1.100)	0.13

Page 1 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.87		
Male	49/86 (57.0)	3.45 (1.74, 4.27)	76/107 (71.0)	3.12 (2.10, 6.57)		0.832 (0.574, 1.204)	0.33
Female	42/65 (64.6)	1.38 (0.72, 4.63)	45/62 (72.6)	2.66 (1.35, 3.98)		0.843 (0.556, 1.277)	0.43

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.28		
Asian	13/19 (68.4)	0.46 (0.23, NE)	14/21 (66.7)	2.89 (1.45, 9.10)		0.618 (0.291, 1.311)	0.23
Non-Asian	77/131 (58.8)	3.45 (1.61, 4.27)	107/147 (72.8)	3.02 (2.10, 3.98)		0.907 (0.673, 1.222)	0.52

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.29		
North America	12/19 (63.2)	1.28 (0.72, NE)	12/20 (60.0)	3.63 (1.28, NE)		0.711 (0.327, 1.546)	0.41
Europe	63/110 (57.3)	3.68 (1.68, 4.63)	92/124 (74.2)	3.02 (2.10, 3.94)		0.944 (0.681, 1.308)	0.73
Rest of world	16/22 (72.7)	0.66 (0.23, 2.99)	17/25 (68.0)	2.89 (1.51, 6.21)		0.564 (0.282, 1.128)	0.11

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.18		
North America and Europe	75/129 (58.1)	3.45 (1.61, 4.27)	104/144 (72.2)	3.06 (2.10, 3.98)		0.911 (0.674, 1.231)	0.55
Rest of world	16/22 (72.7)	0.66 (0.23, 2.99)	17/25 (68.0)	2.89 (1.51, 6.21)		0.564 (0.282, 1.128)	0.11
Baseline ECOG status (screening)					0.25		
0	28/53 (52.8)	4.17 (2.14, 15.18)	42/59 (71.2)	3.09 (2.04, 8.08)		1.056 (0.654, 1.705)	0.83
1	63/98 (64.3)	1.38 (0.72, 3.75)	79/110 (71.8)	2.89 (2.10, 3.98)		0.739 (0.527, 1.037)	0.079

Page 5 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.30		
1	35/67 (52.2)	2.96 (0.92, NE)	56/76 (73.7)	2.43 (1.54, 3.09)		1.112 (0.723, 1.710)	0.61
2	40/61 (65.6)	2.50 (0.99, 4.01)	44/64 (68.8)	4.01 (2.46, 7.46)		0.666 (0.433, 1.026)	0.068
> 2	16/23 (69.6)	2.14 (0.36, 4.63)	21/29 (72.4)	3.71 (1.25, 7.13)		0.743 (0.388, 1.423)	0.37

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.67		
Yes	24/50 (48.0)	4.17 (0.69, NE)	40/57 (70.2)	3.71 (2.10, 9.36)		0.924 (0.546, 1.565)	0.78
No	67/101 (66.3)	2.33 (1.28, 3.94)	81/112 (72.3)	2.66 (1.97, 3.91)		0.818 (0.592, 1.131)	0.23
Liver metastasis					0.15		
Yes	21/28 (75.0)	0.94 (0.59, 2.96)	22/30 (73.3)	3.02 (1.45, 4.37)		0.522 (0.280, 0.973)	0.041
No	70/123 (56.9)	3.75 (1.68, 4.63)	99/139 (71.2)	2.89 (2.10, 4.73)		0.931 (0.683, 1.269)	0.66

Page 7 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.88		
Yes	38/61 (62.3)	2.66 (0.66, 4.27)	58/80 (72.5)	2.14 (1.71, 3.12)		0.900 (0.589, 1.374)	0.62
No	53/90 (58.9)	2.96 (1.61, 4.47)	63/89 (70.8)	3.98 (2.66, 7.13)		0.778 (0.538, 1.126)	0.19

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

Table 14-6.2.502. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.43		
< 1%	31/47 (66.0)	2.99 (0.99, 4.47)	38/55 (69.1)	3.42 (2.10, 8.08)		0.707 (0.439, 1.137)	0.15
≥ 1% and < 50%	34/61 (55.7)	2.50 (0.85, NE)	39/46 (84.8)	1.86 (1.41, 2.89)		1.098 (0.690, 1.747)	0.69
≥ 50%	20/34 (58.8)	3.45 (0.89, 13.40)	39/60 (65.0)	3.42 (2.46, 6.21)		0.954 (0.546, 1.666)	0.87

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-502-teae-sum-grd3.rtf (Date Generated: 28SEP22:02:12:13) Source: adam.adsl, adam.adtts

4.3 Schwerwiegende UE

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious TEAE							
Overall	67/151 (44.4)	7.10 (3.45, NE)	91/169 (53.8)	8.84 (5.42, 12.45)		0.814 (0.589, 1.124)	0.22
Age - at baseline (years)					0.40		
< 65	37/85 (43.5)	6.87 (2.96, NE)	54/91 (59.3)	6.01 (3.02, 11.76)		0.974 (0.634, 1.496)	0.91
≥ 65	30/66 (45.5)	7.10 (2.66, NE)	37/78 (47.4)	9.86 (7.13, 15.77)		0.648 (0.399, 1.055)	0.087

Page 1 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.75		
Male	36/86 (41.9)	6.87 (2.96, NE)	56/107 (52.3)	9.76 (6.01, 15.34)		0.718 (0.462, 1.115)	0.14
Female	31/65 (47.7)	5.16 (1.68, NE)	35/62 (56.5)	7.46 (3.09, 15.77)		0.937 (0.579, 1.514)	0.79

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.10		
Asian	13/19 (68.4)	1.71 (0.23, 7.10)	12/21 (57.1)	4.86 (1.91, NE)		0.457 (0.210, 0.994)	0.060
Non-Asian	53/131 (40.5)	15.18 (4.83, NE)	79/147 (53.7)	8.84 (6.01, 14.03)		0.915 (0.641, 1.306)	0.63

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.20		
North America	7/19 (36.8)	NE (0.72, NE)	9/20 (45.0)	12.45 (1.35, NE)		1.043 (0.400, 2.719)	0.91
Europe	45/110 (40.9)	15.18 (4.34, NE)	68/124 (54.8)	8.80 (5.42, 14.03)		0.885 (0.600, 1.306)	0.54
Rest of world	15/22 (68.2)	1.56 (0.33, 7.10)	14/25 (56.0)	6.24 (3.32, NE)		0.450 (0.217, 0.932)	0.036

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.072		
North America and Europe	52/129 (40.3)	15.18 (4.83, NE)	77/144 (53.5)	8.84 (6.01, 14.55)		0.919 (0.642, 1.317)	0.65
Rest of world	15/22 (68.2)	1.56 (0.33, 7.10)	14/25 (56.0)	6.24 (3.32, NE)		0.450 (0.217, 0.932)	0.036
Baseline ECOG status (screening)					0.50		
0	18/53 (34.0)	15.18 (6.87, NE)	28/59 (47.5)	14.03 (8.80, NE)		0.814 (0.437, 1.516)	0.52
1	49/98 (50.0)	3.45 (1.41, NE)	63/110 (57.3)	6.01 (3.35, 9.76)		0.776 (0.530, 1.135)	0.20

Page 5 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.52		
1	28/67 (41.8)	15.18 (2.79, NE)	42/76 (55.3)	9.10 (3.35, 14.03)		0.916 (0.565, 1.486)	0.74
2	29/61 (47.5)	4.83 (2.43, NE)	32/64 (50.0)	9.86 (7.13, NE)		0.651 (0.388, 1.092)	0.11
> 2	10/23 (43.5)	5.16 (1.38, NE)	17/29 (58.6)	6.24 (2.10, NE)		1.080 (0.495, 2.358)	0.84

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.91		
Yes	22/50 (44.0)	4.83 (1.61, NE)	34/57 (59.6)	9.36 (3.71, 15.51)		0.726 (0.413, 1.275)	0.27
No	45/101 (44.6)	7.10 (2.96, NE)	57/112 (50.9)	8.80 (4.86, 14.55)		0.846 (0.571, 1.254)	0.42
Liver metastasis					0.027		
Yes	20/28 (71.4)	1.41 (1.12, 2.96)	16/30 (53.3)	8.84 (3.02, 15.51)		0.373 (0.186, 0.746)	0.005
No	47/123 (38.2)	15.18 (6.87, NE)	75/139 (54.0)	9.10 (6.01, 14.03)		0.979 (0.674, 1.421)	0.92

Page 7 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.94		
Yes	29/61 (47.5)	4.34 (1.71, NE)	44/80 (55.0)	8.02 (3.35, 15.51)		0.848 (0.524, 1.371)	0.50
No	38/90 (42.2)	7.10 (2.96, NE)	47/89 (52.8)	9.76 (6.01, 14.55)		0.752 (0.485, 1.166)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

Table 14-6.2.503. Summary of Time to First Serious Treatment Emergent Adverse Event (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.85		
< 1%	21/47 (44.7)	7.10 (3.68, NE)	30/55 (54.5)	9.86 (3.09, 18.60)		0.914 (0.520, 1.605)	0.76
≥ 1% and < 50%	26/61 (42.6)	NE (2.43, NE)	30/46 (65.2)	7.29 (2.56, 9.76)		0.934 (0.544, 1.604)	0.81
≥ 50%	16/34 (47.1)	NE (1.41, NE)	28/60 (46.7)	8.05 (4.86, 15.77)		0.710 (0.372, 1.358)	0.28

Page 9 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-503-teae-sum-ser.rtf (Date Generated: 28SEP22:02:12:21) Source: adam.adsl, adam.adtts

4.4 Abbruch der Studienmedikation aufgrund von UE

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first TEAE leading to discontinuation of treatment							
Overall	24/151 (15.9)	NE (13.40, NE)	28/169 (16.6)	NE (NE, NE)		0.790 (0.451, 1.386)	0.40
Age - at baseline (years)					0.51		
< 65	14/85 (16.5)	NE (9.03, NE)	18/91 (19.8)	NE (NE, NE)		0.921 (0.449, 1.891)	0.82
≥ 65	10/66 (15.2)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		0.638 (0.265, 1.536)	0.31

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.56		
Male	15/86 (17.4)	NE (9.03, NE)	17/107 (15.9)	NE (NE, NE)		0.644 (0.311, 1.333)	0.22
Female	9/65 (13.8)	NE (13.40, NE)	11/62 (17.7)	NE (NE, NE)		1.048 (0.435, 2.522)	0.92

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.51		
Asian	2/19 (10.5)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		0.419 (0.042, 4.145)	0.46
Non-Asian	22/131 (16.8)	NE (13.40, NE)	27/147 (18.4)	NE (NE, NE)		0.818 (0.458, 1.458)	0.49

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.26		
North America	2/19 (10.5)	NE (4.47, NE)	4/20 (20.0)	NE (3.65, NE)		1.622 (0.324, 8.112)	0.58
Europe	18/110 (16.4)	NE (9.03, NE)	23/124 (18.5)	NE (NE, NE)		0.832 (0.436, 1.588)	0.57
Rest of world	4/22 (18.2)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.192 (0.023, 1.597)	0.10

Page 4 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.14		
North America and Europe	20/129 (15.5)	NE (13.40, NE)	27/144 (18.8)	NE (NE, NE)		0.910 (0.502, 1.650)	0.75
Rest of world	4/22 (18.2)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.192 (0.023, 1.597)	0.10
Baseline ECOG status (screening)					0.41		
0	7/53 (13.2)	NE (9.03, NE)	10/59 (16.9)	NE (NE, NE)		1.137 (0.414, 3.123)	0.80
1	17/98 (17.3)	NE (13.40, NE)	18/110 (16.4)	NE (NE, NE)		0.654 (0.336, 1.273)	0.21

Page 5 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.77		
1	10/67 (14.9)	NE (9.03, NE)	14/76 (18.4)	NE (NE, NE)		1.027 (0.450, 2.344)	0.95
2	11/61 (18.0)	NE (13.40, NE)	11/64 (17.2)	NE (NE, NE)		0.652 (0.267, 1.593)	0.33
> 2	3/23 (13.0)	NE (NE, NE)	3/29 (10.3)	NE (NE, NE)		0.590 (0.139, 2.513)	0.52

Page 6 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.19		
Yes	8/50 (16.0)	NE (NE, NE)	6/57 (10.5)	NE (NE, NE)		0.447 (0.152, 1.314)	0.14
No	16/101 (15.8)	NE (13.40, NE)	22/112 (19.6)	NE (NE, NE)		0.993 (0.511, 1.930)	0.98
Liver metastasis					0.73		
Yes	5/28 (17.9)	NE (2.96, NE)	7/30 (23.3)	NE (16.03, NE)		0.979 (0.313, 3.067)	0.98
No	19/123 (15.4)	NE (13.40, NE)	21/139 (15.1)	NE (NE, NE)		0.753 (0.395, 1.435)	0.37

Page 7 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.49		
Yes	10/61 (16.4)	NE (13.40, NE)	16/80 (20.0)	NE (NE, NE)		0.943 (0.427, 2.083)	0.89
No	14/90 (15.6)	NE (9.03, NE)	12/89 (13.5)	NE (NE, NE)		0.643 (0.286, 1.445)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

Table 14-6.2.504. Summary of Time to First Treatment Emergent Adverse Event Leading to Discontinuation of Treatment (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.49		
< 1%	6/47 (12.8)	NE (NE, NE)	10/55 (18.2)	NE (NE, NE)		1.229 (0.448, 3.371)	0.69
≥ 1% and < 50%	10/61 (16.4)	NE (NE, NE)	11/46 (23.9)	NE (16.03, NE)		1.079 (0.461, 2.525)	0.86
≥ 50%	6/34 (17.6)	13.40 (9.03, NE)	6/60 (10.0)	NE (NE, NE)		0.445 (0.136, 1.458)	0.16

Page 9 of 9

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-504-teae-sum-disc.rtf (Date Generated: 28SEP22:02:12:28) Source: adam.adsl, adam.adtts

4.5 UE ohne Progressionsereignisse

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first TEAE excluding disease progression events							
Overall	148/151 (98.0)	0.16 (0.13, 0.20)	165/169 (97.6)	0.72 (0.49, 0.82)		0.533 (0.422, 0.673)	< 0.001

Page 1 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Age - at baseline (years)					0.60		
< 65	83/85 (97.6)	0.16 (0.10, 0.20)	88/91 (96.7)	0.49 (0.26, 0.72)		0.519 (0.384, 0.702)	< 0.001
≥ 65	65/66 (98.5)	0.16 (0.13, 0.23)	77/78 (98.7)	0.90 (0.62, 1.25)		0.558 (0.390, 0.799)	< 0.001

Page 2 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.97		
Male	85/86 (98.8)	0.20 (0.13, 0.23)	105/107 (98.1)	0.72 (0.49, 1.12)		0.537 (0.398, 0.724)	< 0.001
Female	63/65 (96.9)	0.13 (0.10, 0.16)	60/62 (96.8)	0.66 (0.26, 0.79)		0.537 (0.366, 0.786)	< 0.001

Page 3 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.024		
Asian	19/19 (100.0)	0.07 (0.03, 0.13)	21/21 (100.0)	0.46 (0.16, 0.89)		0.222 (0.099, 0.498)	< 0.001
Non-Asian	128/131 (97.7)	0.20 (0.13, 0.23)	143/147 (97.3)	0.72 (0.59, 0.92)		0.568 (0.444, 0.727)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.067		
North America	18/19 (94.7)	0.16 (0.07, 0.23)	20/20 (100.0)	0.25 (0.10, 0.72)		0.673 (0.349, 1.297)	0.23
Europe	108/110 (98.2)	0.20 (0.13, 0.23)	120/124 (96.8)	0.72 (0.62, 0.95)		0.549 (0.420, 0.717)	< 0.001
Rest of world	22/22 (100.0)	0.13 (0.07, 0.16)	25/25 (100.0)	0.72 (0.16, 1.41)		0.272 (0.141, 0.524)	< 0.001

Page 5 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.038		
North America and Europe	126/129 (97.7)	0.16 (0.13, 0.23)	140/144 (97.2)	0.72 (0.43, 0.89)		0.568 (0.443, 0.728)	< 0.001
Rest of world	22/22 (100.0)	0.13 (0.07, 0.16)	25/25 (100.0)	0.72 (0.16, 1.41)		0.272 (0.141, 0.524)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Baseline ECOG status (screening)					0.24		
0	52/53 (98.1)	0.20 (0.10, 0.43)	57/59 (96.6)	0.82 (0.69, 1.08)		0.644 (0.446, 0.930)	0.023
1	96/98 (98.0)	0.13 (0.10, 0.20)	108/110 (98.2)	0.62 (0.30, 0.76)		0.463 (0.333, 0.643)	< 0.001

Page 7 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.75		
1	66/67 (98.5)	0.16 (0.10, 0.23)	73/76 (96.1)	0.66 (0.26, 0.89)		0.541 (0.385, 0.759)	< 0.001
2	59/61 (96.7)	0.16 (0.10, 0.20)	63/64 (98.4)	0.77 (0.43, 1.08)		0.491 (0.330, 0.729)	< 0.001
> 2	23/23 (100.0)	0.16 (0.07, 0.30)	29/29 (100.0)	0.72 (0.23, 1.05)		0.596 (0.339, 1.049)	0.065

Page 8 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.85		
Yes	48/50 (96.0)	0.16 (0.07, 0.23)	55/57 (96.5)	0.59 (0.26, 0.92)		0.540 (0.365, 0.797)	0.002
No	100/101 (99.0)	0.16 (0.10, 0.20)	110/112 (98.2)	0.72 (0.62, 0.92)		0.531 (0.396, 0.711)	< 0.001

Page 9 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Liver metastasis					0.067		
Yes	28/28 (100.0)	0.15 (0.07, 0.20)	29/30 (96.7)	0.43 (0.20, 1.41)		0.319 (0.185, 0.547)	< 0.001
No	120/123 (97.6)	0.16 (0.13, 0.23)	136/139 (97.8)	0.72 (0.59, 0.92)		0.576 (0.446, 0.744)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.69		
Yes	59/61 (96.7)	0.13 (0.10, 0.20)	78/80 (97.5)	0.64 (0.30, 1.08)		0.566 (0.393, 0.817)	0.001
No	89/90 (98.9)	0.16 (0.10, 0.23)	87/89 (97.8)	0.72 (0.49, 0.92)		0.508 (0.372, 0.694)	< 0.001

Page 11 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

Table 14-6.2.514. Summary of Time to First Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.35		
< 1%	47/47 (100.0)	0.13 (0.10, 0.20)	54/55 (98.2)	0.66 (0.26, 0.79)		0.464 (0.300, 0.719)	< 0.001
≥ 1% and < 50%	59/61 (96.7)	0.20 (0.10, 0.26)	46/46 (100.0)	0.72 (0.23, 1.08)		0.623 (0.425, 0.914)	0.019
≥ 50%	34/34 (100.0)	0.16 (0.07, 0.20)	58/60 (96.7)	0.74 (0.43, 1.25)		0.382 (0.223, 0.652)	< 0.001

Page 12 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-514-teae-sum-excpd.rtf (Date Generated: 28SEP22:02:12:35) Source: adam.adsl, adam.adtts

4.6 Schwere UE (CTCAE Grad ≥ 3) ohne Progressionsereignisse

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 TEAE excluding disease progression events							
Overall	90/151 (59.6)	2.96 (1.38, 4.14)	114/169 (67.5)	3.35 (2.53, 4.73)		0.803 (0.606, 1.062)	0.13

Page 1 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Age - at baseline (years)					0.50		
< 65	48/85 (56.5)	3.68 (0.99, 8.54)	62/91 (68.1)	3.02 (2.10, 6.57)		0.900 (0.616, 1.316)	0.60
≥ 65	42/66 (63.6)	2.50 (1.12, 4.47)	52/78 (66.7)	3.48 (2.53, 6.21)		0.697 (0.461, 1.053)	0.084

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.61		
Male	48/86 (55.8)	3.94 (1.74, 4.47)	73/107 (68.2)	3.42 (2.50, 7.13)		0.818 (0.562, 1.191)	0.30
Female	42/65 (64.6)	1.38 (0.72, 4.63)	41/62 (66.1)	3.25 (1.71, 4.37)		0.755 (0.494, 1.152)	0.20

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.34		
Asian	13/19 (68.4)	0.46 (0.23, NE)	14/21 (66.7)	2.89 (1.45, 9.10)		0.618 (0.291, 1.311)	0.23
Non-Asian	76/131 (58.0)	3.68 (1.61, 4.47)	100/147 (68.0)	3.35 (2.50, 4.73)		0.853 (0.631, 1.155)	0.31

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.34		
North America	12/19 (63.2)	1.28 (0.72, NE)	11/20 (55.0)	4.37 (1.28, NE)		0.650 (0.295, 1.433)	0.31
Europe	62/110 (56.4)	3.68 (1.68, 5.68)	86/124 (69.4)	3.35 (2.43, 4.73)		0.891 (0.640, 1.241)	0.50
Rest of world	16/22 (72.7)	0.66 (0.23, 2.99)	17/25 (68.0)	2.89 (1.51, 6.21)		0.564 (0.282, 1.128)	0.11

Page 5 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.24		
North America and Europe	74/129 (57.4)	3.68 (1.61, 4.47)	97/144 (67.4)	3.35 (2.46, 4.73)		0.855 (0.629, 1.161)	0.32
Rest of world	16/22 (72.7)	0.66 (0.23, 2.99)	17/25 (68.0)	2.89 (1.51, 6.21)		0.564 (0.282, 1.128)	0.11

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Baseline ECOG status (screening)					0.32		
0	28/53 (52.8)	4.17 (2.14, 15.18)	39/59 (66.1)	3.55 (2.10, 9.86)		0.981 (0.604, 1.593)	0.94
1	62/98 (63.3)	1.38 (0.72, 3.75)	75/110 (68.2)	3.25 (2.50, 4.37)		0.710 (0.504, 1.000)	0.050

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.49		
1	35/67 (52.2)	2.96 (0.92, NE)	51/76 (67.1)	2.79 (1.97, 4.83)		1.001 (0.647, 1.546)	0.98
2	39/61 (63.9)	2.96 (0.99, 4.17)	44/64 (68.8)	4.01 (2.46, 7.46)		0.691 (0.448, 1.067)	0.100
> 2	16/23 (69.6)	2.14 (0.36, 4.63)	19/29 (65.5)	3.94 (1.71, 15.77)		0.665 (0.346, 1.279)	0.23

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.69		
Yes	24/50 (48.0)	4.17 (0.69, NE)	38/57 (66.7)	3.71 (2.73, 11.04)		0.873 (0.514, 1.482)	0.63
No	66/101 (65.3)	2.50 (1.28, 4.01)	76/112 (67.9)	3.02 (2.10, 4.73)		0.775 (0.557, 1.077)	0.13

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Liver metastasis					0.22		
Yes	21/28 (75.0)	0.94 (0.59, 2.96)	22/30 (73.3)	3.02 (1.45, 4.37)		0.522 (0.280, 0.973)	0.041
No	69/123 (56.1)	3.94 (1.68, 5.68)	92/139 (66.2)	3.42 (2.43, 6.21)		0.871 (0.635, 1.193)	0.40

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.92		
Yes	38/61 (62.3)	2.66 (0.66, 4.27)	55/80 (68.8)	2.56 (1.97, 3.42)		0.849 (0.555, 1.300)	0.45
No	52/90 (57.8)	3.45 (1.61, 5.68)	59/89 (66.3)	4.73 (2.73, 8.08)		0.739 (0.507, 1.077)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

Table 14-6.2.515. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.31		
< 1%	31/47 (66.0)	2.99 (0.99, 4.47)	34/55 (61.8)	3.94 (2.14, 9.86)		0.626 (0.385, 1.019)	0.061
≥ 1% and < 50%	34/61 (55.7)	2.50 (0.85, NE)	37/46 (80.4)	1.94 (1.41, 3.71)		1.033 (0.646, 1.653)	0.89
≥ 50%	19/34 (55.9)	3.75 (0.89, NE)	38/60 (63.3)	3.98 (2.66, 6.21)		0.996 (0.562, 1.765)	1.00

Page 12 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-515-teae-sum-grd3-excpd.rtf (Date Generated: 28SEP22:02:12:43) Source: adam.adsl, adam.adtts

4.7 Schwerwiegende UE ohne Progressionsereignisse

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious TEAE excluding disease progression events							
Overall	66/151 (43.7)	7.10 (3.68, NE)	82/169 (48.5)	9.86 (7.29, 15.34)		0.727 (0.522, 1.012)	0.061

Page 1 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Age - at baseline (years)					0.42		
< 65	36/85 (42.4)	6.87 (2.96, NE)	48/91 (52.7)	9.76 (4.01, 15.51)		0.873 (0.562, 1.357)	0.55
≥ 65	30/66 (45.5)	7.10 (2.66, NE)	34/78 (43.6)	10.28 (8.02, NE)		0.578 (0.352, 0.949)	0.033

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.83		
Male	35/86 (40.7)	7.10 (2.96, NE)	53/107 (49.5)	9.86 (7.13, 15.51)		0.682 (0.435, 1.071)	0.099
Female	31/65 (47.7)	5.16 (1.68, NE)	29/62 (46.8)	12.45 (4.01, NE)		0.754 (0.457, 1.244)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.11		
Asian	13/19 (68.4)	1.71 (0.23, 7.10)	11/21 (52.4)	9.10 (3.32, NE)		0.406 (0.183, 0.903)	0.035
Non-Asian	52/131 (39.7)	15.18 (4.83, NE)	71/147 (48.3)	10.28 (7.29, 15.51)		0.818 (0.568, 1.179)	0.29

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.23		
North America	7/19 (36.8)	NE (0.72, NE)	8/20 (40.0)	NE (1.35, NE)		0.927 (0.349, 2.463)	0.90
Europe	44/110 (40.0)	15.18 (4.34, NE)	61/124 (49.2)	9.86 (7.29, 15.51)		0.789 (0.529, 1.177)	0.25
Rest of world	15/22 (68.2)	1.56 (0.33, 7.10)	13/25 (52.0)	9.10 (3.32, NE)		0.411 (0.195, 0.864)	0.022

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.088		
North America and Europe	51/129 (39.5)	15.18 (4.83, NE)	69/144 (47.9)	10.28 (7.46, 15.51)		0.819 (0.566, 1.184)	0.29
Rest of world	15/22 (68.2)	1.56 (0.33, 7.10)	13/25 (52.0)	9.10 (3.32, NE)		0.411 (0.195, 0.864)	0.022

Page 6 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Baseline ECOG status (screening)					0.58		
0	18/53 (34.0)	15.18 (6.87, NE)	25/59 (42.4)	15.97 (9.86, NE)		0.714 (0.378, 1.349)	0.30
1	48/98 (49.0)	4.34 (1.41, NE)	57/110 (51.8)	7.13 (4.01, 12.45)		0.698 (0.473, 1.031)	0.074

Page 7 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.76		
1	28/67 (41.8)	15.18 (2.79, NE)	35/76 (46.1)	10.28 (5.13, 15.97)		0.733 (0.444, 1.209)	0.24
2	28/61 (45.9)	6.87 (2.50, NE)	31/64 (48.4)	9.86 (7.29, NE)		0.654 (0.387, 1.106)	0.12
> 2	10/23 (43.5)	5.16 (1.38, NE)	16/29 (55.2)	6.24 (2.56, NE)		0.980 (0.446, 2.152)	0.96

Page 8 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					1.00		
Yes	22/50 (44.0)	4.83 (1.61, NE)	32/57 (56.1)	11.04 (3.71, 15.77)		0.670 (0.380, 1.181)	0.17
No	44/101 (43.6)	7.10 (2.96, NE)	50/112 (44.6)	9.76 (7.13, NE)		0.739 (0.492, 1.109)	0.15

Page 9 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Liver metastasis					0.034		
Yes	20/28 (71.4)	1.41 (1.12, 2.96)	15/30 (50.0)	8.84 (3.19, 15.51)		0.333 (0.164, 0.679)	0.002
No	46/123 (37.4)	15.18 (6.87, NE)	67/139 (48.2)	10.28 (7.29, 15.97)		0.872 (0.595, 1.278)	0.49

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.91		
Yes	29/61 (47.5)	4.34 (1.71, NE)	39/80 (48.8)	10.28 (3.55, 15.97)		0.736 (0.451, 1.200)	0.22
No	37/90 (41.1)	7.10 (3.45, NE)	43/89 (48.3)	11.04 (7.29, 18.60)		0.689 (0.439, 1.081)	0.11

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

Table 14-6.2.516. Summary of Time to First Serious Treatment Emergent Adverse Event Excluding Disease Progression Events (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W KM Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD KM Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.93		
< 1%	21/47 (44.7)	7.10 (3.68, NE)	27/55 (49.1)	15.51 (3.48, NE)		0.803 (0.451, 1.430)	0.46
≥ 1% and < 50%	26/61 (42.6)	NE (2.43, NE)	27/46 (58.7)	8.84 (2.79, 14.03)		0.813 (0.466, 1.417)	0.48
≥ 50%	15/34 (44.1)	NE (1.41, NE)	25/60 (41.7)	10.28 (6.24, NE)		0.674 (0.344, 1.322)	0.23

Page 12 of 12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Disease progression events are defined as any preferred terms that contain the terms metastasis, metastases, metastatic, tumor pain, NSCLC, non-small cell lung cancer or adenocarcinoma of the lung.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-subgroup.sas
Output: t14-06-002-516-teae-sum-ser-excpd.rtf (Date Generated: 28SEP22:02:12:49) Source: adam.adsl, adam.adtts

4.8 UE von besonderem Interesse

4.8.1 Gesamtrate

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first hepatotoxicity TEAE							
Overall	14/151 (9.3)	NE (NE, NE)	46/169 (27.2)	NE (18.40, NE)		2.721 (1.483, 4.994)	< 0.001
Age - at baseline (years)					0.69		
< 65	6/85 (7.1)	NE (NE, NE)	22/91 (24.2)	NE (18.40, NE)		3.059 (1.236, 7.566)	0.011
≥ 65	8/66 (12.1)	NE (NE, NE)	24/78 (30.8)	NE (NE, NE)		2.439 (1.077, 5.519)	0.024

Page 1 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.64		
Male	10/86 (11.6)	NE (NE, NE)	32/107 (29.9)	18.40 (16.13, NE)		2.345 (1.131, 4.863)	0.017
Female	4/65 (6.2)	NE (NE, NE)	14/62 (22.6)	NE (NE, NE)		3.472 (1.144, 10.539)	0.019

Page 2 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.91		
Asian	3/19 (15.8)	NE (NE, NE)	9/21 (42.9)	16.13 (1.51, NE)		2.281 (0.590, 8.811)	0.21
Non-Asian	11/131 (8.4)	NE (NE, NE)	37/147 (25.2)	NE (18.40, NE)		2.804 (1.420, 5.537)	0.002

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	6/20 (30.0)	NE (2.33, NE)		NE (NE, NE)	-
Europe	10/110 (9.1)	NE (NE, NE)	29/124 (23.4)	NE (18.40, NE)		2.388 (1.154, 4.944)	0.015
Rest of world	4/22 (18.2)	NE (NE, NE)	11/25 (44.0)	16.13 (2.10, NE)		1.925 (0.600, 6.175)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.64		
North America and Europe	10/129 (7.8)	NE (NE, NE)	35/144 (24.3)	NE (18.40, NE)		2.974 (1.459, 6.059)	0.001
Rest of world	4/22 (18.2)	NE (NE, NE)	11/25 (44.0)	16.13 (2.10, NE)		1.925 (0.600, 6.175)	0.26
Baseline ECOG status (screening)					0.30		
0	5/53 (9.4)	NE (NE, NE)	22/59 (37.3)	18.40 (16.13, NE)		3.920 (1.436, 10.704)	0.003
1	9/98 (9.2)	NE (NE, NE)	24/110 (21.8)	NE (NE, NE)		2.044 (0.947, 4.409)	0.063

Page 5 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.13		
1	4/67 (6.0)	NE (NE, NE)	23/76 (30.3)	18.40 (16.13, NE)		5.190 (1.778, 15.151)	< 0.001
2	6/61 (9.8)	NE (NE, NE)	17/64 (26.6)	NE (NE, NE)		2.519 (0.984, 6.449)	0.044
> 2	4/23 (17.4)	NE (NE, NE)	6/29 (20.7)	NE (NE, NE)		0.930 (0.276, 3.135)	0.90

Page 6 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.92		
Yes	4/50 (8.0)	NE (NE, NE)	16/57 (28.1)	18.40 (16.13, NE)		2.718 (0.894, 8.264)	0.066
No	10/101 (9.9)	NE (NE, NE)	30/112 (26.8)	NE (NE, NE)		2.710 (1.313, 5.593)	0.005
Liver metastasis					0.12		
Yes	4/28 (14.3)	NE (NE, NE)	5/30 (16.7)	NE (NE, NE)		1.086 (0.298, 3.954)	0.90
No	10/123 (8.1)	NE (NE, NE)	41/139 (29.5)	NE (18.40, NE)		3.395 (1.682, 6.855)	< 0.001

Page 7 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.91		
Yes	6/61 (9.8)	NE (NE, NE)	22/80 (27.5)	NE (NE, NE)		2.647 (1.053, 6.651)	0.028
No	8/90 (8.9)	NE (NE, NE)	24/89 (27.0)	NE (18.40, NE)		2.708 (1.203, 6.094)	0.012

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.44		
< 1%	5/47 (10.6)	NE (NE, NE)	16/55 (29.1)	18.40 (18.40, NE)		2.705 (0.981, 7.457)	0.044
≥ 1% and < 50%	6/61 (9.8)	NE (NE, NE)	10/46 (21.7)	NE (16.13, NE)		1.836 (0.681, 4.951)	0.24
≥ 50%	1/34 (2.9)	NE (NE, NE)	15/60 (25.0)	NE (NE, NE)		8.895 (1.143, 69.222)	0.010

Page 9 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first pneumonitis TEAE							
Overall	4/151 (2.6)	NE (NE, NE)	4/169 (2.4)	NE (NE, NE)		0.696 (0.174, 2.789)	0.61
Age - at baseline (years)					–		
< 65	0/85 (0.0)		3/91 (3.3)				
≥ 65	4/66 (6.1)		1/78 (1.3)				

Page 10 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	2/86 (2.3)		3/107 (2.8)				
Female	2/65 (3.1)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		0/21 (0.0)				
Non-Asian	4/131 (3.1)		4/147 (2.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		0/20 (0.0)				
Europe	3/110 (2.7)		4/124 (3.2)				
Rest of world	0/22 (0.0)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	4/129 (3.1)		4/144 (2.8)				
Rest of world	0/22 (0.0)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	2/53 (3.8)		2/59 (3.4)				
1	2/98 (2.0)		2/110 (1.8)				

Page 14 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		2/76 (2.6)				
2	3/61 (4.9)		2/64 (3.1)				
> 2	0/23 (0.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		1/57 (1.8)				
No	4/101 (4.0)		3/112 (2.7)				
Liver metastasis					–		
Yes	1/28 (3.6)		1/30 (3.3)				
No	3/123 (2.4)		3/139 (2.2)				

Page 16 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	1/61 (1.6)		1/80 (1.3)				
No	3/90 (3.3)		3/89 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		3/55 (5.5)				
≥ 1% and < 50%	2/61 (3.3)		1/46 (2.2)				
≥ 50%	0/34 (0.0)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first renal toxicity TEAE							
Overall	18/151 (11.9)	NE (NE, NE)	31/169 (18.3)	NE (18.40, NE)		1.188 (0.674, 2.096)	0.56
Age - at baseline (years)					0.86		
< 65	10/85 (11.8)	NE (NE, NE)	16/91 (17.6)	18.40 (18.40, NE)		1.089 (0.509, 2.333)	0.83
≥ 65	8/66 (12.1)	NE (NE, NE)	15/78 (19.2)	NE (NE, NE)		1.291 (0.555, 3.001)	0.57

Page 19 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.54		
Male	11/86 (12.8)	NE (NE, NE)	19/107 (17.8)	NE (18.40, NE)		0.940 (0.449, 1.966)	0.87
Female	7/65 (10.8)	NE (NE, NE)	12/62 (19.4)	NE (NE, NE)		1.521 (0.609, 3.798)	0.37

Page 20 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.59		
Asian	4/19 (21.1)	NE (NE, NE)	5/21 (23.8)	NE (5.16, NE)		0.774 (0.205, 2.918)	0.72
Non-Asian	14/131 (10.7)	NE (NE, NE)	26/147 (17.7)	NE (18.40, NE)		1.287 (0.682, 2.430)	0.45

Page 21 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.30		
North America	4/19 (21.1)	NE (NE, NE)	7/20 (35.0)	NE (2.99, NE)		1.433 (0.431, 4.771)	0.56
Europe	9/110 (8.2)	NE (NE, NE)	20/124 (16.1)	NE (18.40, NE)		1.504 (0.695, 3.255)	0.31
Rest of world	5/22 (22.7)	NE (NE, NE)	4/25 (16.0)	NE (9.33, NE)		0.426 (0.112, 1.624)	0.23

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.13		
North America and Europe	13/129 (10.1)	NE (NE, NE)	27/144 (18.8)	NE (18.40, NE)		1.469 (0.768, 2.811)	0.25
Rest of world	5/22 (22.7)	NE (NE, NE)	4/25 (16.0)	NE (9.33, NE)		0.426 (0.112, 1.624)	0.23
Baseline ECOG status (screening)					0.87		
0	5/53 (9.4)	NE (NE, NE)	9/59 (15.3)	NE (18.40, NE)		1.218 (0.425, 3.492)	0.72
1	13/98 (13.3)	NE (NE, NE)	22/110 (20.0)	NE (NE, NE)		1.115 (0.569, 2.187)	0.76

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.49		
1	6/67 (9.0)	NE (NE, NE)	13/76 (17.1)	18.40 (18.40, NE)		1.649 (0.638, 4.264)	0.31
2	8/61 (13.1)	NE (NE, NE)	14/64 (21.9)	NE (NE, NE)		1.221 (0.525, 2.840)	0.66
> 2	4/23 (17.4)	NE (NE, NE)	4/29 (13.8)	NE (9.33, NE)		0.588 (0.150, 2.305)	0.47

Page 24 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.70		
Yes	5/50 (10.0)	NE (NE, NE)	12/57 (21.1)	NE (18.40, NE)		1.452 (0.519, 4.059)	0.49
No	13/101 (12.9)	NE (NE, NE)	19/112 (17.0)	NE (NE, NE)		1.067 (0.535, 2.128)	0.86
Liver metastasis					0.18		
Yes	5/28 (17.9)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)		0.557 (0.165, 1.885)	0.39
No	13/123 (10.6)	NE (NE, NE)	27/139 (19.4)	NE (18.40, NE)		1.435 (0.749, 2.749)	0.29

Page 25 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.29		
Yes	11/61 (18.0)	NE (NE, NE)	16/80 (20.0)	NE (11.07, NE)		0.836 (0.395, 1.769)	0.65
No	7/90 (7.8)	NE (NE, NE)	15/89 (16.9)	NE (18.40, NE)		1.647 (0.687, 3.949)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

Table 14-6.2.511. Summary of Time to First Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.11		
< 1%	2/47 (4.3)	NE (NE, NE)	12/55 (21.8)	18.40 (NE, NE)		4.730 (1.020, 21.927)	0.027
≥ 1% and < 50%	9/61 (14.8)	NE (NE, NE)	10/46 (21.7)	NE (11.07, NE)		1.022 (0.432, 2.418)	0.96
≥ 50%	6/34 (17.6)	NE (NE, NE)	9/60 (15.0)	NE (NE, NE)		0.745 (0.271, 2.049)	0.58

Page 27 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-511-teae-sum-eoi-cat.rtf (Date Generated: 28SEP22:02:13:40) Source: adam.adsl, adam.adtts

4.8.2 Schwere UE (CTCAE Grad ≥ 3)

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 hepatotoxicity TEAE							
Overall	2/151 (1.3)	NE (NE, NE)	33/169 (19.5)	NE (NE, NE)		13.918 (3.297, 58.761)	< 0.001
Age - at baseline (years)					–		
< 65	0/85 (0.0)	NE (NE, NE)	15/91 (16.5)	NE (NE, NE)		NE (NE, NE)	-
≥ 65	2/66 (3.0)	NE (NE, NE)	18/78 (23.1)	NE (NE, NE)		7.196 (1.632, 31.725)	0.002

Page 1 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	2/86 (2.3)	NE (NE, NE)	21/107 (19.6)	NE (NE, NE)		8.202 (1.868, 36.020)	< 0.001
Female	0/65 (0.0)	NE (NE, NE)	12/62 (19.4)	NE (NE, NE)		NE (NE, NE)	-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	6/21 (28.6)	NE (2.79, NE)		NE (NE, NE)	-
Non-Asian	2/131 (1.5)	NE (NE, NE)	27/147 (18.4)	NE (NE, NE)		11.276 (2.632, 48.316)	< 0.001

Page 3 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	4/20 (20.0)	NE (NE, NE)		NE (NE, NE)	-
Europe	1/110 (0.9)	NE (NE, NE)	22/124 (17.7)	NE (NE, NE)		18.048 (2.354, 138.343)	< 0.001
Rest of world	1/22 (4.5)	NE (NE, NE)	7/25 (28.0)	NE (2.89, NE)		5.546 (0.681, 45.150)	0.071

Page 4 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.36		
North America and Europe	1/129 (0.8)	NE (NE, NE)	26/144 (18.1)	NE (NE, NE)		22.058 (2.924, 166.387)	< 0.001
Rest of world	1/22 (4.5)	NE (NE, NE)	7/25 (28.0)	NE (2.89, NE)		5.546 (0.681, 45.150)	0.071
Baseline ECOG status (screening)					0.91		
0	1/53 (1.9)	NE (NE, NE)	16/59 (27.1)	NE (NE, NE)		15.481 (2.011, 119.167)	< 0.001
1	1/98 (1.0)	NE (NE, NE)	17/110 (15.5)	NE (NE, NE)		12.642 (1.615, 98.958)	0.002

Page 5 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)	NE (NE, NE)	15/76 (19.7)	NE (NE, NE)		NE (NE, NE)	-
2	2/61 (3.3)	NE (NE, NE)	14/64 (21.9)	NE (NE, NE)		6.202 (1.387, 27.736)	0.006
> 2	0/23 (0.0)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		NE (NE, NE)	-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	9/57 (15.8)	NE (NE, NE)		NE (NE, NE)	-
No	2/101 (2.0)	NE (NE, NE)	24/112 (21.4)	NE (NE, NE)		10.880 (2.530, 46.797)	< 0.001
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)		NE (NE, NE)	-
No	2/123 (1.6)	NE (NE, NE)	29/139 (20.9)	NE (NE, NE)		12.324 (2.896, 52.442)	< 0.001

Page 7 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.82		
Yes	1/61 (1.6)	NE (NE, NE)	16/80 (20.0)	NE (NE, NE)		11.857 (1.551, 90.658)	0.002
No	1/90 (1.1)	NE (NE, NE)	17/89 (19.1)	NE (NE, NE)		15.811 (2.032, 123.046)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	1/47 (2.1)	NE (NE, NE)	12/55 (21.8)	NE (NE, NE)		10.055 (1.285, 78.661)	0.006
≥ 1% and < 50%	0/61 (0.0)	NE (NE, NE)	6/46 (13.0)	NE (NE, NE)		NE (NE, NE)	-
≥ 50%	0/34 (0.0)	NE (NE, NE)	12/60 (20.0)	NE (NE, NE)		NE (NE, NE)	-

Page 9 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 pneumonitis TEAE							
Overall	4/151 (2.6)	NE (NE, NE)	2/169 (1.2)	NE (NE, NE)		0.314 (0.063, 1.552)	0.17
Age - at baseline (years)					–		
< 65	0/85 (0.0)		2/91 (2.2)				-
≥ 65	4/66 (6.1)		0/78 (0.0)				-

Page 10 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	2/86 (2.3)		2/107 (1.9)				
Female	2/65 (3.1)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		0/21 (0.0)				
Non-Asian	4/131 (3.1)		2/147 (1.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		0/20 (0.0)				
Europe	3/110 (2.7)		2/124 (1.6)				
Rest of world	0/22 (0.0)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	4/129 (3.1)		2/144 (1.4)				
Rest of world	0/22 (0.0)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	2/53 (3.8)		1/59 (1.7)				
1	2/98 (2.0)		1/110 (0.9)				

Page 14 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		2/76 (2.6)				
2	3/61 (4.9)		0/64 (0.0)				
> 2	0/23 (0.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		0/57 (0.0)				
No	4/101 (4.0)		2/112 (1.8)				
Liver metastasis					–		
Yes	1/28 (3.6)		1/30 (3.3)				
No	3/123 (2.4)		1/139 (0.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	1/61 (1.6)		1/80 (1.3)				
No	3/90 (3.3)		1/89 (1.1)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		2/55 (3.6)				
≥ 1% and < 50%	2/61 (3.3)		0/46 (0.0)				
≥ 50%	0/34 (0.0)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 renal toxicity TEAE							
Overall	3/151 (2.0)	NE (NE, NE)	3/169 (1.8)	NE (NE, NE)		0.629 (0.139, 2.850)	0.58
Age - at baseline (years)					–		
< 65	1/85 (1.2)		3/91 (3.3)				
≥ 65	2/66 (3.0)		0/78 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	2/86 (2.3)		2/107 (1.9)				
Female	1/65 (1.5)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	1/19 (5.3)		0/21 (0.0)				
Non-Asian	2/131 (1.5)		3/147 (2.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		1/20 (5.0)				
Europe	1/110 (0.9)		2/124 (1.6)				
Rest of world	1/22 (4.5)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	2/129 (1.6)		3/144 (2.1)				
Rest of world	1/22 (4.5)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		0/59 (0.0)				
1	3/98 (3.1)		3/110 (2.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		2/76 (2.6)				
2	1/61 (1.6)		1/64 (1.6)				
> 2	1/23 (4.3)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	1/50 (2.0)		1/57 (1.8)				
No	2/101 (2.0)		2/112 (1.8)				
Liver metastasis					–		
Yes	1/28 (3.6)		1/30 (3.3)				
No	2/123 (1.6)		2/139 (1.4)				

Page 25 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		1/80 (1.3)				
No	3/90 (3.3)		2/89 (2.2)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

Table 14-6.2.512. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		0/55 (0.0)				
≥ 1% and < 50%	2/61 (3.3)		2/46 (4.3)				
≥ 50%	1/34 (2.9)		1/60 (1.7)				

Page 27 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-512-teae-sum-grd3-eoi-cat.rtf (Date Generated: 28SEP22:02:13:55) Source: adam.adsl, adam.adtts

4.8.3 SUE

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious hepatotoxicity TEAE							
Overall	0/151 (0.0)	NE (NE, NE)	10/169 (5.9)	NE (NE, NE)		NE (NE, NE)	-
Age - at baseline (years)					–		
< 65	0/85 (0.0)		4/91 (4.4)				-
≥ 65	0/66 (0.0)		6/78 (7.7)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)		5/107 (4.7)				-
Female	0/65 (0.0)		5/62 (8.1)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		2/21 (9.5)				-
Non-Asian	0/131 (0.0)		8/147 (5.4)				-

Page 3 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		2/20 (10.0)				-
Europe	0/110 (0.0)		5/124 (4.0)				-
Rest of world	0/22 (0.0)		3/25 (12.0)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	0/129 (0.0)		7/144 (4.9)				-
Rest of world	0/22 (0.0)		3/25 (12.0)				-
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		4/59 (6.8)				-
1	0/98 (0.0)		6/110 (5.5)				-

Page 5 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)		3/76 (3.9)				-
2	0/61 (0.0)		5/64 (7.8)				-
> 2	0/23 (0.0)		2/29 (6.9)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		1/57 (1.8)				-
No	0/101 (0.0)		9/112 (8.0)				-
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	-
No	0/123 (0.0)	NE (NE, NE)	10/139 (7.2)	NE (NE, NE)		NE (NE, NE)	-

Page 7 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		4/80 (5.0)				-
No	0/90 (0.0)		6/89 (6.7)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		5/55 (9.1)				-
≥ 1% and < 50%	0/61 (0.0)		2/46 (4.3)				-
≥ 50%	0/34 (0.0)		1/60 (1.7)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious pneumonitis TEAE							
Overall	3/151 (2.0)	NE (NE, NE)	1/169 (0.6)	NE (NE, NE)		0.274 (0.029, 2.639)	0.23
Age - at baseline (years)					–		
< 65	0/85 (0.0)		1/91 (1.1)				-
≥ 65	3/66 (4.5)		0/78 (0.0)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	2/86 (2.3)		1/107 (0.9)				
Female	1/65 (1.5)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		0/21 (0.0)				
Non-Asian	3/131 (2.3)		1/147 (0.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		0/20 (0.0)				
Europe	2/110 (1.8)		1/124 (0.8)				
Rest of world	0/22 (0.0)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	3/129 (2.3)		1/144 (0.7)				
Rest of world	0/22 (0.0)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	1/53 (1.9)		0/59 (0.0)				
1	2/98 (2.0)		1/110 (0.9)				

Page 14 of 27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		1/76 (1.3)				
2	2/61 (3.3)		0/64 (0.0)				
> 2	0/23 (0.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		0/57 (0.0)				
No	3/101 (3.0)		1/112 (0.9)				
Liver metastasis					–		
Yes	1/28 (3.6)		0/30 (0.0)				
No	2/123 (1.6)		1/139 (0.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	1/61 (1.6)		1/80 (1.3)				
No	2/90 (2.2)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		1/55 (1.8)				
≥ 1% and < 50%	1/61 (1.6)		0/46 (0.0)				
≥ 50%	0/34 (0.0)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious renal toxicity TEAE							
Overall	1/151 (0.7)	NE (NE, NE)	2/169 (1.2)	NE (NE, NE)		1.433 (0.138, 14.916)	0.77
Age - at baseline (years)					–		
< 65	1/85 (1.2)		2/91 (2.2)				
≥ 65	0/66 (0.0)		0/78 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)		1/107 (0.9)				
Female	1/65 (1.5)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		0/21 (0.0)				
Non-Asian	1/131 (0.8)		2/147 (1.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		0/20 (0.0)				
Europe	1/110 (0.9)		2/124 (1.6)				
Rest of world	0/22 (0.0)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	1/129 (0.8)		2/144 (1.4)				
Rest of world	0/22 (0.0)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		0/59 (0.0)				
1	1/98 (1.0)		2/110 (1.8)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)		2/76 (2.6)				-
2	1/61 (1.6)		0/64 (0.0)				-
> 2	0/23 (0.0)		0/29 (0.0)				-

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		0/57 (0.0)				
No	1/101 (1.0)		2/112 (1.8)				
Liver metastasis					–		
Yes	0/28 (0.0)		1/30 (3.3)				
No	1/123 (0.8)		1/139 (0.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		1/80 (1.3)				
No	1/90 (1.1)		1/89 (1.1)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

Table 14-6.2.513. Summary of Time to First Serious Treatment Emergent Adverse Event of Interest (Safety Analysis Set) (20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		1/55 (1.8)				
≥ 1% and < 50%	1/61 (1.6)		1/46 (2.2)				
≥ 50%	0/34 (0.0)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
If the number of subjects in a level of subgroup is less than 10 in any arm then only the numbers of events and/or subjects are displayed for that subgroup, but not the inferential statistics.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-eoi-cat-subgroup.sas
Output: t14-06-002-513-teae-sum-ser-eoi-cat.rtf (Date Generated: 28SEP22:02:14:08) Source: adam.adsl, adam.adtts

4.9 UE nach SOC und PT, die bei ≥ 10 % bzw. ≥ 10 Studienteilnehmerinnen und Studienteilnehmer und ≥ 1 % der Studienteilnehmerinnen und Studienteilnehmer in einem Studienarm auftraten

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first blood and lymphatic system disorders TEAE							
Overall	49/151 (32.5)	NE (NE, NE)	36/169 (21.3)	NE (18.40, NE)		0.482 (0.313, 0.741)	< 0.001
Age - at baseline (years)					0.18		
< 65	25/85 (29.4)	NE (NE, NE)	22/91 (24.2)	NE (18.40, NE)		0.633 (0.353, 1.135)	0.13
≥ 65	24/66 (36.4)	NE (3.48, NE)	14/78 (17.9)	NE (NE, NE)		0.335 (0.177, 0.632)	< 0.001

Page 1 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.43		
Male	28/86 (32.6)	NE (5.06, NE)	20/107 (18.7)	NE (18.40, NE)		0.398 (0.219, 0.724)	0.002
Female	21/65 (32.3)	NE (3.45, NE)	16/62 (25.8)	NE (NE, NE)		0.610 (0.324, 1.150)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.25		
Asian	13/19 (68.4)	1.81 (0.33, 3.48)	7/21 (33.3)	15.61 (4.83, NE)		0.197 (0.066, 0.588)	0.001
Non-Asian	36/131 (27.5)	NE (NE, NE)	29/147 (19.7)	NE (NE, NE)		0.558 (0.343, 0.908)	0.019

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.42		
North America	2/19 (10.5)	NE (NE, NE)	3/20 (15.0)	NE (11.56, NE)		1.311 (0.231, 7.446)	0.77
Europe	34/110 (30.9)	NE (5.06, NE)	25/124 (20.2)	NE (18.40, NE)		0.489 (0.291, 0.819)	0.006
Rest of world	13/22 (59.1)	2.99 (0.36, NE)	8/25 (32.0)	15.61 (4.83, NE)		0.279 (0.108, 0.720)	0.006

Page 4 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.37		
North America and Europe	36/129 (27.9)	NE (NE, NE)	28/144 (19.4)	NE (18.40, NE)		0.533 (0.325, 0.871)	0.013
Rest of world	13/22 (59.1)	2.99 (0.36, NE)	8/25 (32.0)	15.61 (4.83, NE)		0.279 (0.108, 0.720)	0.006
Baseline ECOG status (screening)					0.62		
0	17/53 (32.1)	NE (NE, NE)	14/59 (23.7)	NE (18.40, NE)		0.578 (0.286, 1.169)	0.13
1	32/98 (32.7)	NE (3.48, NE)	22/110 (20.0)	NE (NE, NE)		0.436 (0.254, 0.749)	0.003

Page 5 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.47		
1	22/67 (32.8)	NE (3.45, NE)	17/76 (22.4)	18.40 (18.40, NE)		0.560 (0.295, 1.060)	0.075
2	19/61 (31.1)	NE (5.06, NE)	10/64 (15.6)	NE (NE, NE)		0.321 (0.149, 0.690)	0.003
> 2	8/23 (34.8)	NE (0.79, NE)	9/29 (31.0)	NE (4.30, NE)		0.643 (0.256, 1.616)	0.37

Page 6 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.38		
Yes	16/50 (32.0)	NE (3.42, NE)	16/57 (28.1)	18.40 (15.61, NE)		0.598 (0.294, 1.214)	0.16
No	33/101 (32.7)	NE (5.06, NE)	20/112 (17.9)	NE (NE, NE)		0.412 (0.238, 0.714)	0.001
Liver metastasis					0.21		
Yes	11/28 (39.3)	NE (1.35, NE)	4/30 (13.3)	NE (NE, NE)		0.268 (0.083, 0.863)	0.016
No	38/123 (30.9)	NE (NE, NE)	32/139 (23.0)	NE (18.40, NE)		0.543 (0.339, 0.868)	0.012

Page 7 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.57		
Yes	25/61 (41.0)	NE (2.86, NE)	22/80 (27.5)	NE (11.56, NE)		0.544 (0.309, 0.957)	0.036
No	24/90 (26.7)	NE (NE, NE)	14/89 (15.7)	NE (18.40, NE)		0.376 (0.195, 0.725)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.56		
< 1%	15/47 (31.9)	NE (3.45, NE)	14/55 (25.5)	18.40 (18.40, NE)		0.663 (0.321, 1.369)	0.27
≥ 1% and < 50%	18/61 (29.5)	NE (2.89, NE)	9/46 (19.6)	NE (15.61, NE)		0.478 (0.219, 1.040)	0.072
≥ 50%	14/34 (41.2)	NE (1.71, NE)	12/60 (20.0)	NE (NE, NE)		0.359 (0.168, 0.770)	0.007

Page 9 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first anaemia TEAE							
Overall	35/151 (23.2)	NE (NE, NE)	29/169 (17.2)	NE (NE, NE)		0.552 (0.338, 0.903)	0.019
Age - at baseline (years)					1.00		
< 65	20/85 (23.5)	NE (NE, NE)	16/91 (17.6)	NE (18.40, NE)		0.562 (0.285, 1.107)	0.092
≥ 65	15/66 (22.7)	NE (NE, NE)	13/78 (16.7)	NE (NE, NE)		0.524 (0.254, 1.081)	0.088

Page 10 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.36		
Male	21/86 (24.4)	NE (NE, NE)	16/107 (15.0)	NE (18.40, NE)		0.449 (0.230, 0.876)	0.017
Female	14/65 (21.5)	NE (NE, NE)	13/62 (21.0)	NE (NE, NE)		0.728 (0.347, 1.526)	0.41

Page 11 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.37		
Asian	10/19 (52.6)	3.48 (1.61, NE)	6/21 (28.6)	15.61 (5.26, NE)		0.243 (0.078, 0.757)	0.011
Non-Asian	25/131 (19.1)	NE (NE, NE)	23/147 (15.6)	NE (NE, NE)		0.653 (0.371, 1.148)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.55		
North America	2/19 (10.5)	NE (NE, NE)	3/20 (15.0)	NE (11.56, NE)		1.355 (0.239, 7.674)	0.74
Europe	23/110 (20.9)	NE (NE, NE)	19/124 (15.3)	NE (NE, NE)		0.565 (0.308, 1.034)	0.065
Rest of world	10/22 (45.5)	3.68 (1.71, NE)	7/25 (28.0)	15.61 (5.26, NE)		0.357 (0.133, 0.958)	0.041

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.51		
North America and Europe	25/129 (19.4)	NE (NE, NE)	22/144 (15.3)	NE (NE, NE)		0.613 (0.346, 1.085)	0.096
Rest of world	10/22 (45.5)	3.68 (1.71, NE)	7/25 (28.0)	15.61 (5.26, NE)		0.357 (0.133, 0.958)	0.041
Baseline ECOG status (screening)					0.31		
0	11/53 (20.8)	NE (NE, NE)	12/59 (20.3)	NE (18.40, NE)		0.781 (0.346, 1.762)	0.56
1	24/98 (24.5)	NE (NE, NE)	17/110 (15.5)	NE (NE, NE)		0.452 (0.243, 0.840)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.16		
1	16/67 (23.9)	NE (NE, NE)	12/76 (15.8)	NE (18.40, NE)		0.535 (0.251, 1.137)	0.10
2	15/61 (24.6)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		0.351 (0.150, 0.817)	0.014
> 2	4/23 (17.4)	NE (NE, NE)	9/29 (31.0)	NE (4.30, NE)		1.349 (0.423, 4.302)	0.62

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.56		
Yes	13/50 (26.0)	NE (3.48, NE)	14/57 (24.6)	NE (15.61, NE)		0.619 (0.284, 1.350)	0.23
No	22/101 (21.8)	NE (NE, NE)	15/112 (13.4)	NE (NE, NE)		0.484 (0.254, 0.923)	0.029
Liver metastasis					0.053		
Yes	9/28 (32.1)	NE (2.79, NE)	2/30 (6.7)	NE (NE, NE)		0.157 (0.033, 0.747)	0.007
No	26/123 (21.1)	NE (NE, NE)	27/139 (19.4)	NE (18.40, NE)		0.695 (0.405, 1.191)	0.19

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.99		
Yes	21/61 (34.4)	NE (3.45, NE)	19/80 (23.8)	NE (NE, NE)		0.555 (0.300, 1.030)	0.062
No	14/90 (15.6)	NE (NE, NE)	10/89 (11.2)	NE (18.40, NE)		0.466 (0.212, 1.027)	0.068

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.41		
< 1%	8/47 (17.0)	NE (NE, NE)	10/55 (18.2)	NE (18.40, NE)		0.911 (0.363, 2.290)	0.85
≥ 1% and < 50%	15/61 (24.6)	NE (NE, NE)	7/46 (15.2)	NE (15.61, NE)		0.420 (0.180, 0.981)	0.057
≥ 50%	10/34 (29.4)	NE (3.42, NE)	11/60 (18.3)	NE (NE, NE)		0.511 (0.219, 1.189)	0.12

Page 18 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first gastrointestinal disorders TEAE							
Overall	88/151 (58.3)	1.41 (0.82, 2.76)	118/169 (69.8)	2.10 (1.45, 2.76)		0.904 (0.683, 1.197)	0.50
Age - at baseline (years)					0.31		
< 65	46/85 (54.1)	1.41 (0.79, NE)	64/91 (70.3)	2.04 (1.02, 2.56)		1.073 (0.733, 1.570)	0.71
≥ 65	42/66 (63.6)	1.41 (0.30, 2.83)	54/78 (69.2)	2.56 (1.68, 3.38)		0.755 (0.500, 1.140)	0.18

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.69		
Male	47/86 (54.7)	1.81 (0.82, NE)	67/107 (62.6)	2.76 (2.04, 3.58)		0.879 (0.601, 1.285)	0.51
Female	41/65 (63.1)	1.02 (0.53, 2.10)	51/62 (82.3)	1.41 (0.72, 2.10)		0.986 (0.653, 1.490)	0.96

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.11		
Asian	15/19 (78.9)	0.20 (0.10, 0.26)	15/21 (71.4)	1.71 (0.23, NE)		0.518 (0.252, 1.064)	0.081
Non-Asian	72/131 (55.0)	1.58 (1.18, 2.83)	103/147 (70.1)	2.14 (1.45, 2.76)		1.002 (0.738, 1.361)	0.97

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.15		
North America	16/19 (84.2)	0.23 (0.13, 1.51)	16/20 (80.0)	2.18 (0.30, 3.71)		0.563 (0.276, 1.146)	0.11
Europe	56/110 (50.9)	2.10 (1.18, NE)	84/124 (67.7)	2.14 (1.61, 2.99)		1.069 (0.759, 1.506)	0.68
Rest of world	16/22 (72.7)	0.23 (0.13, 1.54)	18/25 (72.0)	1.71 (0.49, 2.53)		0.604 (0.308, 1.185)	0.15

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.24		
North America and Europe	72/129 (55.8)	1.58 (0.92, 2.83)	100/144 (69.4)	2.14 (1.61, 2.83)		0.961 (0.706, 1.308)	0.82
Rest of world	16/22 (72.7)	0.23 (0.13, 1.54)	18/25 (72.0)	1.71 (0.49, 2.53)		0.604 (0.308, 1.185)	0.15
Baseline ECOG status (screening)					0.74		
0	33/53 (62.3)	1.41 (0.43, 3.19)	38/59 (64.4)	2.07 (1.31, 4.04)		0.849 (0.533, 1.354)	0.49
1	55/98 (56.1)	1.54 (0.79, 2.83)	80/110 (72.7)	2.14 (1.41, 2.76)		0.892 (0.627, 1.268)	0.53

Page 23 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.29		
1	43/67 (64.2)	1.41 (0.43, 2.83)	49/76 (64.5)	2.14 (1.41, 2.92)		0.761 (0.506, 1.144)	0.20
2	33/61 (54.1)	1.18 (0.23, NE)	45/64 (70.3)	2.07 (1.31, 2.99)		0.942 (0.595, 1.491)	0.82
> 2	12/23 (52.2)	2.04 (0.92, NE)	24/29 (82.8)	2.04 (0.62, 3.38)		1.254 (0.613, 2.563)	0.53

Page 24 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.63		
Yes	26/50 (52.0)	2.27 (0.53, NE)	42/57 (73.7)	2.10 (1.41, 2.92)		0.989 (0.599, 1.631)	0.97
No	62/101 (61.4)	1.38 (0.76, 2.30)	76/112 (67.9)	2.14 (1.31, 2.83)		0.867 (0.619, 1.216)	0.42
Liver metastasis					0.60		
Yes	16/28 (57.1)	1.54 (0.79, NE)	22/30 (73.3)	2.10 (0.72, 2.79)		0.911 (0.477, 1.739)	0.79
No	72/123 (58.5)	1.41 (0.76, 2.76)	96/139 (69.1)	2.14 (1.41, 2.83)		0.883 (0.648, 1.205)	0.45

Page 25 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.78		
Yes	39/61 (63.9)	1.38 (0.53, 2.30)	57/80 (71.3)	1.71 (1.28, 2.76)		0.857 (0.566, 1.297)	0.47
No	49/90 (54.4)	1.51 (0.79, NE)	61/89 (68.5)	2.30 (1.87, 3.15)		0.929 (0.637, 1.356)	0.72

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.015		
< 1%	33/47 (70.2)	0.49 (0.20, 2.10)	36/55 (65.5)	2.56 (1.38, 4.17)		0.557 (0.344, 0.902)	0.016
≥ 1% and < 50%	31/61 (50.8)	2.04 (0.82, NE)	37/46 (80.4)	1.25 (0.99, 2.53)		1.458 (0.914, 2.326)	0.12
≥ 50%	21/34 (61.8)	1.18 (0.20, NE)	41/60 (68.3)	2.14 (1.68, 3.22)		0.840 (0.474, 1.488)	0.53

Page 27 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first abdominal pain TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	20/169 (11.8)	NE (NE, NE)		1.549 (0.714, 3.359)	0.28
Age - at baseline (years)					0.046		
< 65	1/85 (1.2)	NE (NE, NE)	10/91 (11.0)	NE (NE, NE)		8.527 (1.099, 66.182)	0.014
≥ 65	8/66 (12.1)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		0.693 (0.284, 1.691)	0.45

Page 28 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.65		
Male	4/86 (4.7)	NE (NE, NE)	12/107 (11.2)	NE (NE, NE)		1.967 (0.647, 5.979)	0.24
Female	5/65 (7.7)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		1.303 (0.434, 3.911)	0.65

Page 29 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	2/21 (9.5)	NE (5.36, NE)		NE (NE, NE)	NE
Non-Asian	8/131 (6.1)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		1.580 (0.694, 3.597)	0.28

Page 30 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	3/19 (15.8)	NE (3.19, NE)	4/20 (20.0)	NE (5.36, NE)		1.009 (0.232, 4.379)	0.99
Europe	6/110 (5.5)	NE (NE, NE)	15/124 (12.1)	NE (NE, NE)		1.801 (0.706, 4.594)	0.22
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 31 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	9/129 (7.0)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)		1.488 (0.681, 3.252)	0.33
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.73		
0	4/53 (7.5)	NE (NE, NE)	7/59 (11.9)	NE (NE, NE)		1.480 (0.438, 4.997)	0.53
1	5/98 (5.1)	NE (NE, NE)	13/110 (11.8)	NE (NE, NE)		1.600 (0.586, 4.367)	0.37

Page 32 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.93		
1	3/67 (4.5)	NE (NE, NE)	7/76 (9.2)	NE (NE, NE)		1.718 (0.442, 6.675)	0.43
2	4/61 (6.6)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)		1.595 (0.515, 4.937)	0.44
> 2	2/23 (8.7)	NE (4.34, NE)	4/29 (13.8)	NE (NE, NE)		1.174 (0.222, 6.210)	0.85

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.87		
Yes	2/50 (4.0)	NE (NE, NE)	6/57 (10.5)	NE (NE, NE)		1.407 (0.289, 6.853)	0.68
No	7/101 (6.9)	NE (NE, NE)	14/112 (12.5)	NE (NE, NE)		1.616 (0.662, 3.946)	0.30
Liver metastasis					0.46		
Yes	3/28 (10.7)	NE (3.19, NE)	4/30 (13.3)	NE (NE, NE)		1.033 (0.225, 4.746)	0.97
No	6/123 (4.9)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		1.817 (0.726, 4.549)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.16		
Yes	4/61 (6.6)	NE (NE, NE)	15/80 (18.8)	NE (NE, NE)		2.277 (0.753, 6.880)	0.13
No	5/90 (5.6)	NE (NE, NE)	5/89 (5.6)	NE (NE, NE)		0.784 (0.240, 2.556)	0.70

Page 35 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.88		
< 1%	2/47 (4.3)	NE (NE, NE)	6/55 (10.9)	NE (NE, NE)		2.254 (0.467, 10.889)	0.31
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	6/46 (13.0)	NE (NE, NE)		1.660 (0.477, 5.776)	0.43
≥ 50%	3/34 (8.8)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)		1.251 (0.332, 4.707)	0.74

Page 36 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first constipation TEAE							
Overall	29/151 (19.2)	NE (NE, NE)	22/169 (13.0)	NE (NE, NE)		0.537 (0.311, 0.928)	0.028
Age - at baseline (years)					0.006		
< 65	9/85 (10.6)	NE (NE, NE)	14/91 (15.4)	NE (NE, NE)		1.206 (0.522, 2.786)	0.66
≥ 65	20/66 (30.3)	NE (NE, NE)	8/78 (10.3)	NE (NE, NE)		0.242 (0.111, 0.528)	< 0.001

Page 37 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.40		
Male	17/86 (19.8)	NE (NE, NE)	12/107 (11.2)	NE (NE, NE)		0.405 (0.198, 0.828)	0.016
Female	12/65 (18.5)	NE (NE, NE)	10/62 (16.1)	NE (NE, NE)		0.755 (0.327, 1.743)	0.51

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.071		
Asian	8/19 (42.1)	NE (0.36, NE)	2/21 (9.5)	NE (15.57, NE)		0.091 (0.011, 0.773)	0.005
Non-Asian	21/131 (16.0)	NE (NE, NE)	20/147 (13.6)	NE (NE, NE)		0.696 (0.380, 1.275)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.30		
North America	6/19 (31.6)	NE (0.85, NE)	4/20 (20.0)	NE (4.37, NE)		0.557 (0.163, 1.897)	0.36
Europe	15/110 (13.6)	NE (NE, NE)	15/124 (12.1)	NE (NE, NE)		0.741 (0.366, 1.501)	0.41
Rest of world	8/22 (36.4)	NE (0.89, NE)	3/25 (12.0)	NE (15.57, NE)		0.169 (0.036, 0.785)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.14		
North America and Europe	21/129 (16.3)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)		0.667 (0.361, 1.230)	0.20
Rest of world	8/22 (36.4)	NE (0.89, NE)	3/25 (12.0)	NE (15.57, NE)		0.169 (0.036, 0.785)	0.011
Baseline ECOG status (screening)					0.68		
0	7/53 (13.2)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		0.418 (0.128, 1.361)	0.16
1	22/98 (22.4)	NE (7.33, NE)	18/110 (16.4)	NE (NE, NE)		0.553 (0.298, 1.026)	0.063

Page 41 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.79		
1	11/67 (16.4)	NE (NE, NE)	10/76 (13.2)	NE (NE, NE)		0.643 (0.278, 1.489)	0.32
2	13/61 (21.3)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		0.465 (0.200, 1.081)	0.085
> 2	5/23 (21.7)	7.33 (4.34, NE)	4/29 (13.8)	NE (NE, NE)		0.459 (0.113, 1.867)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.57		
Yes	10/50 (20.0)	NE (7.33, NE)	10/57 (17.5)	NE (NE, NE)		0.636 (0.256, 1.578)	0.32
No	19/101 (18.8)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		0.476 (0.236, 0.958)	0.041
Liver metastasis					0.86		
Yes	5/28 (17.9)	7.33 (7.33, NE)	4/30 (13.3)	NE (NE, NE)		0.502 (0.141, 1.791)	0.31
No	24/123 (19.5)	NE (NE, NE)	18/139 (12.9)	NE (NE, NE)		0.537 (0.295, 0.977)	0.045

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.80		
Yes	15/61 (24.6)	NE (7.33, NE)	12/80 (15.0)	NE (NE, NE)		0.480 (0.227, 1.015)	0.055
No	14/90 (15.6)	NE (NE, NE)	10/89 (11.2)	NE (NE, NE)		0.564 (0.256, 1.239)	0.17

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.53		
< 1%	15/47 (31.9)	NE (4.34, NE)	9/55 (16.4)	NE (NE, NE)		0.412 (0.185, 0.918)	0.031
≥ 1% and < 50%	9/61 (14.8)	NE (7.33, NE)	6/46 (13.0)	NE (15.57, NE)		0.632 (0.210, 1.901)	0.40
≥ 50%	4/34 (11.8)	NE (NE, NE)	7/60 (11.7)	NE (NE, NE)		0.872 (0.261, 2.916)	0.83

Page 45 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first diarrhoea TEAE							
Overall	39/151 (25.8)	NE (9.69, NE)	70/169 (41.4)	NE (3.71, NE)		1.419 (0.956, 2.106)	0.079
Age - at baseline (years)					0.62		
< 65	19/85 (22.4)	NE (9.69, NE)	35/91 (38.5)	NE (3.71, NE)		1.533 (0.874, 2.689)	0.13
≥ 65	20/66 (30.3)	NE (NE, NE)	35/78 (44.9)	NE (2.73, NE)		1.297 (0.745, 2.256)	0.35

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.96		
Male	19/86 (22.1)	NE (NE, NE)	38/107 (35.5)	NE (5.26, NE)		1.452 (0.834, 2.530)	0.18
Female	20/65 (30.8)	9.69 (9.69, NE)	32/62 (51.6)	3.71 (2.07, NE)		1.474 (0.847, 2.566)	0.17

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.44		
Asian	3/19 (15.8)	NE (NE, NE)	8/21 (38.1)	NE (1.71, NE)		2.382 (0.636, 8.929)	0.19
Non-Asian	35/131 (26.7)	NE (9.69, NE)	62/147 (42.2)	15.05 (3.52, NE)		1.374 (0.906, 2.084)	0.13

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.47		
North America	9/19 (47.4)	9.69 (0.92, NE)	10/20 (50.0)	4.14 (1.45, NE)		0.907 (0.379, 2.172)	0.84
Europe	24/110 (21.8)	NE (NE, NE)	50/124 (40.3)	NE (3.71, NE)		1.658 (1.017, 2.702)	0.040
Rest of world	6/22 (27.3)	NE (1.54, NE)	10/25 (40.0)	NE (2.14, NE)		1.253 (0.464, 3.381)	0.66

Page 49 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.81		
North America and Europe	33/129 (25.6)	NE (9.69, NE)	60/144 (41.7)	15.05 (3.52, NE)		1.439 (0.938, 2.208)	0.092
Rest of world	6/22 (27.3)	NE (1.54, NE)	10/25 (40.0)	NE (2.14, NE)		1.253 (0.464, 3.381)	0.66
Baseline ECOG status (screening)					0.12		
0	12/53 (22.6)	NE (NE, NE)	28/59 (47.5)	5.26 (2.07, NE)		2.178 (1.099, 4.316)	0.020
1	27/98 (27.6)	9.69 (9.69, NE)	42/110 (38.2)	NE (3.22, NE)		1.081 (0.665, 1.757)	0.76

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.12		
1	18/67 (26.9)	NE (NE, NE)	29/76 (38.2)	NE (2.89, NE)		1.288 (0.715, 2.320)	0.40
2	13/61 (21.3)	NE (NE, NE)	32/64 (50.0)	3.52 (2.07, NE)		2.191 (1.131, 4.242)	0.015
> 2	8/23 (34.8)	9.69 (2.04, NE)	9/29 (31.0)	NE (3.71, NE)		0.619 (0.242, 1.584)	0.33

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.25		
Yes	8/50 (16.0)	9.69 (9.69, NE)	23/57 (40.4)	15.05 (3.52, NE)		2.028 (0.899, 4.578)	0.082
No	31/101 (30.7)	NE (NE, NE)	47/112 (42.0)	NE (2.89, NE)		1.246 (0.791, 1.965)	0.34
Liver metastasis					0.95		
Yes	8/28 (28.6)	9.69 (2.04, NE)	14/30 (46.7)	3.52 (2.14, NE)		1.310 (0.555, 3.094)	0.55
No	31/123 (25.2)	NE (NE, NE)	56/139 (40.3)	NE (4.04, NE)		1.443 (0.928, 2.242)	0.099

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.071		
Yes	21/61 (34.4)	9.69 (2.46, NE)	31/80 (38.8)	15.05 (3.52, NE)		0.952 (0.547, 1.657)	0.87
No	18/90 (20.0)	NE (NE, NE)	39/89 (43.8)	NE (2.79, NE)		2.017 (1.151, 3.534)	0.012

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.43		
< 1%	13/47 (27.7)	NE (2.83, NE)	19/55 (34.5)	NE (4.04, NE)		1.102 (0.548, 2.218)	0.79
≥ 1% and < 50%	18/61 (29.5)	9.69 (9.69, NE)	22/46 (47.8)	3.71 (2.17, NE)		1.310 (0.710, 2.420)	0.40
≥ 50%	7/34 (20.6)	NE (NE, NE)	27/60 (45.0)	4.14 (2.56, NE)		2.299 (0.954, 5.541)	0.044

Page 54 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first nausea TEAE							
Overall	37/151 (24.5)	NE (NE, NE)	44/169 (26.0)	NE (NE, NE)		0.860 (0.556, 1.330)	0.50
Age - at baseline (years)					0.32		
< 65	19/85 (22.4)	NE (NE, NE)	26/91 (28.6)	NE (15.05, NE)		1.068 (0.594, 1.922)	0.83
≥ 65	18/66 (27.3)	NE (5.85, NE)	18/78 (23.1)	NE (NE, NE)		0.665 (0.347, 1.275)	0.22

Page 55 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.25		
Male	17/86 (19.8)	NE (NE, NE)	18/107 (16.8)	NE (NE, NE)		0.676 (0.348, 1.314)	0.26
Female	20/65 (30.8)	NE (5.85, NE)	26/62 (41.9)	10.91 (3.19, NE)		1.146 (0.646, 2.031)	0.65

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.66		
Asian	6/19 (31.6)	NE (0.23, NE)	6/21 (28.6)	NE (5.32, NE)		0.639 (0.204, 1.997)	0.45
Non-Asian	31/131 (23.7)	NE (NE, NE)	38/147 (25.9)	NE (NE, NE)		0.904 (0.564, 1.450)	0.68

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.46		
North America	7/19 (36.8)	NE (0.23, NE)	8/20 (40.0)	NE (2.10, NE)		0.890 (0.336, 2.355)	0.83
Europe	23/110 (20.9)	NE (NE, NE)	31/124 (25.0)	NE (NE, NE)		0.993 (0.577, 1.706)	0.98
Rest of world	7/22 (31.8)	NE (0.53, NE)	5/25 (20.0)	NE (12.19, NE)		0.430 (0.129, 1.430)	0.17

Page 58 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.22		
North America and Europe	30/129 (23.3)	NE (NE, NE)	39/144 (27.1)	NE (NE, NE)		0.967 (0.603, 1.553)	0.89
Rest of world	7/22 (31.8)	NE (0.53, NE)	5/25 (20.0)	NE (12.19, NE)		0.430 (0.129, 1.430)	0.17
Baseline ECOG status (screening)					0.063		
0	15/53 (28.3)	NE (NE, NE)	10/59 (16.9)	NE (NE, NE)		0.476 (0.219, 1.035)	0.066
1	22/98 (22.4)	NE (NE, NE)	34/110 (30.9)	NE (12.19, NE)		1.122 (0.655, 1.920)	0.68

Page 59 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.23		
1	19/67 (28.4)	NE (5.85, NE)	20/76 (26.3)	NE (NE, NE)		0.805 (0.432, 1.501)	0.50
2	15/61 (24.6)	NE (NE, NE)	14/64 (21.9)	NE (NE, NE)		0.660 (0.324, 1.347)	0.27
> 2	3/23 (13.0)	NE (NE, NE)	10/29 (34.5)	NE (3.38, NE)		2.163 (0.602, 7.768)	0.23

Page 60 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.36		
Yes	12/50 (24.0)	NE (NE, NE)	20/57 (35.1)	NE (8.77, NE)		1.058 (0.521, 2.148)	0.88
No	25/101 (24.8)	NE (NE, NE)	24/112 (21.4)	NE (NE, NE)		0.752 (0.430, 1.316)	0.32
Liver metastasis					0.036		
Yes	6/28 (21.4)	NE (NE, NE)	14/30 (46.7)	8.77 (2.10, NE)		1.874 (0.722, 4.865)	0.20
No	31/123 (25.2)	NE (NE, NE)	30/139 (21.6)	NE (NE, NE)		0.701 (0.425, 1.156)	0.17

Page 61 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.17		
Yes	14/61 (23.0)	NE (5.85, NE)	25/80 (31.3)	NE (8.77, NE)		1.170 (0.608, 2.252)	0.65
No	23/90 (25.6)	NE (NE, NE)	19/89 (21.3)	NE (NE, NE)		0.646 (0.355, 1.176)	0.16

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.29		
< 1%	11/47 (23.4)	NE (NE, NE)	12/55 (21.8)	NE (NE, NE)		0.796 (0.352, 1.802)	0.59
≥ 1% and < 50%	13/61 (21.3)	NE (NE, NE)	16/46 (34.8)	NE (4.14, NE)		1.352 (0.664, 2.753)	0.43
≥ 50%	11/34 (32.4)	NE (2.23, NE)	14/60 (23.3)	NE (12.19, NE)		0.550 (0.250, 1.209)	0.14

Page 63 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first stomatitis TEAE							
Overall	19/151 (12.6)	NE (NE, NE)	3/169 (1.8)	NE (NE, NE)		0.125 (0.038, 0.411)	< 0.001
Age - at baseline (years)					0.35		
< 65	8/85 (9.4)	NE (NE, NE)	2/91 (2.2)	NE (NE, NE)		0.211 (0.044, 1.019)	0.030
≥ 65	11/66 (16.7)	NE (NE, NE)	1/78 (1.3)	NE (NE, NE)		0.066 (0.010, 0.449)	< 0.001

Page 64 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.69		
Male	9/86 (10.5)	NE (NE, NE)	2/107 (1.9)	NE (NE, NE)		0.158 (0.037, 0.675)	0.007
Female	10/65 (15.4)	NE (NE, NE)	1/62 (1.6)	NE (NE, NE)		0.091 (0.012, 0.713)	0.004

Page 65 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.34		
Asian	6/19 (31.6)	NE (0.26, NE)	2/21 (9.5)	NE (NE, NE)		0.245 (0.055, 1.089)	0.064
Non-Asian	12/131 (9.2)	NE (NE, NE)	1/147 (0.7)	NE (NE, NE)		0.068 (0.009, 0.522)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	3/19 (15.8)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	11/110 (10.0)	NE (NE, NE)	1/124 (0.8)	NE (NE, NE)		0.073 (0.009, 0.567)	0.001
Rest of world	5/22 (22.7)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.299 (0.065, 1.384)	0.13

Page 67 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.21		
North America and Europe	14/129 (10.9)	NE (NE, NE)	1/144 (0.7)	NE (NE, NE)		0.058 (0.008, 0.441)	< 0.001
Rest of world	5/22 (22.7)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.299 (0.065, 1.384)	0.13
Baseline ECOG status (screening)					–		
0	6/53 (11.3)	NE (NE, NE)	0/59 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
1	13/98 (13.3)	NE (NE, NE)	3/110 (2.7)	NE (NE, NE)		0.172 (0.051, 0.582)	0.002

Page 68 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	12/67 (17.9)	NE (NE, NE)	3/76 (3.9)	NE (NE, NE)		0.192 (0.056, 0.658)	0.004
2	5/61 (8.2)	NE (NE, NE)	0/64 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
> 2	2/23 (8.7)	NE (NE, NE)	0/29 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 69 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.81		
Yes	5/50 (10.0)	NE (NE, NE)	1/57 (1.8)	NE (NE, NE)		0.148 (0.016, 1.362)	0.045
No	14/101 (13.9)	NE (NE, NE)	2/112 (1.8)	NE (NE, NE)		0.116 (0.028, 0.486)	< 0.001
Liver metastasis					0.44		
Yes	3/28 (10.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.296 (0.031, 2.843)	0.26
No	16/123 (13.0)	NE (NE, NE)	2/139 (1.4)	NE (NE, NE)		0.097 (0.023, 0.407)	< 0.001

Page 70 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	10/61 (16.4)	NE (NE, NE)	3/80 (3.8)	NE (NE, NE)		0.195 (0.057, 0.668)	0.006
No	9/90 (10.0)	NE (NE, NE)	0/89 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 71 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	9/47 (19.1)	NE (NE, NE)	2/55 (3.6)	NE (NE, NE)		0.159 (0.037, 0.690)	0.007
≥ 1% and < 50%	6/61 (9.8)	NE (NE, NE)	1/46 (2.2)	NE (NE, NE)		0.208 (0.025, 1.747)	0.11
≥ 50%	4/34 (11.8)	NE (NE, NE)	0/60 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 72 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first vomiting TEAE							
Overall	15/151 (9.9)	NE (NE, NE)	22/169 (13.0)	NE (NE, NE)		1.002 (0.522, 1.921)	1.00
Age - at baseline (years)					0.79		
< 65	10/85 (11.8)	NE (NE, NE)	15/91 (16.5)	NE (NE, NE)		1.127 (0.503, 2.527)	0.77
≥ 65	5/66 (7.6)	NE (NE, NE)	7/78 (9.0)	NE (NE, NE)		0.847 (0.290, 2.475)	0.78

Page 73 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.69		
Male	5/86 (5.8)	NE (NE, NE)	10/107 (9.3)	NE (NE, NE)		1.274 (0.446, 3.635)	0.66
Female	10/65 (15.4)	NE (NE, NE)	12/62 (19.4)	NE (NE, NE)		0.928 (0.406, 2.121)	0.86

Page 74 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.90		
Asian	3/19 (15.8)	NE (3.58, NE)	4/21 (19.0)	NE (12.19, NE)		0.736 (0.156, 3.480)	0.71
Non-Asian	12/131 (9.2)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		1.054 (0.512, 2.172)	0.89

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.97		
North America	3/19 (15.8)	NE (NE, NE)	4/20 (20.0)	NE (5.32, NE)		1.189 (0.279, 5.064)	0.82
Europe	9/110 (8.2)	NE (NE, NE)	14/124 (11.3)	NE (NE, NE)		1.050 (0.460, 2.398)	0.91
Rest of world	3/22 (13.6)	NE (NE, NE)	4/25 (16.0)	NE (12.19, NE)		0.743 (0.152, 3.643)	0.72

Page 76 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.84		
North America and Europe	12/129 (9.3)	NE (NE, NE)	18/144 (12.5)	NE (NE, NE)		1.037 (0.506, 2.125)	0.92
Rest of world	3/22 (13.6)	NE (NE, NE)	4/25 (16.0)	NE (12.19, NE)		0.743 (0.152, 3.643)	0.72
Baseline ECOG status (screening)					0.082		
0	6/53 (11.3)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.339 (0.088, 1.312)	0.11
1	9/98 (9.2)	NE (NE, NE)	19/110 (17.3)	NE (NE, NE)		1.434 (0.661, 3.109)	0.38

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.47		
1	8/67 (11.9)	NE (NE, NE)	7/76 (9.2)	NE (NE, NE)		0.634 (0.238, 1.689)	0.38
2	5/61 (8.2)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)		1.344 (0.438, 4.123)	0.60
> 2	2/23 (8.7)	NE (NE, NE)	6/29 (20.7)	NE (12.19, NE)		1.462 (0.305, 7.020)	0.65

Page 78 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.68		
Yes	5/50 (10.0)	NE (NE, NE)	10/57 (17.5)	NE (NE, NE)		0.891 (0.287, 2.767)	0.84
No	10/101 (9.9)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		0.983 (0.432, 2.239)	0.97
Liver metastasis					0.27		
Yes	6/28 (21.4)	NE (3.58, NE)	5/30 (16.7)	NE (NE, NE)		0.623 (0.193, 2.005)	0.44
No	9/123 (7.3)	NE (NE, NE)	17/139 (12.2)	NE (NE, NE)		1.249 (0.561, 2.780)	0.59

Page 79 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.12		
Yes	9/61 (14.8)	NE (NE, NE)	9/80 (11.3)	NE (NE, NE)		0.610 (0.244, 1.527)	0.30
No	6/90 (6.7)	NE (NE, NE)	13/89 (14.6)	NE (NE, NE)		1.587 (0.605, 4.160)	0.35

Page 80 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)	NE (NE, NE)	5/55 (9.1)	NE (NE, NE)		0.711 (0.209, 2.416)	0.59
≥ 1% and < 50%	9/61 (14.8)	NE (5.42, NE)	7/46 (15.2)	NE (NE, NE)		0.675 (0.251, 1.817)	0.45
≥ 50%	0/34 (0.0)	NE (NE, NE)	9/60 (15.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first general disorders and administration site conditions TEAE							
Overall	98/151 (64.9)	1.48 (0.72, 2.33)	76/169 (45.0)	8.77 (6.51, 16.03)		0.347 (0.252, 0.476)	< 0.001
Age - at baseline (years)					0.013		
< 65	55/85 (64.7)	0.82 (0.72, 2.14)	33/91 (36.3)	16.03 (8.44, NE)		0.238 (0.148, 0.383)	< 0.001
≥ 65	43/66 (65.2)	2.07 (0.72, 3.19)	43/78 (55.1)	6.51 (3.09, 14.03)		0.495 (0.319, 0.767)	0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.49		
Male	56/86 (65.1)	1.54 (0.72, 2.33)	45/107 (42.1)	13.34 (6.51, NE)		0.319 (0.210, 0.486)	< 0.001
Female	42/65 (64.6)	1.45 (0.72, 2.99)	31/62 (50.0)	7.00 (3.25, 14.49)		0.393 (0.243, 0.636)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.31		
Asian	12/19 (63.2)	0.72 (0.16, NE)	6/21 (28.6)	NE (3.09, NE)		0.266 (0.107, 0.659)	0.005
Non-Asian	85/131 (64.9)	1.51 (0.79, 2.33)	70/147 (47.6)	8.44 (5.78, 14.49)		0.364 (0.259, 0.512)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.51		
North America	15/19 (78.9)	0.46 (0.16, 1.48)	10/20 (50.0)	10.15 (0.62, NE)		0.388 (0.178, 0.846)	0.019
Europe	69/110 (62.7)	2.07 (0.79, 2.56)	58/124 (46.8)	7.29 (5.78, 14.85)		0.363 (0.249, 0.529)	< 0.001
Rest of world	14/22 (63.6)	1.54 (0.20, 4.07)	8/25 (32.0)	NE (3.71, NE)		0.238 (0.102, 0.559)	0.001

Page 85 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.33		
North America and Europe	84/129 (65.1)	1.48 (0.72, 2.33)	68/144 (47.2)	8.44 (5.78, 14.85)		0.366 (0.260, 0.516)	< 0.001
Rest of world	14/22 (63.6)	1.54 (0.20, 4.07)	8/25 (32.0)	NE (3.71, NE)		0.238 (0.102, 0.559)	0.001
Baseline ECOG status (screening)					0.003		
0	39/53 (73.6)	1.51 (0.72, 2.33)	18/59 (30.5)	NE (13.34, NE)		0.170 (0.093, 0.312)	< 0.001
1	59/98 (60.2)	1.45 (0.72, 3.19)	58/110 (52.7)	5.42 (3.09, 8.77)		0.475 (0.327, 0.691)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.46		
1	46/67 (68.7)	1.54 (0.72, 2.56)	30/76 (39.5)	13.34 (5.78, NE)		0.283 (0.174, 0.461)	< 0.001
2	39/61 (63.9)	0.79 (0.62, 2.14)	31/64 (48.4)	7.29 (4.99, NE)		0.377 (0.230, 0.618)	< 0.001
> 2	13/23 (56.5)	2.99 (0.26, NE)	15/29 (51.7)	7.00 (2.79, NE)		0.500 (0.233, 1.071)	0.073

Page 87 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.91		
Yes	30/50 (60.0)	1.54 (0.69, 4.24)	26/57 (45.6)	8.77 (4.24, NE)		0.372 (0.214, 0.647)	< 0.001
No	68/101 (67.3)	1.48 (0.72, 2.33)	50/112 (44.6)	7.29 (5.78, NE)		0.342 (0.233, 0.502)	< 0.001
Liver metastasis					0.45		
Yes	15/28 (53.6)	2.33 (0.69, NE)	13/30 (43.3)	8.44 (3.06, NE)		0.359 (0.156, 0.823)	0.016
No	83/123 (67.5)	1.45 (0.72, 2.23)	63/139 (45.3)	10.15 (6.44, NE)		0.340 (0.242, 0.479)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.49		
Yes	39/61 (63.9)	1.54 (0.72, 2.56)	37/80 (46.3)	8.64 (3.71, 16.03)		0.358 (0.223, 0.575)	< 0.001
No	59/90 (65.6)	0.99 (0.72, 2.63)	39/89 (43.8)	13.34 (6.44, NE)		0.326 (0.211, 0.503)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.24		
< 1%	37/47 (78.7)	0.99 (0.46, 2.07)	25/55 (45.5)	8.77 (5.42, NE)		0.214 (0.121, 0.378)	< 0.001
≥ 1% and < 50%	36/61 (59.0)	1.74 (0.72, 3.48)	24/46 (52.2)	8.44 (3.29, 14.03)		0.365 (0.206, 0.645)	< 0.001
≥ 50%	21/34 (61.8)	1.51 (0.23, NE)	24/60 (40.0)	14.49 (4.99, NE)		0.419 (0.231, 0.759)	0.003

Page 90 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first asthenia TEAE							
Overall	21/151 (13.9)	NE (NE, NE)	17/169 (10.1)	NE (NE, NE)		0.527 (0.285, 0.975)	0.052
Age - at baseline (years)					0.22		
< 65	13/85 (15.3)	NE (NE, NE)	7/91 (7.7)	NE (NE, NE)		0.341 (0.143, 0.816)	0.021
≥ 65	8/66 (12.1)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		0.822 (0.334, 2.018)	0.68

Page 91 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.15		
Male	14/86 (16.3)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		0.328 (0.146, 0.736)	0.011
Female	7/65 (10.8)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		0.950 (0.352, 2.564)	0.92

Page 92 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	20/131 (15.3)	NE (NE, NE)	17/147 (11.6)	NE (NE, NE)		0.549 (0.295, 1.022)	0.072

Page 93 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	1/20 (5.0)	NE (6.74, NE)		0.725 (0.065, 8.157)	0.82
Europe	20/110 (18.2)	NE (NE, NE)	16/124 (12.9)	NE (NE, NE)		0.506 (0.268, 0.954)	0.044
Rest of world	0/22 (0.0)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	21/129 (16.3)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)		0.528 (0.286, 0.975)	0.052
Rest of world	0/22 (0.0)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.11		
0	10/53 (18.9)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		0.284 (0.093, 0.869)	0.027
1	11/98 (11.2)	NE (NE, NE)	13/110 (11.8)	NE (16.03, NE)		0.717 (0.332, 1.550)	0.43

Page 95 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.57		
1	5/67 (7.5)	NE (NE, NE)	5/76 (6.6)	NE (NE, NE)		0.727 (0.223, 2.369)	0.62
2	14/61 (23.0)	NE (NE, NE)	9/64 (14.1)	NE (16.03, NE)		0.390 (0.172, 0.882)	0.031
> 2	2/23 (8.7)	NE (NE, NE)	3/29 (10.3)	NE (NE, NE)		0.783 (0.132, 4.657)	0.79

Page 96 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.80		
Yes	5/50 (10.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		0.616 (0.180, 2.112)	0.46
No	16/101 (15.8)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		0.503 (0.246, 1.026)	0.072
Liver metastasis					0.35		
Yes	2/28 (7.1)	NE (NE, NE)	3/30 (10.0)	16.03 (16.03, NE)		1.065 (0.205, 5.539)	0.95
No	19/123 (15.4)	NE (NE, NE)	14/139 (10.1)	NE (NE, NE)		0.484 (0.249, 0.940)	0.040

Page 97 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.27		
Yes	12/61 (19.7)	NE (NE, NE)	8/80 (10.0)	NE (16.03, NE)		0.333 (0.141, 0.787)	0.016
No	9/90 (10.0)	NE (NE, NE)	9/89 (10.1)	NE (NE, NE)		0.792 (0.321, 1.952)	0.62

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.37		
< 1%	6/47 (12.8)	NE (NE, NE)	9/55 (16.4)	NE (14.85, NE)		1.024 (0.370, 2.832)	0.97
≥ 1% and < 50%	10/61 (16.4)	NE (NE, NE)	5/46 (10.9)	NE (16.03, NE)		0.449 (0.170, 1.184)	0.15
≥ 50%	4/34 (11.8)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)		0.343 (0.081, 1.446)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first fatigue TEAE							
Overall	45/151 (29.8)	21.16 (NE, NE)	27/169 (16.0)	NE (NE, NE)		0.394 (0.247, 0.629)	< 0.001
Age - at baseline (years)					0.73		
< 65	24/85 (28.2)	NE (NE, NE)	15/91 (16.5)	NE (NE, NE)		0.426 (0.227, 0.802)	0.009
≥ 65	21/66 (31.8)	21.16 (NE, NE)	12/78 (15.4)	NE (NE, NE)		0.379 (0.191, 0.752)	0.006

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.96		
Male	24/86 (27.9)	NE (NE, NE)	16/107 (15.0)	NE (NE, NE)		0.390 (0.208, 0.732)	0.003
Female	21/65 (32.3)	21.16 (3.68, NE)	11/62 (17.7)	NE (NE, NE)		0.398 (0.196, 0.811)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.81		
Asian	3/19 (15.8)	NE (NE, NE)	2/21 (9.5)	NE (NE, NE)		0.550 (0.098, 3.089)	0.51
Non-Asian	42/131 (32.1)	21.16 (NE, NE)	25/147 (17.0)	NE (NE, NE)		0.378 (0.233, 0.614)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.81		
North America	11/19 (57.9)	1.48 (0.20, NE)	6/20 (30.0)	NE (0.72, NE)		0.394 (0.149, 1.041)	0.059
Europe	31/110 (28.2)	21.16 (NE, NE)	20/124 (16.1)	NE (NE, NE)		0.401 (0.232, 0.693)	0.001
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.246 (0.032, 1.887)	0.19

Page 103 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.63		
North America and Europe	42/129 (32.6)	21.16 (NE, NE)	26/144 (18.1)	NE (NE, NE)		0.403 (0.249, 0.652)	< 0.001
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.246 (0.032, 1.887)	0.19
Baseline ECOG status (screening)					0.19		
0	17/53 (32.1)	21.16 (NE, NE)	6/59 (10.2)	NE (NE, NE)		0.244 (0.100, 0.596)	0.001
1	28/98 (28.6)	NE (NE, NE)	21/110 (19.1)	NE (NE, NE)		0.479 (0.274, 0.838)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.92		
1	20/67 (29.9)	21.16 (4.14, NE)	12/76 (15.8)	NE (NE, NE)		0.429 (0.213, 0.867)	0.018
2	17/61 (27.9)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)		0.386 (0.179, 0.832)	0.018
> 2	8/23 (34.8)	NE (1.41, NE)	6/29 (20.7)	NE (8.44, NE)		0.379 (0.139, 1.032)	0.071

Page 105 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.14		
Yes	13/50 (26.0)	NE (NE, NE)	13/57 (22.8)	NE (NE, NE)		0.609 (0.289, 1.282)	0.21
No	32/101 (31.7)	21.16 (NE, NE)	14/112 (12.5)	NE (NE, NE)		0.302 (0.162, 0.562)	< 0.001
Liver metastasis					0.53		
Yes	8/28 (28.6)	NE (2.33, NE)	6/30 (20.0)	NE (8.44, NE)		0.408 (0.150, 1.108)	0.10
No	37/123 (30.1)	21.16 (NE, NE)	21/139 (15.1)	NE (NE, NE)		0.390 (0.230, 0.661)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.13		
Yes	14/61 (23.0)	NE (NE, NE)	14/80 (17.5)	NE (NE, NE)		0.604 (0.292, 1.251)	0.19
No	31/90 (34.4)	21.16 (NE, NE)	13/89 (14.6)	NE (NE, NE)		0.299 (0.160, 0.557)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.10		
< 1%	19/47 (40.4)	21.16 (2.33, NE)	7/55 (12.7)	NE (NE, NE)		0.224 (0.098, 0.510)	< 0.001
≥ 1% and < 50%	13/61 (21.3)	NE (NE, NE)	10/46 (21.7)	NE (NE, NE)		0.767 (0.332, 1.768)	0.54
≥ 50%	12/34 (35.3)	NE (2.14, NE)	9/60 (15.0)	NE (NE, NE)		0.331 (0.142, 0.772)	0.009

Page 108 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first oedema peripheral TEAE							
Overall	19/151 (12.6)	NE (16.53, NE)	5/169 (3.0)	NE (NE, NE)		0.143 (0.051, 0.404)	< 0.001
Age - at baseline (years)					–		
< 65	9/85 (10.6)	16.53 (11.73, NE)	0/91 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
≥ 65	10/66 (15.2)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		0.280 (0.094, 0.837)	0.015

Page 109 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.41		
Male	10/86 (11.6)	NE (NE, NE)	2/107 (1.9)	NE (NE, NE)		0.110 (0.026, 0.474)	< 0.001
Female	9/65 (13.8)	16.53 (11.73, NE)	3/62 (4.8)	NE (NE, NE)		0.214 (0.053, 0.869)	0.012

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	4/19 (21.1)	NE (3.19, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	15/131 (11.5)	NE (16.53, NE)	5/147 (3.4)	NE (NE, NE)		0.183 (0.063, 0.535)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.97		
North America	5/19 (26.3)	NE (4.34, NE)	1/20 (5.0)	NE (NE, NE)		0.166 (0.019, 1.449)	0.062
Europe	10/110 (9.1)	NE (16.53, NE)	3/124 (2.4)	NE (NE, NE)		0.159 (0.042, 0.601)	0.002
Rest of world	4/22 (18.2)	NE (3.45, NE)	1/25 (4.0)	NE (NE, NE)		0.128 (0.018, 0.933)	0.032

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.87		
North America and Europe	15/129 (11.6)	NE (16.53, NE)	4/144 (2.8)	NE (NE, NE)		0.148 (0.046, 0.480)	< 0.001
Rest of world	4/22 (18.2)	NE (3.45, NE)	1/25 (4.0)	NE (NE, NE)		0.128 (0.018, 0.933)	0.032
Baseline ECOG status (screening)					0.44		
0	8/53 (15.1)	NE (NE, NE)	1/59 (1.7)	NE (NE, NE)		0.085 (0.013, 0.565)	0.003
1	11/98 (11.2)	16.53 (11.73, NE)	4/110 (3.6)	NE (NE, NE)		0.166 (0.045, 0.615)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.79		
1	7/67 (10.4)	16.53 (16.53, NE)	1/76 (1.3)	NE (NE, NE)		0.082 (0.009, 0.755)	0.004
2	10/61 (16.4)	NE (NE, NE)	3/64 (4.7)	NE (NE, NE)		0.187 (0.050, 0.695)	0.005
> 2	2/23 (8.7)	11.73 (11.73, NE)	1/29 (3.4)	NE (NE, NE)		0.182 (0.017, 1.946)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.57		
Yes	4/50 (8.0)	NE (11.73, NE)	2/57 (3.5)	NE (NE, NE)		0.217 (0.034, 1.403)	0.062
No	15/101 (14.9)	NE (16.53, NE)	3/112 (2.7)	NE (NE, NE)		0.126 (0.036, 0.440)	< 0.001
Liver metastasis					0.92		
Yes	4/28 (14.3)	11.73 (3.19, NE)	1/30 (3.3)	NE (NE, NE)		0.135 (0.013, 1.452)	0.040
No	15/123 (12.2)	NE (16.53, NE)	4/139 (2.9)	NE (NE, NE)		0.152 (0.049, 0.472)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.76		
Yes	9/61 (14.8)	16.53 (11.73, NE)	3/80 (3.8)	NE (NE, NE)		0.148 (0.037, 0.601)	0.002
No	10/90 (11.1)	NE (NE, NE)	2/89 (2.2)	NE (NE, NE)		0.130 (0.030, 0.567)	0.002

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.82		
< 1%	11/47 (23.4)	16.53 (5.78, NE)	2/55 (3.6)	NE (NE, NE)		0.106 (0.022, 0.511)	< 0.001
≥ 1% and < 50%	4/61 (6.6)	NE (11.73, NE)	1/46 (2.2)	NE (NE, NE)		0.112 (0.014, 0.862)	0.023
≥ 50%	4/34 (11.8)	NE (NE, NE)	2/60 (3.3)	NE (NE, NE)		0.257 (0.048, 1.388)	0.091

Page 117 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first pyrexia TEAE							
Overall	20/151 (13.2)	NE (NE, NE)	11/169 (6.5)	NE (NE, NE)		0.320 (0.153, 0.665)	0.002
Age - at baseline (years)					0.021		
< 65	12/85 (14.1)	NE (8.48, NE)	1/91 (1.1)	NE (NE, NE)		0.049 (0.008, 0.295)	< 0.001
≥ 65	8/66 (12.1)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		0.712 (0.280, 1.812)	0.49

Page 118 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.27		
Male	13/86 (15.1)	NE (8.48, NE)	6/107 (5.6)	NE (NE, NE)		0.207 (0.072, 0.594)	0.002
Female	7/65 (10.8)	NE (NE, NE)	5/62 (8.1)	NE (NE, NE)		0.554 (0.185, 1.656)	0.31

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.38		
Asian	4/19 (21.1)	NE (3.68, NE)	1/21 (4.8)	NE (NE, NE)		0.189 (0.022, 1.619)	0.096
Non-Asian	16/131 (12.2)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		0.357 (0.163, 0.783)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.38		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.787 (0.172, 18.578)	0.63
Europe	14/110 (12.7)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.237 (0.098, 0.574)	0.002
Rest of world	5/22 (22.7)	NE (3.68, NE)	2/25 (8.0)	NE (NE, NE)		0.295 (0.059, 1.477)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.52		
North America and Europe	15/129 (11.6)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)		0.336 (0.149, 0.756)	0.009
Rest of world	5/22 (22.7)	NE (3.68, NE)	2/25 (8.0)	NE (NE, NE)		0.295 (0.059, 1.477)	0.12
Baseline ECOG status (screening)					0.20		
0	10/53 (18.9)	NE (8.48, NE)	3/59 (5.1)	NE (NE, NE)		0.176 (0.047, 0.651)	0.005
1	10/98 (10.2)	NE (NE, NE)	8/110 (7.3)	NE (NE, NE)		0.459 (0.185, 1.140)	0.11

Page 122 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.21		
1	10/67 (14.9)	NE (NE, NE)	3/76 (3.9)	NE (NE, NE)		0.187 (0.055, 0.638)	0.007
2	9/61 (14.8)	NE (8.48, NE)	5/64 (7.8)	NE (NE, NE)		0.285 (0.088, 0.922)	0.029
> 2	1/23 (4.3)	NE (4.50, NE)	3/29 (10.3)	NE (14.49, NE)		1.676 (0.165, 17.019)	0.65

Page 123 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.50		
Yes	5/50 (10.0)	NE (8.48, NE)	2/57 (3.5)	NE (NE, NE)		0.140 (0.023, 0.834)	0.018
No	15/101 (14.9)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)		0.396 (0.179, 0.877)	0.027
Liver metastasis					0.54		
Yes	4/28 (14.3)	NE (3.68, NE)	1/30 (3.3)	NE (NE, NE)		0.145 (0.012, 1.745)	0.055
No	16/123 (13.0)	NE (NE, NE)	10/139 (7.2)	NE (NE, NE)		0.351 (0.161, 0.767)	0.010

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.33		
Yes	10/61 (16.4)	NE (NE, NE)	4/80 (5.0)	NE (NE, NE)		0.220 (0.073, 0.665)	0.006
No	10/90 (11.1)	NE (NE, NE)	7/89 (7.9)	NE (NE, NE)		0.402 (0.145, 1.113)	0.076

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.26		
< 1%	9/47 (19.1)	NE (8.48, NE)	2/55 (3.6)	NE (NE, NE)		0.114 (0.026, 0.505)	0.001
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	3/46 (6.5)	NE (NE, NE)		0.645 (0.172, 2.422)	0.58
≥ 50%	4/34 (11.8)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)		0.460 (0.124, 1.706)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first hepatobiliary disorders TEAE							
Overall	3/151 (2.0)	NE (NE, NE)	21/169 (12.4)	NE (NE, NE)		5.590 (1.671, 18.702)	0.002
Age - at baseline (years)					0.70		
< 65	1/85 (1.2)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)		7.289 (0.927, 57.316)	0.028
≥ 65	2/66 (3.0)	NE (NE, NE)	12/78 (15.4)	NE (NE, NE)		4.653 (1.049, 20.640)	0.027

Page 127 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	3/86 (3.5)	NE (NE, NE)	11/107 (10.3)	NE (NE, NE)		2.701 (0.759, 9.610)	0.11
Female	0/65 (0.0)	NE (NE, NE)	10/62 (16.1)	NE (NE, NE)		NE (NE, NE)	NE

Page 128 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.42		
Asian	1/19 (5.3)	NE (NE, NE)	3/21 (14.3)	NE (NE, NE)		2.381 (0.264, 21.439)	0.44
Non-Asian	2/131 (1.5)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		7.186 (1.671, 30.901)	0.002

Page 129 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	3/20 (15.0)	NE (12.45, NE)		NE (NE, NE)	NE
Europe	2/110 (1.8)	NE (NE, NE)	14/124 (11.3)	NE (NE, NE)		5.730 (1.304, 25.171)	0.009
Rest of world	1/22 (4.5)	NE (NE, NE)	4/25 (16.0)	NE (NE, NE)		3.073 (0.364, 25.949)	0.29

Page 130 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.53		
North America and Europe	2/129 (1.6)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)		6.841 (1.582, 29.579)	0.003
Rest of world	1/22 (4.5)	NE (NE, NE)	4/25 (16.0)	NE (NE, NE)		3.073 (0.364, 25.949)	0.29
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	10/59 (16.9)	NE (NE, NE)		NE (NE, NE)	NE
1	3/98 (3.1)	NE (NE, NE)	11/110 (10.0)	NE (NE, NE)		2.539 (0.728, 8.853)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		8/76 (10.5)				
2	1/61 (1.6)		8/64 (12.5)				
> 2	1/23 (4.3)		5/29 (17.2)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.48		
Yes	1/50 (2.0)	NE (NE, NE)	4/57 (7.0)	NE (NE, NE)		3.023 (0.355, 25.738)	0.30
No	2/101 (2.0)	NE (NE, NE)	17/112 (15.2)	NE (NE, NE)		7.151 (1.652, 30.959)	0.002
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		NE (NE, NE)	NE
No	3/123 (2.4)	NE (NE, NE)	20/139 (14.4)	NE (NE, NE)		5.381 (1.594, 18.164)	0.002

Page 133 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.34		
Yes	2/61 (3.3)	NE (NE, NE)	9/80 (11.3)	NE (NE, NE)		2.988 (0.652, 13.692)	0.14
No	1/90 (1.1)	NE (NE, NE)	12/89 (13.5)	NE (NE, NE)		10.771 (1.398, 82.954)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		4/55 (7.3)				
≥ 1% and < 50%	1/61 (1.6)		5/46 (10.9)				
≥ 50%	0/34 (0.0)		8/60 (13.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first infections and infestations TEAE							
Overall	58/151 (38.4)	6.28 (4.21, 10.41)	52/169 (30.8)	15.44 (11.40, NE)		0.439 (0.297, 0.650)	< 0.001
Age - at baseline (years)					0.040		
< 65	27/85 (31.8)	10.15 (5.09, NE)	31/91 (34.1)	15.34 (8.84, NE)		0.639 (0.374, 1.093)	0.10
≥ 65	31/66 (47.0)	4.63 (2.79, 7.10)	21/78 (26.9)	NE (10.28, NE)		0.281 (0.157, 0.500)	< 0.001

Page 136 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.067		
Male	32/86 (37.2)	6.28 (3.65, NE)	24/107 (22.4)	NE (15.34, NE)		0.285 (0.161, 0.504)	< 0.001
Female	26/65 (40.0)	6.18 (2.50, NE)	28/62 (45.2)	8.84 (6.24, NE)		0.703 (0.409, 1.211)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.46		
Asian	9/19 (47.4)	6.28 (1.41, NE)	5/21 (23.8)	NE (4.86, NE)		0.379 (0.135, 1.063)	0.072
Non-Asian	49/131 (37.4)	10.15 (4.21, 15.41)	47/147 (32.0)	15.44 (11.40, NE)		0.470 (0.310, 0.714)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.58		
North America	9/19 (47.4)	4.63 (1.41, NE)	7/20 (35.0)	NE (2.89, NE)		0.524 (0.197, 1.397)	0.20
Europe	37/110 (33.6)	10.15 (4.21, NE)	38/124 (30.6)	15.44 (11.40, NE)		0.467 (0.291, 0.750)	0.002
Rest of world	12/22 (54.5)	5.09 (0.79, 7.10)	7/25 (28.0)	NE (4.86, NE)		0.357 (0.147, 0.863)	0.024

Page 139 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.30		
North America and Europe	46/129 (35.7)	10.15 (4.21, 15.41)	45/144 (31.3)	15.44 (11.40, NE)		0.486 (0.316, 0.748)	< 0.001
Rest of world	12/22 (54.5)	5.09 (0.79, 7.10)	7/25 (28.0)	NE (4.86, NE)		0.357 (0.147, 0.863)	0.024
Baseline ECOG status (screening)					0.45		
0	23/53 (43.4)	7.10 (3.42, 15.41)	17/59 (28.8)	NE (12.42, NE)		0.377 (0.196, 0.726)	0.003
1	35/98 (35.7)	6.18 (4.63, NE)	35/110 (31.8)	13.73 (8.05, NE)		0.464 (0.284, 0.759)	0.003

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.34		
1	28/67 (41.8)	5.09 (3.42, 7.10)	30/76 (39.5)	11.04 (4.86, NE)		0.572 (0.333, 0.982)	0.042
2	20/61 (32.8)	10.15 (4.21, NE)	12/64 (18.8)	NE (15.34, NE)		0.266 (0.118, 0.596)	< 0.001
> 2	10/23 (43.5)	15.41 (1.18, NE)	10/29 (34.5)	13.73 (5.95, NE)		0.425 (0.181, 0.998)	0.057

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.71		
Yes	15/50 (30.0)	10.15 (3.48, NE)	17/57 (29.8)	NE (7.69, NE)		0.532 (0.259, 1.090)	0.091
No	43/101 (42.6)	5.09 (3.65, 10.41)	35/112 (31.3)	15.44 (10.28, NE)		0.413 (0.259, 0.658)	< 0.001
Liver metastasis					0.20		
Yes	8/28 (28.6)	NE (2.66, NE)	10/30 (33.3)	11.40 (8.84, NE)		0.715 (0.256, 1.992)	0.52
No	50/123 (40.7)	6.18 (4.21, 10.41)	42/139 (30.2)	NE (12.42, NE)		0.397 (0.260, 0.607)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.83		
Yes	24/61 (39.3)	6.28 (2.79, NE)	25/80 (31.3)	13.31 (8.84, NE)		0.437 (0.240, 0.794)	0.005
No	34/90 (37.8)	7.10 (4.21, NE)	27/89 (30.3)	NE (12.42, NE)		0.448 (0.265, 0.758)	0.003

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.74		
< 1%	17/47 (36.2)	6.18 (4.21, NE)	14/55 (25.5)	NE (11.40, NE)		0.423 (0.196, 0.912)	0.021
≥ 1% and < 50%	20/61 (32.8)	NE (2.96, NE)	16/46 (34.8)	9.72 (4.86, NE)		0.574 (0.295, 1.119)	0.11
≥ 50%	17/34 (50.0)	6.28 (1.41, NE)	19/60 (31.7)	13.73 (8.05, NE)		0.378 (0.201, 0.711)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first investigations TEAE							
Overall	30/151 (19.9)	NE (11.07, NE)	56/169 (33.1)	NE (11.73, NE)		1.434 (0.918, 2.239)	0.11
Age - at baseline (years)					0.92		
< 65	13/85 (15.3)	NE (11.07, NE)	24/91 (26.4)	NE (14.92, NE)		1.440 (0.730, 2.837)	0.29
≥ 65	17/66 (25.8)	NE (NE, NE)	32/78 (41.0)	NE (4.14, NE)		1.407 (0.779, 2.541)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.54		
Male	19/86 (22.1)	NE (NE, NE)	36/107 (33.6)	NE (9.69, NE)		1.277 (0.727, 2.241)	0.39
Female	11/65 (16.9)	NE (11.07, NE)	20/62 (32.3)	NE (11.73, NE)		1.697 (0.820, 3.511)	0.15

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.56		
Asian	7/19 (36.8)	NE (0.23, NE)	10/21 (47.6)	3.38 (1.51, NE)		1.057 (0.399, 2.799)	0.89
Non-Asian	23/131 (17.6)	NE (11.07, NE)	45/147 (30.6)	NE (14.92, NE)		1.483 (0.896, 2.454)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.30		
North America	3/19 (15.8)	NE (NE, NE)	10/20 (50.0)	2.79 (1.28, NE)		3.480 (0.928, 13.055)	0.044
Europe	20/110 (18.2)	NE (11.07, NE)	36/124 (29.0)	NE (11.73, NE)		1.265 (0.729, 2.193)	0.41
Rest of world	7/22 (31.8)	NE (0.26, NE)	10/25 (40.0)	NE (2.07, NE)		0.982 (0.379, 2.543)	0.98

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.40		
North America and Europe	23/129 (17.8)	NE (11.07, NE)	46/144 (31.9)	NE (11.73, NE)		1.542 (0.933, 2.547)	0.090
Rest of world	7/22 (31.8)	NE (0.26, NE)	10/25 (40.0)	NE (2.07, NE)		0.982 (0.379, 2.543)	0.98
Baseline ECOG status (screening)					0.33		
0	9/53 (17.0)	NE (11.07, NE)	21/59 (35.6)	NE (4.14, NE)		2.011 (0.899, 4.498)	0.076
1	21/98 (21.4)	NE (NE, NE)	35/110 (31.8)	NE (8.05, NE)		1.168 (0.682, 1.999)	0.58

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.71		
1	12/67 (17.9)	NE (NE, NE)	20/76 (26.3)	NE (NE, NE)		1.400 (0.685, 2.862)	0.35
2	12/61 (19.7)	11.07 (11.07, NE)	26/64 (40.6)	11.73 (5.82, NE)		1.566 (0.780, 3.145)	0.21
> 2	6/23 (26.1)	NE (4.34, NE)	10/29 (34.5)	NE (3.48, NE)		1.070 (0.403, 2.837)	0.90

Page 150 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.17		
Yes	9/50 (18.0)	NE (NE, NE)	26/57 (45.6)	9.69 (2.10, NE)		2.156 (1.004, 4.629)	0.043
No	21/101 (20.8)	NE (11.07, NE)	30/112 (26.8)	NE (NE, NE)		1.126 (0.643, 1.971)	0.68
Liver metastasis					0.54		
Yes	6/28 (21.4)	NE (NE, NE)	8/30 (26.7)	14.92 (14.92, NE)		1.108 (0.392, 3.130)	0.85
No	24/123 (19.5)	NE (11.07, NE)	48/139 (34.5)	NE (9.69, NE)		1.535 (0.937, 2.515)	0.086

Page 151 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.47		
Yes	13/61 (21.3)	NE (NE, NE)	31/80 (38.8)	14.92 (5.82, NE)		1.667 (0.865, 3.212)	0.12
No	17/90 (18.9)	NE (11.07, NE)	25/89 (28.1)	NE (NE, NE)		1.216 (0.657, 2.250)	0.53

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.23		
< 1%	12/47 (25.5)	NE (6.60, NE)	18/55 (32.7)	NE (4.14, NE)		1.145 (0.556, 2.359)	0.72
≥ 1% and < 50%	12/61 (19.7)	NE (11.07, NE)	15/46 (32.6)	NE (3.48, NE)		1.343 (0.630, 2.860)	0.45
≥ 50%	3/34 (8.8)	NE (NE, NE)	19/60 (31.7)	NE (8.05, NE)		3.533 (1.064, 11.730)	0.030

Page 153 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first alanine aminotransferase increased TEAE							
Overall	1/151 (0.7)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		14.881 (1.986, 111.486)	< 0.001
Age - at baseline (years)					–		
< 65	1/85 (1.2)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		5.222 (0.633, 43.108)	0.087
≥ 65	0/66 (0.0)	NE (NE, NE)	12/78 (15.4)	NE (NE, NE)		NE (NE, NE)	NE

Page 154 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	1/86 (1.2)	NE (NE, NE)	15/107 (14.0)	NE (NE, NE)		11.519 (1.516, 87.537)	0.003
Female	0/65 (0.0)	NE (NE, NE)	3/62 (4.8)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	5/21 (23.8)	NE (3.38, NE)		NE (NE, NE)	NE
Non-Asian	1/131 (0.8)	NE (NE, NE)	13/147 (8.8)	NE (NE, NE)		10.668 (1.398, 81.400)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	3/20 (15.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	1/110 (0.9)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		7.437 (0.944, 58.577)	0.025
Rest of world	0/22 (0.0)	NE (NE, NE)	6/25 (24.0)	NE (4.07, NE)		NE (NE, NE)	NE

Page 157 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	1/129 (0.8)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)		10.227 (1.327, 78.792)	0.006
Rest of world	0/22 (0.0)	NE (NE, NE)	6/25 (24.0)	NE (4.07, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	1/53 (1.9)	NE (NE, NE)	8/59 (13.6)	NE (NE, NE)		7.336 (0.908, 59.256)	0.027
1	0/98 (0.0)	NE (NE, NE)	10/110 (9.1)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		8/76 (10.5)				
2	0/61 (0.0)		9/64 (14.1)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	6/57 (10.5)	NE (NE, NE)		NE (NE, NE)	NE
No	1/101 (1.0)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		10.335 (1.343, 79.547)	0.005
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		NE (NE, NE)	NE
No	1/123 (0.8)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		13.148 (1.742, 99.246)	0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)	NE (NE, NE)	11/80 (13.8)	NE (NE, NE)		NE (NE, NE)	NE
No	1/90 (1.1)	NE (NE, NE)	7/89 (7.9)	NE (NE, NE)		6.436 (0.802, 51.623)	0.045

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)	NE (NE, NE)	10/55 (18.2)	NE (NE, NE)		NE (NE, NE)	NE
≥ 1% and < 50%	0/61 (0.0)	NE (NE, NE)	3/46 (6.5)	NE (NE, NE)		NE (NE, NE)	NE
≥ 50%	0/34 (0.0)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)		NE (NE, NE)	NE

Page 162 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first aspartate aminotransferase increased TEAE							
Overall	1/151 (0.7)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		14.609 (1.953, 109.274)	< 0.001
Age - at baseline (years)					–		
< 65	1/85 (1.2)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		5.222 (0.633, 43.108)	0.087
≥ 65	0/66 (0.0)	NE (NE, NE)	12/78 (15.4)	NE (NE, NE)		NE (NE, NE)	NE

Page 163 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	1/86 (1.2)	NE (NE, NE)	16/107 (15.0)	NE (NE, NE)		12.103 (1.600, 91.529)	0.002
Female	0/65 (0.0)	NE (NE, NE)	2/62 (3.2)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	6/21 (28.6)	NE (3.38, NE)		NE (NE, NE)	NE
Non-Asian	1/131 (0.8)	NE (NE, NE)	12/147 (8.2)	NE (NE, NE)		9.774 (1.275, 74.904)	0.007

Page 165 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	1/110 (0.9)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		7.437 (0.944, 58.577)	0.025
Rest of world	0/22 (0.0)	NE (NE, NE)	7/25 (28.0)	NE (4.07, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	1/129 (0.8)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)		9.318 (1.203, 72.202)	0.009
Rest of world	0/22 (0.0)	NE (NE, NE)	7/25 (28.0)	NE (4.07, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	1/53 (1.9)	NE (NE, NE)	8/59 (13.6)	NE (NE, NE)		7.203 (0.895, 57.952)	0.029
1	0/98 (0.0)	NE (NE, NE)	10/110 (9.1)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		8/76 (10.5)				
2	0/61 (0.0)		9/64 (14.1)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	7/57 (12.3)	NE (NE, NE)		NE (NE, NE)	NE
No	1/101 (1.0)	NE (NE, NE)	11/112 (9.8)	NE (NE, NE)		9.373 (1.212, 72.474)	0.009
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		NE (NE, NE)	NE
No	1/123 (0.8)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		12.926 (1.715, 97.412)	0.001

Page 169 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)	NE (NE, NE)	10/80 (12.5)	NE (NE, NE)		NE (NE, NE)	NE
No	1/90 (1.1)	NE (NE, NE)	8/89 (9.0)	NE (NE, NE)		7.159 (0.909, 56.383)	0.030

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		9/55 (16.4)				
≥ 1% and < 50%	0/61 (0.0)		3/46 (6.5)				
≥ 50%	0/34 (0.0)		5/60 (8.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first metabolism and nutrition disorders TEAE							
Overall	53/151 (35.1)	13.90 (5.55, NE)	74/169 (43.8)	12.02 (5.52, 19.35)		0.970 (0.680, 1.382)	0.87
Age - at baseline (years)					0.37		
< 65	26/85 (30.6)	13.90 (13.90, NE)	38/91 (41.8)	12.02 (4.17, 19.35)		1.133 (0.688, 1.865)	0.63
≥ 65	27/66 (40.9)	NE (2.76, NE)	36/78 (46.2)	9.00 (4.17, NE)		0.810 (0.490, 1.338)	0.42

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.15		
Male	33/86 (38.4)	NE (3.52, NE)	45/107 (42.1)	14.00 (6.90, NE)		0.748 (0.474, 1.181)	0.22
Female	20/65 (30.8)	13.90 (2.96, NE)	29/62 (46.8)	5.55 (2.79, NE)		1.377 (0.782, 2.423)	0.27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.54		
Asian	10/19 (52.6)	2.23 (0.26, NE)	12/21 (57.1)	5.21 (0.76, NE)		0.807 (0.348, 1.870)	0.63
Non-Asian	42/131 (32.1)	13.90 (5.55, NE)	62/147 (42.2)	14.00 (5.55, 19.35)		1.027 (0.693, 1.522)	0.90

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.44		
North America	12/19 (63.2)	1.38 (0.26, NE)	11/20 (55.0)	2.64 (0.59, NE)		0.654 (0.296, 1.445)	0.31
Europe	32/110 (29.1)	13.90 (13.90, NE)	50/124 (40.3)	14.69 (6.90, NE)		1.090 (0.698, 1.704)	0.71
Rest of world	9/22 (40.9)	NE (0.46, NE)	13/25 (52.0)	5.52 (1.15, NE)		0.928 (0.394, 2.186)	0.87

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.82		
North America and Europe	44/129 (34.1)	13.90 (5.55, NE)	61/144 (42.4)	14.00 (5.55, 19.35)		0.981 (0.665, 1.448)	0.92
Rest of world	9/22 (40.9)	NE (0.46, NE)	13/25 (52.0)	5.52 (1.15, NE)		0.928 (0.394, 2.186)	0.87
Baseline ECOG status (screening)					0.33		
0	19/53 (35.8)	13.90 (3.52, NE)	21/59 (35.6)	18.40 (5.55, NE)		0.718 (0.380, 1.354)	0.31
1	34/98 (34.7)	NE (3.78, NE)	53/110 (48.2)	6.90 (3.48, 14.69)		1.067 (0.692, 1.645)	0.77

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.76		
1	23/67 (34.3)	NE (2.96, NE)	30/76 (39.5)	18.40 (5.52, NE)		0.973 (0.564, 1.678)	0.92
2	21/61 (34.4)	13.90 (3.52, NE)	32/64 (50.0)	5.55 (4.11, NE)		1.056 (0.607, 1.838)	0.84
> 2	9/23 (39.1)	NE (1.38, NE)	12/29 (41.4)	14.00 (3.71, NE)		0.728 (0.310, 1.710)	0.47

Page 177 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.67		
Yes	17/50 (34.0)	NE (2.96, NE)	27/57 (47.4)	12.02 (4.14, NE)		0.744 (0.397, 1.396)	0.37
No	36/101 (35.6)	13.90 (5.55, NE)	47/112 (42.0)	14.69 (4.17, NE)		1.039 (0.675, 1.599)	0.87
Liver metastasis					0.29		
Yes	14/28 (50.0)	2.23 (0.69, NE)	14/30 (46.7)	4.17 (2.10, NE)		0.660 (0.316, 1.377)	0.28
No	39/123 (31.7)	13.90 (13.90, NE)	60/139 (43.2)	14.00 (5.55, 19.35)		1.068 (0.711, 1.603)	0.75

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.69		
Yes	20/61 (32.8)	NE (NE, NE)	34/80 (42.5)	12.02 (4.17, NE)		1.086 (0.626, 1.884)	0.77
No	33/90 (36.7)	13.90 (3.52, NE)	40/89 (44.9)	14.00 (4.63, NE)		0.892 (0.560, 1.420)	0.63

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.19		
< 1%	17/47 (36.2)	NE (2.96, NE)	25/55 (45.5)	14.00 (3.81, NE)		1.038 (0.558, 1.931)	0.91
≥ 1% and < 50%	19/61 (31.1)	13.90 (3.78, NE)	23/46 (50.0)	4.14 (2.10, NE)		1.312 (0.723, 2.383)	0.39
≥ 50%	15/34 (44.1)	NE (1.41, NE)	22/60 (36.7)	19.35 (4.90, NE)		0.593 (0.304, 1.158)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first decreased appetite TEAE							
Overall	29/151 (19.2)	NE (NE, NE)	39/169 (23.1)	NE (NE, NE)		0.962 (0.596, 1.553)	0.88
Age - at baseline (years)					0.90		
< 65	15/85 (17.6)	NE (NE, NE)	19/91 (20.9)	NE (NE, NE)		0.957 (0.486, 1.883)	0.90
≥ 65	14/66 (21.2)	NE (NE, NE)	20/78 (25.6)	NE (NE, NE)		0.957 (0.487, 1.881)	0.90

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.90		
Male	15/86 (17.4)	NE (NE, NE)	24/107 (22.4)	NE (NE, NE)		0.924 (0.481, 1.774)	0.81
Female	14/65 (21.5)	NE (NE, NE)	15/62 (24.2)	NE (NE, NE)		0.998 (0.485, 2.055)	1.00

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.43		
Asian	6/19 (31.6)	NE (0.30, NE)	11/21 (52.4)	10.23 (0.76, NE)		1.392 (0.502, 3.857)	0.52
Non-Asian	23/131 (17.6)	NE (NE, NE)	28/147 (19.0)	NE (NE, NE)		0.847 (0.490, 1.464)	0.56

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.36		
North America	7/19 (36.8)	NE (0.30, NE)	5/20 (25.0)	NE (2.79, NE)		0.561 (0.187, 1.685)	0.32
Europe	18/110 (16.4)	NE (NE, NE)	24/124 (19.4)	NE (NE, NE)		0.931 (0.507, 1.713)	0.82
Rest of world	4/22 (18.2)	NE (NE, NE)	10/25 (40.0)	15.57 (4.90, NE)		1.811 (0.558, 5.871)	0.32

Page 184 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.26		
North America and Europe	25/129 (19.4)	NE (NE, NE)	29/144 (20.1)	NE (NE, NE)		0.836 (0.492, 1.421)	0.52
Rest of world	4/22 (18.2)	NE (NE, NE)	10/25 (40.0)	15.57 (4.90, NE)		1.811 (0.558, 5.871)	0.32
Baseline ECOG status (screening)					0.78		
0	8/53 (15.1)	NE (NE, NE)	11/59 (18.6)	NE (NE, NE)		1.048 (0.424, 2.592)	0.92
1	21/98 (21.4)	NE (NE, NE)	28/110 (25.5)	NE (15.44, NE)		0.908 (0.516, 1.597)	0.75

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.26		
1	16/67 (23.9)	NE (NE, NE)	17/76 (22.4)	NE (NE, NE)		0.791 (0.401, 1.562)	0.51
2	8/61 (13.1)	NE (NE, NE)	17/64 (26.6)	NE (15.44, NE)		1.641 (0.711, 3.787)	0.25
> 2	5/23 (21.7)	NE (3.71, NE)	5/29 (17.2)	NE (14.00, NE)		0.470 (0.142, 1.552)	0.23

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.45		
Yes	11/50 (22.0)	NE (3.71, NE)	14/57 (24.6)	NE (14.00, NE)		0.554 (0.244, 1.256)	0.17
No	18/101 (17.8)	NE (NE, NE)	25/112 (22.3)	NE (NE, NE)		1.169 (0.641, 2.133)	0.61
Liver metastasis					0.42		
Yes	9/28 (32.1)	NE (2.23, NE)	9/30 (30.0)	NE (4.17, NE)		0.651 (0.251, 1.687)	0.38
No	20/123 (16.3)	NE (NE, NE)	30/139 (21.6)	NE (NE, NE)		1.081 (0.615, 1.901)	0.79

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.37		
Yes	9/61 (14.8)	NE (NE, NE)	18/80 (22.5)	NE (NE, NE)		1.258 (0.567, 2.787)	0.58
No	20/90 (22.2)	NE (NE, NE)	21/89 (23.6)	NE (15.57, NE)		0.813 (0.443, 1.492)	0.52

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.53		
< 1%	9/47 (19.1)	NE (NE, NE)	14/55 (25.5)	NE (14.00, NE)		1.148 (0.502, 2.628)	0.75
≥ 1% and < 50%	9/61 (14.8)	NE (NE, NE)	9/46 (19.6)	NE (15.57, NE)		1.006 (0.405, 2.499)	0.99
≥ 50%	10/34 (29.4)	NE (3.52, NE)	14/60 (23.3)	NE (15.44, NE)		0.630 (0.282, 1.407)	0.27

Page 189 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first musculoskeletal and connective tissue disorders TEAE							
Overall	57/151 (37.7)	13.08 (6.47, NE)	74/169 (43.8)	8.54 (7.46, 11.76)		0.847 (0.602, 1.192)	0.36
Age - at baseline (years)					0.96		
< 65	31/85 (36.5)	13.08 (4.01, NE)	38/91 (41.8)	9.56 (5.09, NE)		0.856 (0.537, 1.365)	0.53
≥ 65	26/66 (39.4)	18.66 (2.07, NE)	36/78 (46.2)	8.21 (4.90, 11.83)		0.844 (0.513, 1.388)	0.52

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.050		
Male	33/86 (38.4)	NE (3.94, NE)	39/107 (36.4)	9.76 (8.21, NE)		0.612 (0.383, 0.978)	0.041
Female	24/65 (36.9)	18.66 (3.71, NE)	35/62 (56.5)	4.57 (2.07, 7.46)		1.304 (0.780, 2.178)	0.30

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.034		
Asian	10/19 (52.6)	0.95 (0.10, NE)	8/21 (38.1)	9.56 (2.76, NE)		0.315 (0.124, 0.799)	0.023
Non-Asian	46/131 (35.1)	18.66 (6.47, NE)	65/147 (44.2)	8.28 (5.09, 11.76)		0.976 (0.672, 1.418)	0.91

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.040		
North America	10/19 (52.6)	1.41 (0.07, NE)	8/20 (40.0)	NE (2.33, NE)		0.438 (0.183, 1.051)	0.081
Europe	36/110 (32.7)	18.66 (6.47, NE)	55/124 (44.4)	8.08 (5.09, 11.63)		1.107 (0.729, 1.680)	0.63
Rest of world	11/22 (50.0)	1.68 (0.13, NE)	11/25 (44.0)	9.56 (2.66, NE)		0.420 (0.180, 0.980)	0.055

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.085		
North America and Europe	46/129 (35.7)	18.66 (6.47, NE)	63/144 (43.8)	8.28 (5.09, 11.76)		0.953 (0.654, 1.388)	0.81
Rest of world	11/22 (50.0)	1.68 (0.13, NE)	11/25 (44.0)	9.56 (2.66, NE)		0.420 (0.180, 0.980)	0.055
Baseline ECOG status (screening)					0.65		
0	22/53 (41.5)	18.66 (2.56, NE)	28/59 (47.5)	9.56 (7.49, NE)		0.921 (0.531, 1.600)	0.78
1	35/98 (35.7)	13.08 (3.94, NE)	46/110 (41.8)	8.08 (3.98, NE)		0.794 (0.517, 1.219)	0.32

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.42		
1	27/67 (40.3)	13.08 (6.47, NE)	30/76 (39.5)	11.63 (5.09, NE)		0.707 (0.427, 1.171)	0.20
2	20/61 (32.8)	NE (4.01, NE)	31/64 (48.4)	8.08 (4.57, 9.66)		1.120 (0.637, 1.969)	0.69
> 2	10/23 (43.5)	3.94 (0.72, NE)	13/29 (44.8)	9.56 (2.76, NE)		0.695 (0.310, 1.558)	0.39

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.66		
Yes	16/50 (32.0)	NE (2.56, NE)	27/57 (47.4)	8.21 (3.98, NE)		0.950 (0.511, 1.766)	0.89
No	41/101 (40.6)	13.08 (3.94, NE)	47/112 (42.0)	8.54 (5.09, NE)		0.799 (0.529, 1.204)	0.30
Liver metastasis					0.021		
Yes	14/28 (50.0)	1.41 (0.62, NE)	9/30 (30.0)	NE (2.66, NE)		0.359 (0.164, 0.786)	0.014
No	43/123 (35.0)	18.66 (6.47, NE)	65/139 (46.8)	8.28 (5.09, 11.63)		1.013 (0.691, 1.483)	0.94

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.76		
Yes	25/61 (41.0)	13.08 (2.14, NE)	36/80 (45.0)	7.49 (3.68, 9.66)		0.772 (0.463, 1.286)	0.33
No	32/90 (35.6)	18.66 (6.47, NE)	38/89 (42.7)	11.63 (8.08, NE)		0.905 (0.571, 1.435)	0.69

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.76		
< 1%	20/47 (42.6)	13.08 (2.56, NE)	24/55 (43.6)	8.54 (3.98, NE)		0.868 (0.478, 1.576)	0.65
≥ 1% and < 50%	17/61 (27.9)	NE (4.01, NE)	19/46 (41.3)	9.76 (8.08, 11.83)		0.953 (0.500, 1.818)	0.89
≥ 50%	16/34 (47.1)	6.47 (0.16, NE)	27/60 (45.0)	8.21 (3.48, NE)		0.738 (0.390, 1.396)	0.35

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first arthralgia TEAE							
Overall	21/151 (13.9)	NE (13.08, NE)	26/169 (15.4)	NE (NE, NE)		0.810 (0.461, 1.426)	0.48
Age - at baseline (years)					0.94		
< 65	12/85 (14.1)	NE (13.08, NE)	14/91 (15.4)	NE (NE, NE)		0.829 (0.385, 1.782)	0.63
≥ 65	9/66 (13.6)	NE (NE, NE)	12/78 (15.4)	NE (NE, NE)		0.812 (0.356, 1.848)	0.64

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.58		
Male	12/86 (14.0)	NE (NE, NE)	15/107 (14.0)	NE (NE, NE)		0.702 (0.336, 1.467)	0.37
Female	9/65 (13.8)	NE (13.08, NE)	11/62 (17.7)	NE (NE, NE)		1.030 (0.428, 2.480)	0.95

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.39		
Asian	4/19 (21.1)	NE (NE, NE)	3/21 (14.3)	NE (9.56, NE)		0.346 (0.074, 1.617)	0.20
Non-Asian	17/131 (13.0)	NE (13.08, NE)	23/147 (15.6)	NE (NE, NE)		0.898 (0.484, 1.666)	0.74

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.55		
North America	2/19 (10.5)	NE (4.86, NE)	3/20 (15.0)	NE (6.21, NE)		1.242 (0.220, 7.028)	0.81
Europe	14/110 (12.7)	NE (13.08, NE)	19/124 (15.3)	NE (NE, NE)		0.889 (0.449, 1.759)	0.74
Rest of world	5/22 (22.7)	NE (NE, NE)	4/25 (16.0)	NE (9.56, NE)		0.363 (0.101, 1.304)	0.15

Page 202 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.29		
North America and Europe	16/129 (12.4)	NE (13.08, NE)	22/144 (15.3)	NE (NE, NE)		0.928 (0.491, 1.755)	0.82
Rest of world	5/22 (22.7)	NE (NE, NE)	4/25 (16.0)	NE (9.56, NE)		0.363 (0.101, 1.304)	0.15
Baseline ECOG status (screening)					0.035		
0	5/53 (9.4)	NE (NE, NE)	13/59 (22.0)	NE (NE, NE)		1.948 (0.703, 5.393)	0.20
1	16/98 (16.3)	NE (13.08, NE)	13/110 (11.8)	NE (NE, NE)		0.451 (0.222, 0.916)	0.032

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.41		
1	11/67 (16.4)	NE (13.08, NE)	12/76 (15.8)	NE (NE, NE)		0.778 (0.343, 1.764)	0.55
2	6/61 (9.8)	NE (NE, NE)	11/64 (17.2)	NE (NE, NE)		1.231 (0.472, 3.211)	0.69
> 2	4/23 (17.4)	NE (3.94, NE)	3/29 (10.3)	NE (9.56, NE)		0.291 (0.069, 1.220)	0.098

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.51		
Yes	6/50 (12.0)	NE (NE, NE)	11/57 (19.3)	NE (9.66, NE)		0.862 (0.321, 2.318)	0.78
No	15/101 (14.9)	NE (13.08, NE)	15/112 (13.4)	NE (NE, NE)		0.738 (0.363, 1.502)	0.41
Liver metastasis					0.22		
Yes	3/28 (10.7)	NE (4.86, NE)	7/30 (23.3)	NE (4.17, NE)		1.247 (0.350, 4.440)	0.75
No	18/123 (14.6)	NE (13.08, NE)	19/139 (13.7)	NE (NE, NE)		0.699 (0.370, 1.319)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.20		
Yes	8/61 (13.1)	NE (13.08, NE)	16/80 (20.0)	NE (9.56, NE)		1.009 (0.447, 2.281)	0.98
No	13/90 (14.4)	NE (NE, NE)	10/89 (11.2)	NE (NE, NE)		0.652 (0.288, 1.475)	0.31

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.39		
< 1%	5/47 (10.6)	NE (13.08, NE)	8/55 (14.5)	NE (NE, NE)		0.945 (0.316, 2.823)	0.92
≥ 1% and < 50%	6/61 (9.8)	NE (NE, NE)	9/46 (19.6)	NE (NE, NE)		1.422 (0.522, 3.878)	0.51
≥ 50%	7/34 (20.6)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)		0.552 (0.203, 1.505)	0.25

Page 207 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first back pain TEAE							
Overall	16/151 (10.6)	NE (NE, NE)	23/169 (13.6)	NE (NE, NE)		0.952 (0.511, 1.772)	0.88
Age - at baseline (years)					0.21		
< 65	12/85 (14.1)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)		0.745 (0.342, 1.619)	0.48
≥ 65	4/66 (6.1)	NE (NE, NE)	11/78 (14.1)	NE (NE, NE)		1.543 (0.508, 4.686)	0.47

Page 208 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.46		
Male	9/86 (10.5)	NE (NE, NE)	12/107 (11.2)	NE (NE, NE)		0.692 (0.305, 1.569)	0.42
Female	7/65 (10.8)	NE (NE, NE)	11/62 (17.7)	NE (NE, NE)		1.392 (0.547, 3.547)	0.49

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	2/19 (10.5)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	13/131 (9.9)	NE (NE, NE)	22/147 (15.0)	NE (NE, NE)		1.123 (0.573, 2.198)	0.74

Page 210 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	5/19 (26.3)	NE (0.85, NE)	3/20 (15.0)	NE (NE, NE)		0.445 (0.120, 1.645)	0.26
Europe	10/110 (9.1)	NE (NE, NE)	20/124 (16.1)	NE (NE, NE)		1.302 (0.615, 2.754)	0.50
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	15/129 (11.6)	NE (NE, NE)	23/144 (16.0)	NE (NE, NE)		1.027 (0.544, 1.938)	0.94
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.90		
0	5/53 (9.4)	NE (NE, NE)	7/59 (11.9)	NE (NE, NE)		1.179 (0.378, 3.676)	0.78
1	11/98 (11.2)	NE (NE, NE)	16/110 (14.5)	NE (NE, NE)		0.807 (0.389, 1.675)	0.60

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.19		
1	8/67 (11.9)	NE (NE, NE)	10/76 (13.2)	NE (NE, NE)		0.899 (0.359, 2.247)	0.83
2	5/61 (8.2)	NE (NE, NE)	12/64 (18.8)	NE (NE, NE)		1.534 (0.555, 4.239)	0.43
> 2	3/23 (13.0)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.222 (0.024, 2.033)	0.15

Page 213 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.099		
Yes	8/50 (16.0)	NE (NE, NE)	7/57 (12.3)	NE (NE, NE)		0.485 (0.180, 1.304)	0.17
No	8/101 (7.9)	NE (NE, NE)	16/112 (14.3)	NE (NE, NE)		1.410 (0.615, 3.237)	0.43
Liver metastasis					0.85		
Yes	4/28 (14.3)	NE (NE, NE)	5/30 (16.7)	NE (7.26, NE)		0.868 (0.255, 2.954)	0.83
No	12/123 (9.8)	NE (NE, NE)	18/139 (12.9)	NE (NE, NE)		0.982 (0.482, 2.000)	0.96

Page 214 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.82		
Yes	7/61 (11.5)	NE (NE, NE)	12/80 (15.0)	NE (NE, NE)		1.089 (0.440, 2.695)	0.86
No	9/90 (10.0)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		0.783 (0.334, 1.838)	0.60

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.55		
< 1%	5/47 (10.6)	NE (NE, NE)	8/55 (14.5)	NE (NE, NE)		1.099 (0.372, 3.249)	0.87
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	6/46 (13.0)	NE (11.83, NE)		1.231 (0.362, 4.182)	0.76
≥ 50%	6/34 (17.6)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)		0.635 (0.223, 1.810)	0.40

Page 216 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first neoplasms benign, malignant and unspecified (incl cysts and polyps) TEAE							
Overall	14/151 (9.3)	NE (NE, NE)	33/169 (19.5)	NE (NE, NE)		1.583 (0.851, 2.944)	0.15
Age - at baseline (years)					0.27		
< 65	8/85 (9.4)	NE (NE, NE)	23/91 (25.3)	NE (NE, NE)		2.196 (0.980, 4.920)	0.052
≥ 65	6/66 (9.1)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		0.920 (0.350, 2.415)	0.87

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.040		
Male	11/86 (12.8)	NE (NE, NE)	17/107 (15.9)	NE (NE, NE)		0.884 (0.418, 1.871)	0.75
Female	3/65 (4.6)	NE (NE, NE)	16/62 (25.8)	NE (16.39, NE)		4.482 (1.317, 15.251)	0.009

Page 218 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.38		
Asian	2/19 (10.5)	NE (NE, NE)	2/21 (9.5)	NE (9.10, NE)		0.419 (0.042, 4.145)	0.46
Non-Asian	12/131 (9.2)	NE (NE, NE)	31/147 (21.1)	NE (NE, NE)		1.744 (0.898, 3.388)	0.10

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.13		
North America	2/19 (10.5)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		0.809 (0.129, 5.074)	0.83
Europe	8/110 (7.3)	NE (NE, NE)	28/124 (22.6)	NE (NE, NE)		2.326 (1.053, 5.137)	0.032
Rest of world	4/22 (18.2)	NE (NE, NE)	3/25 (12.0)	NE (9.10, NE)		0.382 (0.077, 1.887)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.080		
North America and Europe	10/129 (7.8)	NE (NE, NE)	30/144 (20.8)	NE (NE, NE)		2.067 (1.010, 4.232)	0.045
Rest of world	4/22 (18.2)	NE (NE, NE)	3/25 (12.0)	NE (9.10, NE)		0.382 (0.077, 1.887)	0.25
Baseline ECOG status (screening)					0.50		
0	4/53 (7.5)	NE (NE, NE)	6/59 (10.2)	NE (NE, NE)		1.113 (0.308, 4.019)	0.87
1	10/98 (10.2)	NE (NE, NE)	27/110 (24.5)	NE (16.13, NE)		1.670 (0.818, 3.411)	0.17

Page 221 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.45		
1	6/67 (9.0)	NE (NE, NE)	17/76 (22.4)	NE (NE, NE)		2.072 (0.823, 5.216)	0.12
2	6/61 (9.8)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		0.911 (0.313, 2.650)	0.87
> 2	2/23 (8.7)	NE (NE, NE)	8/29 (27.6)	16.39 (7.13, NE)		2.488 (0.496, 12.468)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.29		
Yes	7/50 (14.0)	NE (6.28, NE)	13/57 (22.8)	NE (16.13, NE)		1.005 (0.394, 2.564)	0.99
No	7/101 (6.9)	NE (NE, NE)	20/112 (17.9)	NE (NE, NE)		2.122 (0.903, 4.985)	0.082
Liver metastasis					0.90		
Yes	3/28 (10.7)	NE (NE, NE)	6/30 (20.0)	NE (16.13, NE)		1.356 (0.370, 4.979)	0.67
No	11/123 (8.9)	NE (NE, NE)	27/139 (19.4)	NE (NE, NE)		1.646 (0.819, 3.307)	0.16

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.47		
Yes	5/61 (8.2)	NE (NE, NE)	17/80 (21.3)	NE (16.13, NE)		1.957 (0.721, 5.310)	0.18
No	9/90 (10.0)	NE (NE, NE)	16/89 (18.0)	NE (NE, NE)		1.362 (0.611, 3.037)	0.46

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.57		
< 1%	3/47 (6.4)	NE (NE, NE)	13/55 (23.6)	NE (NE, NE)		3.032 (0.866, 10.613)	0.069
≥ 1% and < 50%	7/61 (11.5)	NE (NE, NE)	13/46 (28.3)	NE (9.10, NE)		1.786 (0.722, 4.418)	0.22
≥ 50%	3/34 (8.8)	NE (NE, NE)	7/60 (11.7)	NE (16.39, NE)		1.009 (0.261, 3.899)	0.99

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first non-small cell lung cancer TEAE							
Overall	6/151 (4.0)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		2.029 (0.820, 5.018)	0.13
Age - at baseline (years)					0.90		
< 65	4/85 (4.7)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)		2.161 (0.717, 6.508)	0.18
≥ 65	2/66 (3.0)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		1.901 (0.391, 9.227)	0.43

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.33		
Male	4/86 (4.7)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.343 (0.429, 4.206)	0.63
Female	2/65 (3.1)	NE (NE, NE)	9/62 (14.5)	NE (NE, NE)		3.717 (0.828, 16.697)	0.073

Page 227 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	6/131 (4.6)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		2.021 (0.817, 5.000)	0.13

Page 228 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.650 (0.166, 16.396)	0.68
Europe	4/110 (3.6)	NE (NE, NE)	16/124 (12.9)	NE (NE, NE)		2.517 (0.851, 7.444)	0.091
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 229 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	5/129 (3.9)	NE (NE, NE)	18/144 (12.5)	NE (NE, NE)		2.424 (0.913, 6.433)	0.073
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.91		
0	1/53 (1.9)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		1.914 (0.201, 18.251)	0.57
1	5/98 (5.1)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		1.921 (0.721, 5.115)	0.20

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)	NE (NE, NE)	9/76 (11.8)	NE (NE, NE)		6.460 (0.833, 50.111)	0.043
2	5/61 (8.2)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)		0.754 (0.229, 2.482)	0.66
> 2	0/23 (0.0)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		NE (NE, NE)	NE

Page 231 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.61		
Yes	2/50 (4.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		1.547 (0.318, 7.518)	0.61
No	4/101 (4.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)		2.363 (0.780, 7.160)	0.12
Liver metastasis					0.23		
Yes	2/28 (7.1)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.806 (0.132, 4.930)	0.83
No	4/123 (3.3)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		2.657 (0.902, 7.825)	0.071

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.49		
Yes	3/61 (4.9)	NE (NE, NE)	7/80 (8.8)	NE (NE, NE)		1.326 (0.351, 5.006)	0.69
No	3/90 (3.3)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		2.843 (0.818, 9.879)	0.095

Page 233 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.38		
< 1%	1/47 (2.1)	NE (NE, NE)	9/55 (16.4)	NE (NE, NE)		6.151 (0.793, 47.704)	0.049
≥ 1% and < 50%	3/61 (4.9)	NE (NE, NE)	5/46 (10.9)	NE (NE, NE)		1.572 (0.387, 6.394)	0.54
≥ 50%	2/34 (5.9)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)		0.943 (0.178, 5.008)	0.95

Page 234 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first nervous system disorders TEAE							
Overall	57/151 (37.7)	7.59 (3.52, NE)	47/169 (27.8)	NE (17.97, NE)		0.490 (0.330, 0.729)	< 0.001
Age - at baseline (years)					0.43		
< 65	31/85 (36.5)	5.36 (3.52, NE)	27/91 (29.7)	17.97 (10.02, NE)		0.534 (0.311, 0.917)	0.020
≥ 65	26/66 (39.4)	NE (3.02, NE)	20/78 (25.6)	NE (NE, NE)		0.458 (0.258, 0.813)	0.008

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.87		
Male	30/86 (34.9)	7.59 (3.52, NE)	26/107 (24.3)	NE (NE, NE)		0.506 (0.294, 0.871)	0.012
Female	27/65 (41.5)	8.87 (1.74, NE)	21/62 (33.9)	17.97 (8.31, NE)		0.505 (0.286, 0.895)	0.022

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.064		
Asian	9/19 (47.4)	NE (0.72, NE)	3/21 (14.3)	NE (9.43, NE)		0.069 (0.011, 0.458)	< 0.001
Non-Asian	47/131 (35.9)	7.59 (4.57, NE)	44/147 (29.9)	NE (17.97, NE)		0.583 (0.382, 0.890)	0.012

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.27		
North America	12/19 (63.2)	3.02 (0.66, 8.87)	8/20 (40.0)	NE (1.64, NE)		0.401 (0.165, 0.979)	0.045
Europe	36/110 (32.7)	7.59 (4.83, NE)	35/124 (28.2)	NE (17.97, NE)		0.598 (0.369, 0.968)	0.035
Rest of world	9/22 (40.9)	NE (0.95, NE)	4/25 (16.0)	NE (10.02, NE)		0.207 (0.059, 0.718)	0.010

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.16		
North America and Europe	48/129 (37.2)	7.59 (3.52, NE)	43/144 (29.9)	NE (17.97, NE)		0.546 (0.357, 0.834)	0.005
Rest of world	9/22 (40.9)	NE (0.95, NE)	4/25 (16.0)	NE (10.02, NE)		0.207 (0.059, 0.718)	0.010
Baseline ECOG status (screening)					0.22		
0	22/53 (41.5)	7.59 (4.57, NE)	13/59 (22.0)	NE (17.97, NE)		0.340 (0.163, 0.707)	0.002
1	35/98 (35.7)	5.36 (3.48, NE)	34/110 (30.9)	NE (9.43, NE)		0.568 (0.353, 0.916)	0.021

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.10		
1	25/67 (37.3)	NE (3.48, NE)	25/76 (32.9)	NE (4.17, NE)		0.671 (0.388, 1.160)	0.16
2	26/61 (42.6)	5.36 (3.52, 8.87)	13/64 (20.3)	NE (17.97, NE)		0.238 (0.114, 0.499)	< 0.001
> 2	6/23 (26.1)	NE (3.48, NE)	9/29 (31.0)	NE (10.02, NE)		0.850 (0.307, 2.356)	0.76

Page 240 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.59		
Yes	15/50 (30.0)	NE (4.83, NE)	16/57 (28.1)	17.97 (10.02, NE)		0.548 (0.270, 1.113)	0.11
No	42/101 (41.6)	4.86 (3.48, NE)	31/112 (27.7)	NE (NE, NE)		0.480 (0.299, 0.773)	0.002
Liver metastasis					0.92		
Yes	12/28 (42.9)	NE (1.71, NE)	9/30 (30.0)	NE (3.38, NE)		0.483 (0.203, 1.154)	0.10
No	45/123 (36.6)	7.59 (4.57, NE)	38/139 (27.3)	NE (17.97, NE)		0.483 (0.309, 0.754)	0.001

Page 241 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.30		
Yes	22/61 (36.1)	8.87 (3.09, NE)	24/80 (30.0)	17.97 (9.43, NE)		0.585 (0.325, 1.054)	0.076
No	35/90 (38.9)	7.59 (3.48, NE)	23/89 (25.8)	NE (NE, NE)		0.410 (0.239, 0.704)	0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.046		
< 1%	23/47 (48.9)	3.48 (1.48, NE)	15/55 (27.3)	NE (10.64, NE)		0.385 (0.203, 0.732)	0.003
≥ 1% and < 50%	20/61 (32.8)	8.87 (4.57, NE)	20/46 (43.5)	NE (3.15, NE)		1.018 (0.539, 1.923)	0.96
≥ 50%	11/34 (32.4)	NE (3.52, NE)	10/60 (16.7)	NE (17.97, NE)		0.290 (0.124, 0.679)	0.005

Page 243 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first neuropathy peripheral TEAE							
Overall	16/151 (10.6)	NE (NE, NE)	1/169 (0.6)	NE (NE, NE)		0.034 (0.004, 0.286)	< 0.001
Age - at baseline (years)					–		
< 65	9/85 (10.6)	NE (7.39, NE)	1/91 (1.1)	NE (NE, NE)		0.058 (0.006, 0.543)	< 0.001
≥ 65	7/66 (10.6)	NE (NE, NE)	0/78 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 244 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	7/86 (8.1)		1/107 (0.9)				
Female	9/65 (13.8)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	2/19 (10.5)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	14/131 (10.7)	NE (8.87, NE)	1/147 (0.7)	NE (NE, NE)		0.038 (0.004, 0.320)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	5/19 (26.3)	NE (3.52, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	9/110 (8.2)	NE (NE, NE)	1/124 (0.8)	NE (NE, NE)		0.059 (0.006, 0.544)	< 0.001
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	14/129 (10.9)	NE (8.87, NE)	1/144 (0.7)	NE (NE, NE)		0.038 (0.005, 0.326)	< 0.001
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	7/53 (13.2)		1/59 (1.7)				
1	9/98 (9.2)		0/110 (0.0)				

Page 248 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	7/67 (10.4)		1/76 (1.3)				
2	7/61 (11.5)		0/64 (0.0)				
> 2	2/23 (8.7)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	4/50 (8.0)	NE (NE, NE)	0/57 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	12/101 (11.9)	NE (8.87, NE)	1/112 (0.9)	NE (NE, NE)		0.045 (0.005, 0.400)	< 0.001
Liver metastasis					–		
Yes	2/28 (7.1)	NE (3.68, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	14/123 (11.4)	NE (8.87, NE)	1/139 (0.7)	NE (NE, NE)		0.039 (0.005, 0.333)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	7/61 (11.5)		1/80 (1.3)				
No	9/90 (10.0)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		0/55 (0.0)				
≥ 1% and < 50%	5/61 (8.2)		1/46 (2.2)				
≥ 50%	5/34 (14.7)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first psychiatric disorders TEAE							
Overall	14/151 (9.3)	NE (NE, NE)	21/169 (12.4)	NE (NE, NE)		1.023 (0.522, 2.005)	0.95
Age - at baseline (years)					0.91		
< 65	10/85 (11.8)	NE (NE, NE)	14/91 (15.4)	NE (17.25, NE)		0.971 (0.437, 2.156)	0.95
≥ 65	4/66 (6.1)	NE (NE, NE)	7/78 (9.0)	NE (NE, NE)		1.271 (0.386, 4.189)	0.70

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.73		
Male	5/86 (5.8)	NE (NE, NE)	10/107 (9.3)	NE (17.25, NE)		0.977 (0.325, 2.943)	0.97
Female	9/65 (13.8)	NE (NE, NE)	11/62 (17.7)	NE (NE, NE)		1.068 (0.451, 2.527)	0.88

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.51		
Asian	3/19 (15.8)	NE (NE, NE)	3/21 (14.3)	NE (NE, NE)		0.732 (0.165, 3.242)	0.70
Non-Asian	11/131 (8.4)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		1.107 (0.523, 2.345)	0.79

Page 255 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.61		
North America	4/19 (21.1)	NE (4.24, NE)	4/20 (20.0)	NE (NE, NE)		0.856 (0.223, 3.277)	0.83
Europe	7/110 (6.4)	NE (NE, NE)	14/124 (11.3)	NE (NE, NE)		1.302 (0.528, 3.211)	0.58
Rest of world	3/22 (13.6)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		0.697 (0.160, 3.027)	0.66

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.47		
North America and Europe	11/129 (8.5)	NE (NE, NE)	18/144 (12.5)	NE (NE, NE)		1.120 (0.529, 2.371)	0.77
Rest of world	3/22 (13.6)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		0.697 (0.160, 3.027)	0.66
Baseline ECOG status (screening)					0.12		
0	7/53 (13.2)	NE (NE, NE)	5/59 (8.5)	NE (NE, NE)		0.507 (0.158, 1.624)	0.25
1	7/98 (7.1)	NE (NE, NE)	16/110 (14.5)	NE (NE, NE)		1.492 (0.626, 3.559)	0.38

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.39		
1	4/67 (6.0)	NE (NE, NE)	10/76 (13.2)	NE (17.25, NE)		1.927 (0.611, 6.076)	0.26
2	7/61 (11.5)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		0.774 (0.283, 2.116)	0.63
> 2	3/23 (13.0)	NE (NE, NE)	3/29 (10.3)	NE (9.13, NE)		0.497 (0.101, 2.431)	0.40

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.99		
Yes	6/50 (12.0)	NE (NE, NE)	10/57 (17.5)	NE (17.25, NE)		0.922 (0.328, 2.590)	0.88
No	8/101 (7.9)	NE (NE, NE)	11/112 (9.8)	NE (NE, NE)		1.036 (0.421, 2.548)	0.94
Liver metastasis					0.87		
Yes	3/28 (10.7)	NE (NE, NE)	5/30 (16.7)	NE (9.13, NE)		1.012 (0.237, 4.324)	0.99
No	11/123 (8.9)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		1.014 (0.472, 2.178)	0.97

Page 259 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.61		
Yes	7/61 (11.5)	NE (NE, NE)	10/80 (12.5)	NE (NE, NE)		0.891 (0.340, 2.337)	0.82
No	7/90 (7.8)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		1.084 (0.421, 2.794)	0.87

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.50		
< 1%	7/47 (14.9)	NE (NE, NE)	7/55 (12.7)	NE (17.25, NE)		0.692 (0.251, 1.912)	0.49
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	7/46 (15.2)	NE (NE, NE)		1.669 (0.464, 6.003)	0.42
≥ 50%	2/34 (5.9)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)		1.101 (0.220, 5.506)	0.91

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first renal and urinary disorders TEAE							
Overall	6/151 (4.0)	NE (NE, NE)	24/169 (14.2)	NE (NE, NE)		2.612 (1.077, 6.332)	0.030
Age - at baseline (years)					0.90		
< 65	2/85 (2.4)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)		2.971 (0.653, 13.511)	0.15
≥ 65	4/66 (6.1)	NE (NE, NE)	16/78 (20.5)	NE (15.24, NE)		2.265 (0.754, 6.798)	0.14

Page 262 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.47		
Male	2/86 (2.3)	NE (NE, NE)	14/107 (13.1)	NE (NE, NE)		3.631 (0.836, 15.761)	0.073
Female	4/65 (6.2)	NE (NE, NE)	10/62 (16.1)	NE (NE, NE)		2.123 (0.680, 6.630)	0.19

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.94		
Asian	1/19 (5.3)	NE (NE, NE)	4/21 (19.0)	NE (NE, NE)		3.365 (0.396, 28.597)	0.25
Non-Asian	5/131 (3.8)	NE (NE, NE)	20/147 (13.6)	NE (NE, NE)		2.511 (0.959, 6.578)	0.059

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.98		
North America	1/19 (5.3)	NE (NE, NE)	3/20 (15.0)	NE (NE, NE)		2.595 (0.283, 23.819)	0.39
Europe	4/110 (3.6)	NE (NE, NE)	16/124 (12.9)	NE (NE, NE)		2.365 (0.800, 6.993)	0.12
Rest of world	1/22 (4.5)	NE (NE, NE)	5/25 (20.0)	NE (9.00, NE)		3.044 (0.358, 25.879)	0.30

Page 265 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.86		
North America and Europe	5/129 (3.9)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)		2.485 (0.945, 6.533)	0.063
Rest of world	1/22 (4.5)	NE (NE, NE)	5/25 (20.0)	NE (9.00, NE)		3.044 (0.358, 25.879)	0.30
Baseline ECOG status (screening)					0.66		
0	3/53 (5.7)	NE (NE, NE)	9/59 (15.3)	NE (NE, NE)		1.997 (0.541, 7.376)	0.30
1	3/98 (3.1)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		3.141 (0.926, 10.646)	0.058

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.22		
1	4/67 (6.0)	NE (NE, NE)	7/76 (9.2)	NE (NE, NE)		1.128 (0.338, 3.768)	0.85
2	1/61 (1.6)	NE (NE, NE)	13/64 (20.3)	NE (15.24, NE)		8.524 (1.108, 65.560)	0.014
> 2	1/23 (4.3)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		2.644 (0.313, 22.364)	0.37

Page 267 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	7/57 (12.3)	NE (NE, NE)		NE (NE, NE)	NE
No	6/101 (5.9)	NE (NE, NE)	17/112 (15.2)	NE (NE, NE)		1.964 (0.782, 4.932)	0.15
Liver metastasis					0.51		
Yes	2/28 (7.1)	NE (NE, NE)	5/30 (16.7)	NE (4.99, NE)		1.272 (0.256, 6.314)	0.78
No	4/123 (3.3)	NE (NE, NE)	19/139 (13.7)	NE (NE, NE)		3.124 (1.068, 9.137)	0.031

Page 268 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.26		
Yes	2/61 (3.3)	NE (NE, NE)	15/80 (18.8)	NE (11.07, NE)		4.328 (1.003, 18.677)	0.034
No	4/90 (4.4)	NE (NE, NE)	9/89 (10.1)	NE (NE, NE)		1.603 (0.491, 5.236)	0.44

Page 269 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	4/47 (8.5)	NE (NE, NE)	5/55 (9.1)	NE (NE, NE)		0.836 (0.235, 2.978)	0.79
≥ 1% and < 50%	0/61 (0.0)	NE (NE, NE)	6/46 (13.0)	NE (11.07, NE)		NE (NE, NE)	NE
≥ 50%	1/34 (2.9)	NE (NE, NE)	13/60 (21.7)	NE (15.24, NE)		6.566 (0.844, 51.086)	0.037

Page 270 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first respiratory, thoracic and mediastinal disorders TEAE							
Overall	65/151 (43.0)	6.28 (2.79, NE)	71/169 (42.0)	11.01 (7.43, NE)		0.692 (0.491, 0.976)	0.037
Age - at baseline (years)					0.43		
< 65	35/85 (41.2)	9.76 (2.79, NE)	40/91 (44.0)	8.97 (4.47, NE)		0.767 (0.485, 1.211)	0.26
≥ 65	30/66 (45.5)	5.55 (2.00, NE)	31/78 (39.7)	15.28 (7.10, NE)		0.620 (0.370, 1.038)	0.069

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.74		
Male	35/86 (40.7)	NE (2.79, NE)	41/107 (38.3)	15.28 (7.10, NE)		0.674 (0.426, 1.065)	0.094
Female	30/65 (46.2)	3.81 (2.10, NE)	30/62 (48.4)	9.23 (3.29, NE)		0.733 (0.439, 1.226)	0.24

Page 272 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.44		
Asian	7/19 (36.8)	NE (1.41, NE)	5/21 (23.8)	NE (4.47, NE)		0.458 (0.141, 1.483)	0.20
Non-Asian	58/131 (44.3)	3.81 (2.79, NE)	66/147 (44.9)	9.33 (6.14, 16.49)		0.728 (0.508, 1.044)	0.086

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.68		
North America	13/19 (68.4)	1.41 (0.66, NE)	11/20 (55.0)	9.23 (0.36, NE)		0.655 (0.294, 1.461)	0.31
Europe	44/110 (40.0)	9.76 (3.45, NE)	53/124 (42.7)	11.01 (6.14, NE)		0.751 (0.499, 1.129)	0.17
Rest of world	8/22 (36.4)	NE (1.45, NE)	7/25 (28.0)	NE (4.47, NE)		0.520 (0.187, 1.444)	0.22

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.52		
North America and Europe	57/129 (44.2)	5.55 (2.79, NE)	64/144 (44.4)	9.33 (6.14, NE)		0.725 (0.504, 1.044)	0.086
Rest of world	8/22 (36.4)	NE (1.45, NE)	7/25 (28.0)	NE (4.47, NE)		0.520 (0.187, 1.444)	0.22
Baseline ECOG status (screening)					0.63		
0	24/53 (45.3)	9.76 (2.33, NE)	25/59 (42.4)	15.28 (8.97, NE)		0.574 (0.322, 1.025)	0.061
1	41/98 (41.8)	5.55 (2.79, NE)	46/110 (41.8)	9.00 (4.47, NE)		0.756 (0.494, 1.157)	0.20

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.46		
1	32/67 (47.8)	2.79 (1.87, NE)	29/76 (38.2)	15.28 (5.52, NE)		0.625 (0.377, 1.036)	0.072
2	22/61 (36.1)	9.76 (3.75, NE)	30/64 (46.9)	9.59 (7.10, 16.49)		0.763 (0.429, 1.355)	0.36
> 2	11/23 (47.8)	3.68 (1.18, NE)	12/29 (41.4)	NE (3.29, NE)		0.662 (0.298, 1.470)	0.33

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.93		
Yes	17/50 (34.0)	NE (2.79, NE)	20/57 (35.1)	NE (5.52, NE)		0.719 (0.378, 1.367)	0.33
No	48/101 (47.5)	3.81 (2.33, NE)	51/112 (45.5)	9.33 (6.14, 16.49)		0.693 (0.462, 1.039)	0.076
Liver metastasis					0.22		
Yes	11/28 (39.3)	3.68 (1.61, NE)	16/30 (53.3)	5.52 (1.61, 9.00)		0.982 (0.449, 2.144)	0.96
No	54/123 (43.9)	6.28 (2.79, NE)	55/139 (39.6)	14.55 (8.97, NE)		0.627 (0.428, 0.920)	0.017

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.89		
Yes	24/61 (39.3)	5.55 (2.79, NE)	31/80 (38.8)	9.59 (6.14, NE)		0.686 (0.396, 1.189)	0.18
No	41/90 (45.6)	3.81 (2.37, NE)	40/89 (44.9)	14.55 (5.42, NE)		0.698 (0.448, 1.087)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.24		
< 1%	21/47 (44.7)	5.55 (1.94, NE)	30/55 (54.5)	5.52 (3.38, 9.33)		0.997 (0.569, 1.749)	0.99
≥ 1% and < 50%	27/61 (44.3)	3.81 (2.33, NE)	17/46 (37.0)	15.28 (6.14, NE)		0.456 (0.244, 0.853)	0.017
≥ 50%	14/34 (41.2)	NE (2.14, NE)	22/60 (36.7)	14.55 (7.10, NE)		0.706 (0.361, 1.384)	0.32

Page 279 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first cough TEAE							
Overall	25/151 (16.6)	NE (7.66, NE)	22/169 (13.0)	NE (NE, NE)		0.478 (0.260, 0.876)	0.013
Age - at baseline (years)					0.29		
< 65	12/85 (14.1)	NE (9.76, NE)	12/91 (13.2)	NE (NE, NE)		0.674 (0.294, 1.543)	0.34
≥ 65	13/66 (19.7)	NE (7.66, NE)	10/78 (12.8)	NE (17.31, NE)		0.310 (0.124, 0.775)	0.009

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.87		
Male	15/86 (17.4)	NE (7.56, NE)	14/107 (13.1)	NE (16.49, NE)		0.447 (0.210, 0.952)	0.035
Female	10/65 (15.4)	NE (7.66, NE)	8/62 (12.9)	NE (NE, NE)		0.530 (0.195, 1.435)	0.19

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.53		
Asian	4/19 (21.1)	NE (6.28, NE)	2/21 (9.5)	NE (NE, NE)		0.411 (0.081, 2.090)	0.29
Non-Asian	21/131 (16.0)	NE (7.66, NE)	20/147 (13.6)	NE (NE, NE)		0.505 (0.264, 0.968)	0.033

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.27		
North America	5/19 (26.3)	NE (5.78, NE)	1/20 (5.0)	NE (NE, NE)		0.172 (0.019, 1.527)	0.068
Europe	16/110 (14.5)	NE (7.66, NE)	19/124 (15.3)	NE (17.31, NE)		0.591 (0.287, 1.216)	0.14
Rest of world	4/22 (18.2)	NE (6.28, NE)	2/25 (8.0)	NE (NE, NE)		0.356 (0.073, 1.742)	0.21

Page 283 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.47		
North America and Europe	21/129 (16.3)	NE (7.66, NE)	20/144 (13.9)	NE (NE, NE)		0.514 (0.268, 0.985)	0.038
Rest of world	4/22 (18.2)	NE (6.28, NE)	2/25 (8.0)	NE (NE, NE)		0.356 (0.073, 1.742)	0.21
Baseline ECOG status (screening)					0.42		
0	13/53 (24.5)	NE (7.56, NE)	9/59 (15.3)	NE (17.31, NE)		0.349 (0.134, 0.909)	0.021
1	12/98 (12.2)	NE (7.66, NE)	13/110 (11.8)	NE (NE, NE)		0.594 (0.264, 1.336)	0.20

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.061		
1	17/67 (25.4)	7.66 (7.56, NE)	7/76 (9.2)	NE (NE, NE)		0.251 (0.102, 0.614)	0.001
2	5/61 (8.2)	NE (9.76, NE)	9/64 (14.1)	NE (17.31, NE)		0.755 (0.203, 2.807)	0.65
> 2	3/23 (13.0)	NE (5.78, NE)	6/29 (20.7)	NE (5.16, NE)		1.055 (0.277, 4.020)	0.94

Page 285 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.40		
Yes	8/50 (16.0)	NE (5.78, NE)	6/57 (10.5)	NE (NE, NE)		0.386 (0.139, 1.070)	0.073
No	17/101 (16.8)	NE (7.66, NE)	16/112 (14.3)	NE (17.31, NE)		0.530 (0.254, 1.107)	0.078
Liver metastasis					0.74		
Yes	4/28 (14.3)	NE (5.78, NE)	4/30 (13.3)	11.40 (11.40, NE)		0.524 (0.114, 2.404)	0.40
No	21/123 (17.1)	NE (7.66, NE)	18/139 (12.9)	NE (NE, NE)		0.463 (0.238, 0.903)	0.019

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.92		
Yes	8/61 (13.1)	NE (6.28, NE)	8/80 (10.0)	NE (NE, NE)		0.512 (0.190, 1.382)	0.18
No	17/90 (18.9)	NE (7.56, NE)	14/89 (15.7)	NE (17.31, NE)		0.468 (0.215, 1.016)	0.045

Page 287 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.20		
< 1%	8/47 (17.0)	NE (7.66, NE)	10/55 (18.2)	NE (16.49, NE)		0.667 (0.263, 1.694)	0.40
≥ 1% and < 50%	9/61 (14.8)	9.76 (5.78, NE)	2/46 (4.3)	NE (NE, NE)		0.145 (0.027, 0.765)	0.007
≥ 50%	6/34 (17.6)	NE (7.56, NE)	10/60 (16.7)	NE (17.31, NE)		0.735 (0.262, 2.057)	0.56

Page 288 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first dyspnoea TEAE							
Overall	27/151 (17.9)	NE (NE, NE)	32/169 (18.9)	NE (NE, NE)		0.786 (0.466, 1.326)	0.37
Age - at baseline (years)					0.98		
< 65	15/85 (17.6)	NE (NE, NE)	17/91 (18.7)	NE (NE, NE)		0.767 (0.387, 1.519)	0.46
≥ 65	12/66 (18.2)	NE (6.93, NE)	15/78 (19.2)	NE (NE, NE)		0.798 (0.357, 1.781)	0.57

Page 289 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.84		
Male	16/86 (18.6)	NE (NE, NE)	22/107 (20.6)	NE (NE, NE)		0.811 (0.421, 1.562)	0.54
Female	11/65 (16.9)	NE (6.93, NE)	10/62 (16.1)	NE (NE, NE)		0.731 (0.307, 1.741)	0.48

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.52		
Asian	2/19 (10.5)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		0.428 (0.042, 4.358)	0.48
Non-Asian	25/131 (19.1)	NE (6.93, NE)	31/147 (21.1)	NE (NE, NE)		0.801 (0.466, 1.376)	0.42

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	7/19 (36.8)	6.93 (2.00, NE)	4/20 (20.0)	NE (4.07, NE)		0.422 (0.124, 1.441)	0.16
Europe	18/110 (16.4)	NE (NE, NE)	28/124 (22.6)	NE (NE, NE)		0.996 (0.543, 1.827)	0.99
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	25/129 (19.4)	NE (6.93, NE)	32/144 (22.2)	NE (NE, NE)		0.843 (0.493, 1.441)	0.53
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.67		
0	10/53 (18.9)	NE (NE, NE)	10/59 (16.9)	NE (NE, NE)		0.582 (0.242, 1.396)	0.24
1	17/98 (17.3)	NE (6.93, NE)	22/110 (20.0)	NE (NE, NE)		0.900 (0.473, 1.715)	0.75

Page 293 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.14		
1	15/67 (22.4)	NE (5.55, NE)	12/76 (15.8)	NE (NE, NE)		0.574 (0.260, 1.265)	0.15
2	6/61 (9.8)	NE (NE, NE)	14/64 (21.9)	NE (14.55, NE)		1.395 (0.526, 3.697)	0.51
> 2	6/23 (26.1)	NE (3.68, NE)	6/29 (20.7)	NE (NE, NE)		0.637 (0.214, 1.893)	0.44

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.76		
Yes	6/50 (12.0)	NE (6.93, NE)	7/57 (12.3)	NE (NE, NE)		0.755 (0.247, 2.310)	0.62
No	21/101 (20.8)	NE (NE, NE)	25/112 (22.3)	NE (NE, NE)		0.825 (0.458, 1.486)	0.52
Liver metastasis					0.76		
Yes	6/28 (21.4)	NE (3.68, NE)	8/30 (26.7)	NE (4.07, NE)		0.982 (0.347, 2.778)	0.98
No	21/123 (17.1)	NE (NE, NE)	24/139 (17.3)	NE (NE, NE)		0.717 (0.393, 1.309)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.16		
Yes	6/61 (9.8)	NE (6.93, NE)	14/80 (17.5)	NE (NE, NE)		1.272 (0.463, 3.489)	0.63
No	21/90 (23.3)	NE (NE, NE)	18/89 (20.2)	NE (NE, NE)		0.646 (0.346, 1.207)	0.18

Page 296 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.42		
< 1%	14/47 (29.8)	NE (4.67, NE)	13/55 (23.6)	NE (NE, NE)		0.613 (0.287, 1.309)	0.21
≥ 1% and < 50%	10/61 (16.4)	NE (NE, NE)	9/46 (19.6)	NE (NE, NE)		0.833 (0.336, 2.064)	0.70
≥ 50%	3/34 (8.8)	NE (6.93, NE)	10/60 (16.7)	NE (14.55, NE)		1.587 (0.433, 5.820)	0.49

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first skin and subcutaneous tissue disorders TEAE							
Overall	57/151 (37.7)	5.68 (3.61, NE)	41/169 (24.3)	NE (16.56, NE)		0.406 (0.269, 0.612)	< 0.001
Age - at baseline (years)					0.97		
< 65	31/85 (36.5)	5.59 (3.48, NE)	21/91 (23.1)	NE (NE, NE)		0.429 (0.247, 0.743)	0.003
≥ 65	26/66 (39.4)	5.68 (3.61, NE)	20/78 (25.6)	NE (13.77, NE)		0.362 (0.194, 0.678)	0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.99		
Male	35/86 (40.7)	5.68 (3.02, NE)	27/107 (25.2)	NE (16.56, NE)		0.380 (0.222, 0.649)	< 0.001
Female	22/65 (33.8)	NE (3.48, NE)	14/62 (22.6)	NE (NE, NE)		0.439 (0.229, 0.841)	0.015

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.67		
Asian	8/19 (42.1)	NE (0.33, NE)	8/21 (38.1)	13.70 (2.37, NE)		0.520 (0.198, 1.366)	0.20
Non-Asian	49/131 (37.4)	5.68 (3.48, NE)	33/147 (22.4)	NE (NE, NE)		0.383 (0.243, 0.604)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.62		
North America	9/19 (47.4)	7.95 (0.76, NE)	7/20 (35.0)	NE (2.20, NE)		0.550 (0.213, 1.423)	0.23
Europe	37/110 (33.6)	5.68 (3.61, NE)	27/124 (21.8)	NE (16.56, NE)		0.420 (0.251, 0.702)	< 0.001
Rest of world	11/22 (50.0)	1.74 (0.23, NE)	7/25 (28.0)	NE (4.60, NE)		0.279 (0.112, 0.696)	0.009

Page 301 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.34		
North America and Europe	46/129 (35.7)	5.68 (3.61, NE)	34/144 (23.6)	NE (16.56, NE)		0.434 (0.274, 0.687)	< 0.001
Rest of world	11/22 (50.0)	1.74 (0.23, NE)	7/25 (28.0)	NE (4.60, NE)		0.279 (0.112, 0.696)	0.009
Baseline ECOG status (screening)					0.58		
0	23/53 (43.4)	4.14 (2.30, NE)	14/59 (23.7)	NE (13.77, NE)		0.347 (0.176, 0.683)	0.002
1	34/98 (34.7)	5.68 (3.48, NE)	27/110 (24.5)	NE (16.56, NE)		0.442 (0.264, 0.739)	0.002

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.32		
1	23/67 (34.3)	7.95 (4.14, NE)	18/76 (23.7)	NE (10.25, NE)		0.462 (0.253, 0.843)	0.014
2	27/61 (44.3)	3.48 (2.14, NE)	15/64 (23.4)	NE (16.56, NE)		0.291 (0.149, 0.567)	< 0.001
> 2	7/23 (30.4)	NE (3.48, NE)	8/29 (27.6)	NE (NE, NE)		0.752 (0.281, 2.011)	0.56

Page 303 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.054		
Yes	15/50 (30.0)	NE (2.99, NE)	19/57 (33.3)	NE (13.70, NE)		0.736 (0.372, 1.454)	0.39
No	42/101 (41.6)	5.59 (3.48, NE)	22/112 (19.6)	NE (NE, NE)		0.286 (0.168, 0.488)	< 0.001
Liver metastasis					0.49		
Yes	7/28 (25.0)	NE (3.48, NE)	6/30 (20.0)	NE (6.90, NE)		0.510 (0.176, 1.476)	0.24
No	50/123 (40.7)	5.59 (3.48, NE)	35/139 (25.2)	NE (16.56, NE)		0.388 (0.249, 0.605)	< 0.001

Page 304 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.64		
Yes	19/61 (31.1)	NE (3.48, NE)	17/80 (21.3)	NE (NE, NE)		0.497 (0.256, 0.966)	0.037
No	38/90 (42.2)	5.68 (2.99, NE)	24/89 (27.0)	NE (13.77, NE)		0.368 (0.218, 0.622)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.002		
< 1%	20/47 (42.6)	4.14 (2.30, NE)	13/55 (23.6)	NE (13.77, NE)		0.345 (0.167, 0.712)	0.003
≥ 1% and < 50%	16/61 (26.2)	NE (3.48, NE)	18/46 (39.1)	10.25 (3.15, NE)		1.061 (0.548, 2.054)	0.86
≥ 50%	17/34 (50.0)	5.59 (0.95, NE)	9/60 (15.0)	NE (NE, NE)		0.171 (0.075, 0.387)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first alopecia TEAE							
Overall	35/151 (23.2)	NE (NE, NE)	3/169 (1.8)	NE (NE, NE)		0.064 (0.020, 0.209)	< 0.001
Age - at baseline (years)					0.89		
< 65	22/85 (25.9)	NE (NE, NE)	2/91 (2.2)	NE (NE, NE)		0.072 (0.017, 0.303)	< 0.001
≥ 65	13/66 (19.7)	NE (NE, NE)	1/78 (1.3)	NE (NE, NE)		0.054 (0.007, 0.418)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.47		
Male	18/86 (20.9)	NE (NE, NE)	1/107 (0.9)	NE (NE, NE)		0.038 (0.005, 0.284)	< 0.001
Female	17/65 (26.2)	NE (NE, NE)	2/62 (3.2)	NE (NE, NE)		0.104 (0.024, 0.448)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	6/19 (31.6)	NE (0.56, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	29/131 (22.1)	NE (NE, NE)	3/147 (2.0)	NE (NE, NE)		0.078 (0.023, 0.256)	< 0.001

Page 309 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	6/19 (31.6)	NE (0.76, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	22/110 (20.0)	NE (NE, NE)	3/124 (2.4)	NE (NE, NE)		0.102 (0.030, 0.345)	< 0.001
Rest of world	7/22 (31.8)	NE (0.56, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	28/129 (21.7)	NE (NE, NE)	3/144 (2.1)	NE (NE, NE)		0.081 (0.024, 0.268)	< 0.001
Rest of world	7/22 (31.8)	NE (0.56, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	17/53 (32.1)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.133 (0.039, 0.458)	< 0.001
1	18/98 (18.4)	NE (NE, NE)	0/110 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 311 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	15/67 (22.4)	NE (NE, NE)	1/76 (1.3)	NE (NE, NE)		0.052 (0.007, 0.402)	< 0.001
2	16/61 (26.2)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)		0.100 (0.024, 0.418)	< 0.001
> 2	4/23 (17.4)	NE (3.61, NE)	0/29 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 312 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.23		
Yes	10/50 (20.0)	NE (NE, NE)	2/57 (3.5)	NE (NE, NE)		0.149 (0.034, 0.651)	0.005
No	25/101 (24.8)	NE (NE, NE)	1/112 (0.9)	NE (NE, NE)		0.030 (0.004, 0.229)	< 0.001
Liver metastasis					–		
Yes	3/28 (10.7)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	32/123 (26.0)	NE (NE, NE)	3/139 (2.2)	NE (NE, NE)		0.068 (0.021, 0.223)	< 0.001

Page 313 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	10/61 (16.4)	NE (NE, NE)	0/80 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	25/90 (27.8)	NE (NE, NE)	3/89 (3.4)	NE (NE, NE)		0.099 (0.030, 0.330)	< 0.001

Page 314 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	9/47 (19.1)	NE (NE, NE)	1/55 (1.8)	NE (NE, NE)		0.081 (0.010, 0.632)	0.002
≥ 1% and < 50%	13/61 (21.3)	NE (NE, NE)	1/46 (2.2)	NE (NE, NE)		0.089 (0.012, 0.651)	0.003
≥ 50%	11/34 (32.4)	NE (3.61, NE)	0/60 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 315 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first vascular disorders TEAE							
Overall	15/151 (9.9)	NE (15.18, NE)	17/169 (10.1)	NE (NE, NE)		0.676 (0.324, 1.408)	0.28
Age - at baseline (years)					0.57		
< 65	7/85 (8.2)	NE (8.34, NE)	9/91 (9.9)	NE (NE, NE)		0.852 (0.304, 2.386)	0.76
≥ 65	8/66 (12.1)	15.18 (15.18, NE)	8/78 (10.3)	NE (NE, NE)		0.531 (0.191, 1.478)	0.22

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.47		
Male	6/86 (7.0)	NE (NE, NE)	10/107 (9.3)	NE (NE, NE)		0.923 (0.340, 2.509)	0.88
Female	9/65 (13.8)	15.18 (8.34, NE)	7/62 (11.3)	NE (NE, NE)		0.552 (0.192, 1.588)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.23		
Asian	3/19 (15.8)	NE (NE, NE)	1/21 (4.8)	NE (6.47, NE)		0.276 (0.032, 2.361)	0.23
Non-Asian	12/131 (9.2)	NE (15.18, NE)	16/147 (10.9)	NE (NE, NE)		0.795 (0.357, 1.769)	0.56

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.088		
North America	6/19 (31.6)	8.34 (7.23, NE)	3/20 (15.0)	NE (10.41, NE)		0.272 (0.066, 1.125)	0.063
Europe	6/110 (5.5)	NE (15.18, NE)	13/124 (10.5)	NE (NE, NE)		1.376 (0.505, 3.752)	0.52
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (6.47, NE)		0.256 (0.032, 2.051)	0.20

Page 319 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.21		
North America and Europe	12/129 (9.3)	NE (15.18, NE)	16/144 (11.1)	NE (NE, NE)		0.804 (0.362, 1.786)	0.58
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (6.47, NE)		0.256 (0.032, 2.051)	0.20
Baseline ECOG status (screening)					0.81		
0	5/53 (9.4)	NE (8.34, NE)	6/59 (10.2)	NE (NE, NE)		0.757 (0.194, 2.949)	0.66
1	10/98 (10.2)	NE (NE, NE)	11/110 (10.0)	NE (NE, NE)		0.601 (0.257, 1.404)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.70		
1	6/67 (9.0)	15.18 (15.18, NE)	8/76 (10.5)	NE (NE, NE)		0.802 (0.257, 2.502)	0.70
2	5/61 (8.2)	NE (8.34, NE)	6/64 (9.4)	NE (NE, NE)		0.744 (0.210, 2.639)	0.64
> 2	4/23 (17.4)	7.23 (7.23, NE)	3/29 (10.3)	NE (NE, NE)		0.335 (0.080, 1.406)	0.15

Page 321 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.88		
Yes	5/50 (10.0)	NE (7.23, NE)	7/57 (12.3)	NE (NE, NE)		0.628 (0.184, 2.138)	0.45
No	10/101 (9.9)	NE (15.18, NE)	10/112 (8.9)	NE (NE, NE)		0.669 (0.266, 1.685)	0.38
Liver metastasis					0.29		
Yes	5/28 (17.9)	7.23 (7.23, NE)	3/30 (10.0)	NE (15.21, NE)		0.246 (0.049, 1.250)	0.081
No	10/123 (8.1)	NE (15.18, NE)	14/139 (10.1)	NE (NE, NE)		0.873 (0.371, 2.056)	0.75

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.26		
Yes	10/61 (16.4)	NE (7.23, NE)	9/80 (11.3)	NE (NE, NE)		0.435 (0.173, 1.096)	0.074
No	5/90 (5.6)	NE (15.18, NE)	8/89 (9.0)	NE (NE, NE)		1.136 (0.352, 3.663)	0.83

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.505. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.21		
< 1%	6/47 (12.8)	NE (15.18, NE)	4/55 (7.3)	NE (NE, NE)		0.369 (0.098, 1.387)	0.13
≥ 1% and < 50%	6/61 (9.8)	8.34 (7.23, NE)	2/46 (4.3)	NE (NE, NE)		0.238 (0.033, 1.729)	0.078
≥ 50%	2/34 (5.9)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)		1.787 (0.380, 8.408)	0.46

Page 324 of 324

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-505-teae-sum-soc-pref-10pct.rtf (Date Generated: 18JAN23:07:08:38) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first neutropenia TEAE							
Overall	15/151 (9.9)	NE (NE, NE)	3/169 (1.8)	NE (NE, NE)		0.152 (0.045, 0.515)	< 0.001
Age - at baseline (years)					–		
< 65	7/85 (8.2)		2/91 (2.2)				
≥ 65	8/66 (12.1)		1/78 (1.3)				

Page 1 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.50		
Male	6/86 (7.0)	NE (NE, NE)	2/107 (1.9)	NE (NE, NE)		0.220 (0.047, 1.020)	0.044
Female	9/65 (13.8)	NE (NE, NE)	1/62 (1.6)	NE (NE, NE)		0.098 (0.012, 0.782)	0.007

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.82		
Asian	4/19 (21.1)	NE (2.99, NE)	1/21 (4.8)	NE (NE, NE)		0.154 (0.020, 1.173)	0.057
Non-Asian	11/131 (8.4)	NE (NE, NE)	2/147 (1.4)	NE (NE, NE)		0.149 (0.033, 0.676)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	10/110 (9.1)	NE (NE, NE)	2/124 (1.6)	NE (NE, NE)		0.162 (0.035, 0.746)	0.007
Rest of world	4/22 (18.2)	NE (3.42, NE)	1/25 (4.0)	NE (NE, NE)		0.146 (0.021, 1.035)	0.050

Page 4 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.85		
North America and Europe	11/129 (8.5)	NE (NE, NE)	2/144 (1.4)	NE (NE, NE)		0.150 (0.033, 0.681)	0.004
Rest of world	4/22 (18.2)	NE (3.42, NE)	1/25 (4.0)	NE (NE, NE)		0.146 (0.021, 1.035)	0.050
Baseline ECOG status (screening)					0.89		
0	6/53 (11.3)	NE (NE, NE)	1/59 (1.7)	NE (NE, NE)		0.137 (0.016, 1.175)	0.031
1	9/98 (9.2)	NE (NE, NE)	2/110 (1.8)	NE (NE, NE)		0.162 (0.037, 0.701)	0.009

Page 5 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	9/67 (13.4)	NE (NE, NE)	2/76 (2.6)	NE (NE, NE)		0.177 (0.038, 0.830)	0.013
2	3/61 (4.9)	NE (NE, NE)	0/64 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
> 2	3/23 (13.0)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.209 (0.028, 1.539)	0.14

Page 6 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.34		
Yes	5/50 (10.0)	NE (NE, NE)	2/57 (3.5)	NE (NE, NE)		0.227 (0.044, 1.173)	0.059
No	10/101 (9.9)	NE (NE, NE)	1/112 (0.9)	NE (NE, NE)		0.083 (0.011, 0.646)	0.002
Liver metastasis					0.60		
Yes	3/28 (10.7)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.253 (0.023, 2.730)	0.20
No	12/123 (9.8)	NE (NE, NE)	2/139 (1.4)	NE (NE, NE)		0.126 (0.029, 0.545)	0.001

Page 7 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	7/61 (11.5)		2/80 (2.5)				
No	8/90 (8.9)		1/89 (1.1)				

Page 8 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		2/55 (3.6)				
≥ 1% and < 50%	4/61 (6.6)		0/46 (0.0)				
≥ 50%	6/34 (17.6)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first cardiac disorders TEAE							
Overall	8/151 (5.3)	NE (NE, NE)	13/169 (7.7)	NE (NE, NE)		0.969 (0.393, 2.385)	0.95
Age - at baseline (years)					0.63		
< 65	6/85 (7.1)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)		0.976 (0.349, 2.725)	0.96
≥ 65	2/66 (3.0)	NE (9.13, NE)	5/78 (6.4)	NE (NE, NE)		0.882 (0.124, 6.286)	0.89

Page 10 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.099		
Male	6/86 (7.0)	NE (9.13, NE)	6/107 (5.6)	NE (NE, NE)		0.399 (0.114, 1.404)	0.13
Female	2/65 (3.1)	NE (NE, NE)	7/62 (11.3)	NE (NE, NE)		2.916 (0.628, 13.538)	0.16

Page 11 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	2/19 (10.5)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	6/131 (4.6)	NE (NE, NE)	13/147 (8.8)	NE (NE, NE)		1.281 (0.473, 3.468)	0.62

Page 12 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	2/19 (10.5)	NE (9.13, NE)	1/20 (5.0)	NE (NE, NE)		0.407 (0.038, 4.411)	0.45
Europe	5/110 (4.5)	NE (NE, NE)	12/124 (9.7)	NE (NE, NE)		1.388 (0.493, 3.905)	0.55
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 13 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	7/129 (5.4)	NE (NE, NE)	13/144 (9.0)	NE (NE, NE)		1.123 (0.439, 2.871)	0.81
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.28		
0	2/53 (3.8)	NE (NE, NE)	6/59 (10.2)	NE (NE, NE)		1.741 (0.364, 8.314)	0.50
1	6/98 (6.1)	NE (9.13, NE)	7/110 (6.4)	NE (NE, NE)		0.700 (0.225, 2.181)	0.53

Page 14 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		4/76 (5.3)				
2	3/61 (4.9)		5/64 (7.8)				
> 2	3/23 (13.0)		4/29 (13.8)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.15		
Yes	4/50 (8.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		0.457 (0.108, 1.933)	0.30
No	4/101 (4.0)	NE (NE, NE)	10/112 (8.9)	NE (NE, NE)		1.455 (0.430, 4.925)	0.54
Liver metastasis					0.75		
Yes	1/28 (3.6)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.615 (0.061, 6.154)	0.73
No	7/123 (5.7)	NE (NE, NE)	12/139 (8.6)	NE (NE, NE)		1.011 (0.386, 2.646)	0.98

Page 16 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.63		
Yes	2/61 (3.3)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		1.627 (0.330, 8.012)	0.56
No	6/90 (6.7)	NE (NE, NE)	8/89 (9.0)	NE (NE, NE)		0.724 (0.239, 2.191)	0.57

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.60		
< 1%	4/47 (8.5)	NE (NE, NE)	6/55 (10.9)	NE (NE, NE)		0.930 (0.271, 3.198)	0.91
≥ 1% and < 50%	3/61 (4.9)	NE (NE, NE)	2/46 (4.3)	NE (NE, NE)		0.729 (0.133, 4.009)	0.73
≥ 50%	1/34 (2.9)	NE (9.13, NE)	5/60 (8.3)	NE (NE, NE)		1.852 (0.191, 17.971)	0.57

Page 18 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first eye disorders TEAE							
Overall	11/151 (7.3)	NE (NE, NE)	12/169 (7.1)	NE (19.38, NE)		0.634 (0.285, 1.410)	0.28
Age - at baseline (years)					0.017		
< 65	7/85 (8.2)	NE (NE, NE)	1/91 (1.1)	NE (NE, NE)		0.106 (0.012, 0.919)	0.011
≥ 65	4/66 (6.1)	NE (NE, NE)	11/78 (14.1)	NE (19.38, NE)		1.498 (0.493, 4.550)	0.49

Page 19 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.45		
Male	5/86 (5.8)	NE (NE, NE)	8/107 (7.5)	19.38 (19.38, NE)		0.658 (0.217, 1.996)	0.49
Female	6/65 (9.2)	NE (NE, NE)	4/62 (6.5)	NE (NE, NE)		0.553 (0.157, 1.948)	0.36

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					1.00		
Asian	1/19 (5.3)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		0.789 (0.051, 12.259)	0.87
Non-Asian	10/131 (7.6)	NE (NE, NE)	11/147 (7.5)	NE (19.38, NE)		0.622 (0.271, 1.427)	0.28

Page 21 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.14		
North America	5/19 (26.3)	NE (3.02, NE)	1/20 (5.0)	NE (4.86, NE)		0.118 (0.017, 0.847)	0.021
Europe	5/110 (4.5)	NE (NE, NE)	8/124 (6.5)	NE (19.38, NE)		0.848 (0.301, 2.387)	0.78
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		2.371 (0.254, 22.170)	0.44

Page 22 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.27		
North America and Europe	10/129 (7.8)	NE (NE, NE)	9/144 (6.3)	NE (19.38, NE)		0.475 (0.205, 1.101)	0.11
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		2.371 (0.254, 22.170)	0.44
Baseline ECOG status (screening)					0.15		
0	6/53 (11.3)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.315 (0.087, 1.147)	0.095
1	5/98 (5.1)	NE (NE, NE)	9/110 (8.2)	NE (19.38, NE)		0.996 (0.337, 2.939)	0.99

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.41		
1	5/67 (7.5)	NE (NE, NE)	3/76 (3.9)	NE (NE, NE)		0.470 (0.118, 1.880)	0.29
2	5/61 (8.2)	NE (NE, NE)	5/64 (7.8)	NE (19.38, NE)		0.355 (0.099, 1.275)	0.14
> 2	1/23 (4.3)	NE (4.37, NE)	4/29 (13.8)	NE (NE, NE)		2.131 (0.226, 20.092)	0.49

Page 24 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.72		
Yes	1/50 (2.0)	NE (NE, NE)	2/57 (3.5)	NE (NE, NE)		0.549 (0.061, 4.962)	0.63
No	10/101 (9.9)	NE (NE, NE)	10/112 (8.9)	NE (19.38, NE)		0.668 (0.284, 1.570)	0.37
Liver metastasis					–		
Yes	3/28 (10.7)	NE (4.37, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	8/123 (6.5)	NE (NE, NE)	12/139 (8.6)	NE (19.38, NE)		0.886 (0.368, 2.132)	0.80

Page 25 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.63		
Yes	3/61 (4.9)	NE (NE, NE)	5/80 (6.3)	NE (19.38, NE)		0.860 (0.190, 3.898)	0.84
No	8/90 (8.9)	NE (NE, NE)	7/89 (7.9)	NE (NE, NE)		0.558 (0.215, 1.444)	0.27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	4/47 (8.5)		4/55 (7.3)				
≥ 1% and < 50%	5/61 (8.2)		4/46 (8.7)				
≥ 50%	1/34 (2.9)		2/60 (3.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first abdominal pain upper TEAE							
Overall	5/151 (3.3)	NE (13.83, NE)	11/169 (6.5)	NE (NE, NE)		1.407 (0.444, 4.459)	0.53
Age - at baseline (years)					–		
< 65	5/85 (5.9)	NE (9.69, NE)	6/91 (6.6)	NE (NE, NE)		0.773 (0.206, 2.899)	0.68
≥ 65	0/66 (0.0)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.72		
Male	1/86 (1.2)	NE (NE, NE)	4/107 (3.7)	NE (NE, NE)		2.941 (0.340, 25.417)	0.31
Female	4/65 (6.2)	NE (9.69, NE)	7/62 (11.3)	NE (NE, NE)		1.318 (0.375, 4.640)	0.66

Page 29 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	2/21 (9.5)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	5/131 (3.8)	NE (13.83, NE)	9/147 (6.1)	NE (NE, NE)		1.135 (0.342, 3.764)	0.83

Page 30 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (9.69, NE)	1/20 (5.0)	NE (12.19, NE)		0.488 (0.048, 5.008)	0.61
Europe	4/110 (3.6)	NE (13.83, NE)	8/124 (6.5)	NE (NE, NE)		1.417 (0.399, 5.031)	0.57
Rest of world	0/22 (0.0)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 31 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	5/129 (3.9)	NE (13.83, NE)	9/144 (6.3)	NE (NE, NE)		1.148 (0.347, 3.799)	0.81
Rest of world	0/22 (0.0)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.59		
0	2/53 (3.8)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		1.316 (0.227, 7.626)	0.76
1	3/98 (3.1)	13.83 (9.69, NE)	8/110 (7.3)	NE (NE, NE)		1.404 (0.311, 6.335)	0.63

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		4/76 (5.3)				
2	1/61 (1.6)		5/64 (7.8)				
> 2	2/23 (8.7)		2/29 (6.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.76		
Yes	2/50 (4.0)	NE (9.69, NE)	4/57 (7.0)	NE (NE, NE)		1.336 (0.200, 8.926)	0.74
No	3/101 (3.0)	NE (13.83, NE)	7/112 (6.3)	NE (NE, NE)		1.509 (0.365, 6.243)	0.56
Liver metastasis					–		
Yes	1/28 (3.6)	9.69 (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	4/123 (3.3)	NE (13.83, NE)	11/139 (7.9)	NE (NE, NE)		1.872 (0.568, 6.168)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	3/61 (4.9)		4/80 (5.0)				
No	2/90 (2.2)		7/89 (7.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		4/55 (7.3)				
≥ 1% and < 50%	2/61 (3.3)		5/46 (10.9)				
≥ 50%	1/34 (2.9)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first chest pain TEAE							
Overall	2/151 (1.3)	NE (NE, NE)	15/169 (8.9)	NE (NE, NE)		4.295 (0.909, 20.302)	0.038
Age - at baseline (years)					–		
< 65	1/85 (1.2)		7/91 (7.7)				
≥ 65	1/66 (1.5)		8/78 (10.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)		9/107 (8.4)				
Female	2/65 (3.1)		6/62 (9.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	2/131 (1.5)	NE (NE, NE)	14/147 (9.5)	NE (NE, NE)		3.934 (0.834, 18.561)	0.054

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	1/110 (0.9)	NE (NE, NE)	12/124 (9.7)	NE (NE, NE)		6.611 (0.758, 57.690)	0.039
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (13.34, NE)		1.436 (0.134, 15.344)	0.77

Page 40 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.31		
North America and Europe	1/129 (0.8)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)		6.945 (0.810, 59.527)	0.033
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (13.34, NE)		1.436 (0.134, 15.344)	0.77
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		NE (NE, NE)	NE
1	2/98 (2.0)	NE (8.11, NE)	12/110 (10.9)	NE (NE, NE)		3.350 (0.687, 16.327)	0.098

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		7/76 (9.2)				
2	0/61 (0.0)		7/64 (10.9)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		NE (NE, NE)	NE
No	2/101 (2.0)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		3.428 (0.706, 16.641)	0.092
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		NE (NE, NE)	NE
No	2/123 (1.6)	NE (NE, NE)	14/139 (10.1)	NE (NE, NE)		3.933 (0.828, 18.673)	0.055

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.72		
Yes	1/61 (1.6)	NE (8.11, NE)	6/80 (7.5)	NE (NE, NE)		3.260 (0.353, 30.092)	0.25
No	1/90 (1.1)	NE (NE, NE)	9/89 (10.1)	NE (NE, NE)		5.047 (0.612, 41.594)	0.098

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	1/47 (2.1)		6/55 (10.9)				
≥ 1% and < 50%	1/61 (1.6)		3/46 (6.5)				
≥ 50%	0/34 (0.0)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first malaise TEAE							
Overall	10/151 (6.6)	NE (NE, NE)	4/169 (2.4)	NE (NE, NE)		0.304 (0.099, 0.930)	0.034
Age - at baseline (years)					–		
< 65	5/85 (5.9)		1/91 (1.1)				
≥ 65	5/66 (7.6)		3/78 (3.8)				

Page 46 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	6/86 (7.0)		2/107 (1.9)				
Female	4/65 (6.2)		2/62 (3.2)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	4/19 (21.1)		1/21 (4.8)				
Non-Asian	6/131 (4.6)		3/147 (2.0)				

Page 48 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	7/110 (6.4)	NE (NE, NE)	3/124 (2.4)	NE (NE, NE)		0.324 (0.086, 1.221)	0.087
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.243 (0.032, 1.848)	0.19

Page 49 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.75		
North America and Europe	7/129 (5.4)	NE (NE, NE)	3/144 (2.1)	NE (NE, NE)		0.332 (0.088, 1.253)	0.094
Rest of world	3/22 (13.6)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.243 (0.032, 1.848)	0.19
Baseline ECOG status (screening)					–		
0	7/53 (13.2)		1/59 (1.7)				
1	3/98 (3.1)		3/110 (2.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	4/67 (6.0)		0/76 (0.0)				
2	6/61 (9.8)		2/64 (3.1)				
> 2	0/23 (0.0)		2/29 (6.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	4/50 (8.0)		1/57 (1.8)				
No	6/101 (5.9)		3/112 (2.7)				
Liver metastasis					0.28		
Yes	2/28 (7.1)	NE (3.09, NE)	2/30 (6.7)	NE (NE, NE)		0.580 (0.074, 4.568)	0.59
No	8/123 (6.5)	NE (NE, NE)	2/139 (1.4)	NE (NE, NE)		0.196 (0.044, 0.871)	0.022

Page 52 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	5/61 (8.2)		1/80 (1.3)				
No	5/90 (5.6)		3/89 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	4/47 (8.5)		1/55 (1.8)				
≥ 1% and < 50%	4/61 (6.6)		0/46 (0.0)				
≥ 50%	1/34 (2.9)		3/60 (5.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first mucosal inflammation TEAE							
Overall	11/151 (7.3)	NE (NE, NE)	1/169 (0.6)	NE (NE, NE)		0.069 (0.010, 0.490)	< 0.001
Age - at baseline (years)					–		
< 65	7/85 (8.2)		1/91 (1.1)				
≥ 65	4/66 (6.1)		0/78 (0.0)				

Page 55 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	5/86 (5.8)		1/107 (0.9)				
Female	6/65 (9.2)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	11/131 (8.4)	NE (NE, NE)	1/147 (0.7)	NE (NE, NE)		0.068 (0.010, 0.478)	< 0.001

Page 57 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	10/110 (9.1)	NE (NE, NE)	1/124 (0.8)	NE (NE, NE)		0.073 (0.011, 0.502)	0.001
Rest of world	0/22 (0.0)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 58 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	11/129 (8.5)	NE (NE, NE)	1/144 (0.7)	NE (NE, NE)		0.069 (0.010, 0.483)	< 0.001
Rest of world	0/22 (0.0)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	6/53 (11.3)		0/59 (0.0)				
1	5/98 (5.1)		1/110 (0.9)				

Page 59 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	7/67 (10.4)		0/76 (0.0)				
2	4/61 (6.6)		1/64 (1.6)				
> 2	0/23 (0.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	5/50 (10.0)		0/57 (0.0)				
No	6/101 (5.9)		1/112 (0.9)				
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	11/123 (8.9)	NE (NE, NE)	1/139 (0.7)	NE (NE, NE)		0.069 (0.010, 0.490)	< 0.001

Page 61 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	3/61 (4.9)		0/80 (0.0)				
No	8/90 (8.9)		1/89 (1.1)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		0/55 (0.0)				
≥ 1% and < 50%	4/61 (6.6)		0/46 (0.0)				
≥ 50%	3/34 (8.8)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first pneumonia TEAE							
Overall	14/151 (9.3)	18.37 (9.23, NE)	5/169 (3.0)	NE (NE, NE)		0.185 (0.059, 0.581)	< 0.001
Age - at baseline (years)					0.32		
< 65	8/85 (9.4)	NE (9.03, NE)	4/91 (4.4)	NE (NE, NE)		0.297 (0.080, 1.100)	0.045
≥ 65	6/66 (9.1)	18.37 (NE, NE)	1/78 (1.3)	NE (NE, NE)		0.081 (0.009, 0.740)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.71		
Male	6/86 (7.0)	NE (9.03, NE)	2/107 (1.9)	NE (NE, NE)		0.170 (0.026, 1.099)	0.021
Female	8/65 (12.3)	18.37 (9.23, NE)	3/62 (4.8)	NE (NE, NE)		0.235 (0.057, 0.974)	0.025

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	2/19 (10.5)	NE (6.28, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	12/131 (9.2)	18.37 (9.23, NE)	5/147 (3.4)	NE (NE, NE)		0.221 (0.069, 0.707)	0.003

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	2/19 (10.5)	NE (4.24, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	10/110 (9.1)	18.37 (9.03, NE)	5/124 (4.0)	NE (NE, NE)		0.281 (0.088, 0.896)	0.019
Rest of world	2/22 (9.1)	NE (6.28, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 67 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	12/129 (9.3)	18.37 (9.23, NE)	5/144 (3.5)	NE (NE, NE)		0.221 (0.069, 0.711)	0.003
Rest of world	2/22 (9.1)	NE (6.28, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.33		
0	6/53 (11.3)	18.37 (9.03, NE)	1/59 (1.7)	NE (NE, NE)		0.067 (0.006, 0.774)	0.003
1	8/98 (8.2)	NE (9.23, NE)	4/110 (3.6)	NE (NE, NE)		0.285 (0.082, 0.992)	0.038

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	7/67 (10.4)		2/76 (2.6)				
2	4/61 (6.6)		2/64 (3.1)				
> 2	3/23 (13.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.92		
Yes	5/50 (10.0)	NE (9.23, NE)	2/57 (3.5)	NE (NE, NE)		0.215 (0.030, 1.534)	0.060
No	9/101 (8.9)	18.37 (18.37, NE)	3/112 (2.7)	NE (NE, NE)		0.183 (0.047, 0.710)	0.006
Liver metastasis					0.008		
Yes	2/28 (7.1)	9.23 (NE, NE)	4/30 (13.3)	NE (8.84, NE)		1.184 (0.224, 6.246)	0.85
No	12/123 (9.8)	18.37 (18.37, NE)	1/139 (0.7)	NE (NE, NE)		0.042 (0.005, 0.371)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.98		
Yes	8/61 (13.1)	NE (9.23, NE)	3/80 (3.8)	NE (NE, NE)		0.181 (0.046, 0.715)	0.007
No	6/90 (6.7)	18.37 (9.03, NE)	2/89 (2.2)	NE (NE, NE)		0.169 (0.024, 1.212)	0.025

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.27		
< 1%	1/47 (2.1)	NE (18.37, NE)	1/55 (1.8)	NE (NE, NE)		0.687 (0.051, 9.181)	0.79
≥ 1% and < 50%	7/61 (11.5)	9.23 (9.23, NE)	3/46 (6.5)	NE (NE, NE)		0.281 (0.063, 1.250)	0.078
≥ 50%	6/34 (17.6)	NE (9.03, NE)	1/60 (1.7)	NE (NE, NE)		0.073 (0.008, 0.684)	0.002

Page 72 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first injury, poisoning and procedural complications TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	16/169 (9.5)	NE (NE, NE)		1.171 (0.526, 2.605)	0.71
Age - at baseline (years)					0.64		
< 65	3/85 (3.5)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		1.605 (0.424, 6.077)	0.50
≥ 65	6/66 (9.1)	NE (NE, NE)	10/78 (12.8)	NE (16.76, NE)		0.878 (0.315, 2.450)	0.81

Page 73 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.073		
Male	7/86 (8.1)	NE (NE, NE)	8/107 (7.5)	NE (17.31, NE)		0.477 (0.167, 1.359)	0.19
Female	2/65 (3.1)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		3.565 (0.772, 16.458)	0.086

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.27		
Asian	2/19 (10.5)	NE (4.73, NE)	1/21 (4.8)	NE (NE, NE)		0.382 (0.039, 3.749)	0.42
Non-Asian	7/131 (5.3)	NE (NE, NE)	15/147 (10.2)	NE (NE, NE)		1.410 (0.588, 3.380)	0.46

Page 75 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.52		
North America	3/19 (15.8)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		0.548 (0.102, 2.933)	0.50
Europe	4/110 (3.6)	NE (NE, NE)	11/124 (8.9)	NE (17.31, NE)		1.583 (0.517, 4.844)	0.44
Rest of world	2/22 (9.1)	NE (4.73, NE)	3/25 (12.0)	NE (NE, NE)		1.124 (0.204, 6.204)	0.90

Page 76 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.86		
North America and Europe	7/129 (5.4)	NE (NE, NE)	13/144 (9.0)	NE (NE, NE)		1.207 (0.496, 2.938)	0.69
Rest of world	2/22 (9.1)	NE (4.73, NE)	3/25 (12.0)	NE (NE, NE)		1.124 (0.204, 6.204)	0.90
Baseline ECOG status (screening)					0.18		
0	4/53 (7.5)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.597 (0.139, 2.574)	0.50
1	5/98 (5.1)	NE (NE, NE)	13/110 (11.8)	NE (16.76, NE)		1.602 (0.585, 4.391)	0.37

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	6/67 (9.0)	NE (NE, NE)	6/76 (7.9)	NE (NE, NE)		0.727 (0.246, 2.152)	0.58
2	3/61 (4.9)	NE (NE, NE)	5/64 (7.8)	NE (17.31, NE)		0.787 (0.182, 3.402)	0.76
> 2	0/23 (0.0)	NE (NE, NE)	5/29 (17.2)	NE (NE, NE)		NE (NE, NE)	NE

Page 78 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.36		
Yes	1/50 (2.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		2.944 (0.368, 23.567)	0.31
No	8/101 (7.9)	NE (NE, NE)	11/112 (9.8)	NE (17.31, NE)		0.968 (0.398, 2.356)	0.94
Liver metastasis					0.97		
Yes	2/28 (7.1)	NE (4.73, NE)	3/30 (10.0)	NE (NE, NE)		0.843 (0.155, 4.575)	0.85
No	7/123 (5.7)	NE (NE, NE)	13/139 (9.4)	NE (NE, NE)		1.195 (0.487, 2.935)	0.71

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.62		
Yes	5/61 (8.2)	NE (NE, NE)	8/80 (10.0)	NE (17.31, NE)		0.929 (0.317, 2.723)	0.90
No	4/90 (4.4)	NE (NE, NE)	8/89 (9.0)	NE (NE, NE)		1.390 (0.427, 4.524)	0.60

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		7/55 (12.7)				
≥ 1% and < 50%	2/61 (3.3)		4/46 (8.7)				
≥ 50%	2/34 (5.9)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first blood alkaline phosphatase increased TEAE							
Overall	3/151 (2.0)	NE (NE, NE)	13/169 (7.7)	NE (NE, NE)		3.326 (0.958, 11.545)	0.048
Age - at baseline (years)					0.74		
< 65	1/85 (1.2)	NE (NE, NE)	3/91 (3.3)	NE (NE, NE)		1.998 (0.215, 18.583)	0.55
≥ 65	2/66 (3.0)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		3.908 (0.861, 17.743)	0.058

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.13		
Male	1/86 (1.2)	NE (NE, NE)	11/107 (10.3)	NE (NE, NE)		7.508 (0.965, 58.393)	0.024
Female	2/65 (3.1)	NE (NE, NE)	2/62 (3.2)	NE (NE, NE)		0.947 (0.144, 6.233)	0.96

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	6/21 (28.6)	16.13 (4.50, NE)		NE (NE, NE)	NE
Non-Asian	3/131 (2.3)	NE (NE, NE)	7/147 (4.8)	NE (NE, NE)		1.909 (0.505, 7.226)	0.34

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		3/20 (15.0)				
Europe	2/110 (1.8)		3/124 (2.4)				
Rest of world	1/22 (4.5)		7/25 (28.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	2/129 (1.6)		6/144 (4.2)				
Rest of world	1/22 (4.5)		7/25 (28.0)				
Baseline ECOG status (screening)					0.29		
0	2/53 (3.8)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		1.415 (0.268, 7.480)	0.69
1	1/98 (1.0)	NE (NE, NE)	9/110 (8.2)	NE (NE, NE)		7.155 (0.919, 55.689)	0.029

Page 86 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		6/76 (7.9)				
2	2/61 (3.3)		6/64 (9.4)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	1/50 (2.0)		7/57 (12.3)				
No	2/101 (2.0)		6/112 (5.4)				
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)		NE (NE, NE)	NE
No	3/123 (2.4)	NE (NE, NE)	9/139 (6.5)	NE (NE, NE)		2.174 (0.601, 7.867)	0.24

Page 88 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	1/61 (1.6)		7/80 (8.8)				
No	2/90 (2.2)		6/89 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	1/47 (2.1)		5/55 (9.1)				
≥ 1% and < 50%	0/61 (0.0)		2/46 (4.3)				
≥ 50%	1/34 (2.9)		5/60 (8.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first hypokalaemia TEAE							
Overall	4/151 (2.6)	NE (NE, NE)	13/169 (7.7)	NE (NE, NE)		2.459 (0.821, 7.371)	0.10
Age - at baseline (years)					0.51		
< 65	3/85 (3.5)	NE (NE, NE)	7/91 (7.7)	NE (NE, NE)		1.848 (0.494, 6.909)	0.37
≥ 65	1/66 (1.5)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		4.329 (0.540, 34.739)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.55		
Male	2/86 (2.3)	NE (NE, NE)	5/107 (4.7)	NE (NE, NE)		1.805 (0.361, 9.031)	0.48
Female	2/65 (3.1)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		3.385 (0.743, 15.424)	0.10

Page 92 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	1/21 (4.8)	NE (5.29, NE)		NE (NE, NE)	NE
Non-Asian	4/131 (3.1)	NE (NE, NE)	12/147 (8.2)	NE (NE, NE)		2.309 (0.761, 7.009)	0.14

Page 93 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	2/19 (10.5)	NE (NE, NE)	3/20 (15.0)	NE (NE, NE)		1.413 (0.247, 8.085)	0.70
Europe	2/110 (1.8)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		3.327 (0.741, 14.942)	0.10
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 94 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	4/129 (3.1)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)		2.341 (0.771, 7.108)	0.13
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.96		
0	1/53 (1.9)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		2.462 (0.271, 22.350)	0.42
1	3/98 (3.1)	NE (NE, NE)	10/110 (9.1)	NE (NE, NE)		2.393 (0.676, 8.472)	0.17

Page 95 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		4/76 (5.3)				
2	0/61 (0.0)		6/64 (9.4)				
> 2	2/23 (8.7)		3/29 (10.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.36		
Yes	3/50 (6.0)	NE (NE, NE)	7/57 (12.3)	NE (NE, NE)		1.535 (0.416, 5.662)	0.53
No	1/101 (1.0)	NE (NE, NE)	6/112 (5.4)	NE (NE, NE)		4.811 (0.598, 38.714)	0.11
Liver metastasis					0.36		
Yes	1/28 (3.6)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.806 (0.059, 11.078)	0.88
No	3/123 (2.4)	NE (NE, NE)	12/139 (8.6)	NE (NE, NE)		3.041 (0.875, 10.573)	0.070

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	1/61 (1.6)		8/80 (10.0)				
No	3/90 (3.3)		5/89 (5.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		2/55 (3.6)				
≥ 1% and < 50%	1/61 (1.6)		6/46 (13.0)				
≥ 50%	1/34 (2.9)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first myalgia TEAE							
Overall	15/151 (9.9)	NE (NE, NE)	9/169 (5.3)	NE (NE, NE)		0.419 (0.190, 0.923)	0.037
Age - at baseline (years)					0.90		
< 65	10/85 (11.8)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		0.428 (0.165, 1.112)	0.095
≥ 65	5/66 (7.6)	NE (NE, NE)	3/78 (3.8)	NE (NE, NE)		0.398 (0.100, 1.588)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.66		
Male	6/86 (7.0)	NE (NE, NE)	5/107 (4.7)	NE (NE, NE)		0.513 (0.151, 1.744)	0.28
Female	9/65 (13.8)	NE (NE, NE)	4/62 (6.5)	NE (NE, NE)		0.363 (0.124, 1.062)	0.082

Page 101 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.20		
Asian	5/19 (26.3)	NE (0.16, NE)	1/21 (4.8)	NE (NE, NE)		0.167 (0.020, 1.412)	0.062
Non-Asian	10/131 (7.6)	NE (NE, NE)	8/147 (5.4)	NE (NE, NE)		0.542 (0.222, 1.323)	0.20

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.43		
North America	1/19 (5.3)	NE (NE, NE)	1/20 (5.0)	NE (NE, NE)		0.898 (0.063, 12.910)	0.94
Europe	9/110 (8.2)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.490 (0.191, 1.261)	0.16
Rest of world	5/22 (22.7)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.160 (0.018, 1.415)	0.056

Page 103 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.20		
North America and Europe	10/129 (7.8)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)		0.550 (0.226, 1.337)	0.21
Rest of world	5/22 (22.7)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.160 (0.018, 1.415)	0.056
Baseline ECOG status (screening)					0.23		
0	7/53 (13.2)	NE (NE, NE)	2/59 (3.4)	NE (NE, NE)		0.189 (0.046, 0.776)	0.025
1	8/98 (8.2)	NE (NE, NE)	7/110 (6.4)	NE (NE, NE)		0.633 (0.240, 1.673)	0.38

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.89		
1	6/67 (9.0)	NE (NE, NE)	4/76 (5.3)	NE (NE, NE)		0.494 (0.148, 1.654)	0.27
2	8/61 (13.1)	NE (NE, NE)	4/64 (6.3)	NE (NE, NE)		0.332 (0.106, 1.037)	0.068
> 2	1/23 (4.3)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.776 (0.051, 11.755)	0.86

Page 105 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.075		
Yes	4/50 (8.0)	NE (NE, NE)	6/57 (10.5)	NE (NE, NE)		1.091 (0.324, 3.669)	0.89
No	11/101 (10.9)	NE (NE, NE)	3/112 (2.7)	NE (NE, NE)		0.172 (0.056, 0.527)	0.003
Liver metastasis					0.26		
Yes	5/28 (17.9)	NE (NE, NE)	1/30 (3.3)	NE (10.25, NE)		0.133 (0.023, 0.759)	0.038
No	10/123 (8.1)	NE (NE, NE)	8/139 (5.8)	NE (NE, NE)		0.578 (0.233, 1.430)	0.25

Page 106 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.36		
Yes	7/61 (11.5)	NE (NE, NE)	3/80 (3.8)	NE (NE, NE)		0.242 (0.064, 0.909)	0.029
No	8/90 (8.9)	NE (NE, NE)	6/89 (6.7)	NE (NE, NE)		0.613 (0.221, 1.701)	0.37

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		3/55 (5.5)				
≥ 1% and < 50%	6/61 (9.8)		2/46 (4.3)				
≥ 50%	5/34 (14.7)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first pain in extremity TEAE							
Overall	8/151 (5.3)	NE (NE, NE)	12/169 (7.1)	NE (NE, NE)		1.243 (0.515, 3.001)	0.63
Age - at baseline (years)					0.37		
< 65	4/85 (4.7)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)		1.746 (0.533, 5.719)	0.36
≥ 65	4/66 (6.1)	NE (NE, NE)	4/78 (5.1)	NE (NE, NE)		0.786 (0.203, 3.037)	0.73

Page 109 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.31		
Male	4/86 (4.7)	NE (NE, NE)	4/107 (3.7)	NE (NE, NE)		0.763 (0.195, 2.982)	0.70
Female	4/65 (6.2)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		1.953 (0.598, 6.381)	0.27

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.79		
Asian	1/19 (5.3)	NE (NE, NE)	2/21 (9.5)	NE (NE, NE)		1.670 (0.162, 17.169)	0.67
Non-Asian	7/131 (5.3)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		1.181 (0.456, 3.058)	0.74

Page 111 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	2/19 (10.5)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	5/110 (4.5)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		1.484 (0.504, 4.372)	0.48
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		2.229 (0.253, 19.672)	0.48

Page 112 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.53		
North America and Europe	7/129 (5.4)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)		1.077 (0.407, 2.851)	0.88
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		2.229 (0.253, 19.672)	0.48
Baseline ECOG status (screening)					0.50		
0	3/53 (5.7)	NE (NE, NE)	6/59 (10.2)	NE (NE, NE)		1.746 (0.449, 6.789)	0.43
1	5/98 (5.1)	NE (NE, NE)	6/110 (5.5)	NE (NE, NE)		0.990 (0.312, 3.144)	0.99

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.83		
1	5/67 (7.5)	NE (NE, NE)	9/76 (11.8)	NE (NE, NE)		1.473 (0.500, 4.340)	0.48
2	2/61 (3.3)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)		0.945 (0.134, 6.654)	0.95
> 2	1/23 (4.3)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.758 (0.052, 11.144)	0.84

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.077		
Yes	5/50 (10.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		0.473 (0.117, 1.908)	0.30
No	3/101 (3.0)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)		2.574 (0.703, 9.421)	0.14
Liver metastasis					0.69		
Yes	2/28 (7.1)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.946 (0.133, 6.720)	0.96
No	6/123 (4.9)	NE (NE, NE)	10/139 (7.2)	NE (NE, NE)		1.361 (0.504, 3.680)	0.55

Page 115 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.38		
Yes	2/61 (3.3)	NE (NE, NE)	6/80 (7.5)	NE (NE, NE)		2.229 (0.454, 10.955)	0.31
No	6/90 (6.7)	NE (NE, NE)	6/89 (6.7)	NE (NE, NE)		0.913 (0.305, 2.730)	0.88

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		3/55 (5.5)				
≥ 1% and < 50%	2/61 (3.3)		1/46 (2.2)				
≥ 50%	3/34 (8.8)		6/60 (10.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first dizziness TEAE							
Overall	7/151 (4.6)	NE (NE, NE)	10/169 (5.9)	NE (NE, NE)		0.824 (0.319, 2.132)	0.70
Age - at baseline (years)					–		
< 65	2/85 (2.4)		7/91 (7.7)				
≥ 65	5/66 (7.6)		3/78 (3.8)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	4/86 (4.7)		4/107 (3.7)				
Female	3/65 (4.6)		6/62 (9.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	7/131 (5.3)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		0.816 (0.316, 2.105)	0.69

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	2/19 (10.5)	NE (NE, NE)	2/20 (10.0)	NE (6.74, NE)		0.806 (0.124, 5.225)	0.83
Europe	5/110 (4.5)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.714 (0.239, 2.129)	0.58
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 121 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	7/129 (5.4)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)		0.710 (0.273, 1.843)	0.51
Rest of world	0/22 (0.0)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	5/53 (9.4)		3/59 (5.1)				
1	2/98 (2.0)		7/110 (6.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.72		
1	4/67 (6.0)	NE (NE, NE)	7/76 (9.2)	NE (NE, NE)		1.080 (0.330, 3.533)	0.90
2	2/61 (3.3)	NE (NE, NE)	2/64 (3.1)	NE (17.97, NE)		0.320 (0.034, 3.034)	0.33
> 2	1/23 (4.3)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.753 (0.045, 12.518)	0.84

Page 123 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	5/57 (8.8)	NE (17.97, NE)		NE (NE, NE)	NE
No	7/101 (6.9)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)		0.505 (0.162, 1.571)	0.24
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	3/30 (10.0)	NE (6.93, NE)		NE (NE, NE)	NE
No	7/123 (5.7)	NE (NE, NE)	7/139 (5.0)	NE (NE, NE)		0.577 (0.205, 1.622)	0.32

Page 124 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.29		
Yes	1/61 (1.6)	NE (NE, NE)	4/80 (5.0)	NE (17.97, NE)		1.997 (0.246, 16.223)	0.53
No	6/90 (6.7)	NE (NE, NE)	6/89 (6.7)	NE (NE, NE)		0.719 (0.233, 2.216)	0.58

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		2/55 (3.6)				
≥ 1% and < 50%	0/61 (0.0)		3/46 (6.5)				
≥ 50%	2/34 (5.9)		3/60 (5.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first dysgeusia TEAE							
Overall	14/151 (9.3)	NE (NE, NE)	4/169 (2.4)	NE (NE, NE)		0.226 (0.077, 0.661)	0.004
Age - at baseline (years)					–		
< 65	8/85 (9.4)	NE (NE, NE)	0/91 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
≥ 65	6/66 (9.1)	NE (NE, NE)	4/78 (5.1)	NE (NE, NE)		0.506 (0.150, 1.702)	0.28

Page 127 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	7/86 (8.1)		2/107 (1.9)				
Female	7/65 (10.8)		2/62 (3.2)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	4/19 (21.1)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	10/131 (7.6)	NE (NE, NE)	4/147 (2.7)	NE (NE, NE)		0.315 (0.103, 0.962)	0.040

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	4/19 (21.1)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	8/110 (7.3)	NE (NE, NE)	4/124 (3.2)	NE (NE, NE)		0.390 (0.124, 1.228)	0.11
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 130 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	12/129 (9.3)	NE (NE, NE)	4/144 (2.8)	NE (NE, NE)		0.264 (0.089, 0.783)	0.014
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	6/53 (11.3)	NE (NE, NE)	0/59 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
1	8/98 (8.2)	NE (NE, NE)	4/110 (3.6)	NE (NE, NE)		0.375 (0.119, 1.179)	0.098

Page 131 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	6/67 (9.0)		3/76 (3.9)				
2	6/61 (9.8)		1/64 (1.6)				
> 2	2/23 (8.7)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	5/50 (10.0)	NE (NE, NE)	0/57 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	9/101 (8.9)	NE (NE, NE)	4/112 (3.6)	NE (NE, NE)		0.364 (0.117, 1.133)	0.080
Liver metastasis					0.40		
Yes	4/28 (14.3)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.396 (0.081, 1.938)	0.27
No	10/123 (8.1)	NE (NE, NE)	2/139 (1.4)	NE (NE, NE)		0.158 (0.036, 0.683)	0.006

Page 133 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.35		
Yes	3/61 (4.9)	NE (NE, NE)	2/80 (2.5)	NE (NE, NE)		0.497 (0.084, 2.951)	0.43
No	11/90 (12.2)	NE (NE, NE)	2/89 (2.2)	NE (NE, NE)		0.157 (0.038, 0.649)	0.006

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		1/55 (1.8)				
≥ 1% and < 50%	5/61 (8.2)		2/46 (4.3)				
≥ 50%	3/34 (8.8)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first headache TEAE							
Overall	13/151 (8.6)	NE (NE, NE)	12/169 (7.1)	NE (NE, NE)		0.602 (0.274, 1.327)	0.21
Age - at baseline (years)					0.23		
< 65	10/85 (11.8)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		0.439 (0.152, 1.264)	0.11
≥ 65	3/66 (4.5)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		1.143 (0.317, 4.124)	0.85

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.50		
Male	4/86 (4.7)	NE (NE, NE)	6/107 (5.6)	NE (NE, NE)		0.956 (0.260, 3.523)	0.95
Female	9/65 (13.8)	NE (NE, NE)	6/62 (9.7)	NE (NE, NE)		0.488 (0.179, 1.330)	0.17

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.33		
Asian	3/19 (15.8)	NE (5.85, NE)	1/21 (4.8)	NE (9.43, NE)		< 0.001 (< 0.001, < 0.001)	0.059
Non-Asian	10/131 (7.6)	NE (NE, NE)	11/147 (7.5)	NE (NE, NE)		0.747 (0.314, 1.775)	0.51

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.18		
North America	1/19 (5.3)	NE (NE, NE)	4/20 (20.0)	NE (6.90, NE)		3.219 (0.372, 27.845)	0.27
Europe	9/110 (8.2)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.507 (0.185, 1.387)	0.18
Rest of world	3/22 (13.6)	NE (5.85, NE)	1/25 (4.0)	NE (NE, NE)		0.245 (0.028, 2.128)	0.19

Page 139 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.31		
North America and Europe	10/129 (7.8)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)		0.725 (0.306, 1.714)	0.47
Rest of world	3/22 (13.6)	NE (5.85, NE)	1/25 (4.0)	NE (NE, NE)		0.245 (0.028, 2.128)	0.19
Baseline ECOG status (screening)					0.17		
0	7/53 (13.2)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.294 (0.074, 1.162)	0.063
1	6/98 (6.1)	NE (NE, NE)	9/110 (8.2)	NE (NE, NE)		0.940 (0.348, 2.539)	0.91

Page 140 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.29		
1	4/67 (6.0)	NE (NE, NE)	7/76 (9.2)	NE (NE, NE)		1.339 (0.405, 4.424)	0.64
2	8/61 (13.1)	NE (7.59, NE)	4/64 (6.3)	NE (NE, NE)		0.274 (0.081, 0.930)	0.034
> 2	1/23 (4.3)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.462 (0.039, 5.451)	0.58

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.91		
Yes	5/50 (10.0)	NE (7.59, NE)	5/57 (8.8)	NE (NE, NE)		0.544 (0.145, 2.051)	0.35
No	8/101 (7.9)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)		0.624 (0.231, 1.680)	0.36
Liver metastasis					0.92		
Yes	2/28 (7.1)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.829 (0.119, 5.774)	0.85
No	11/123 (8.9)	NE (NE, NE)	10/139 (7.2)	NE (NE, NE)		0.582 (0.247, 1.368)	0.22

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.017		
Yes	4/61 (6.6)	NE (NE, NE)	10/80 (12.5)	NE (NE, NE)		1.488 (0.479, 4.621)	0.50
No	9/90 (10.0)	NE (NE, NE)	2/89 (2.2)	NE (NE, NE)		0.142 (0.031, 0.658)	0.005

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.19		
< 1%	6/47 (12.8)	NE (NE, NE)	2/55 (3.6)	NE (NE, NE)		0.228 (0.047, 1.092)	0.049
≥ 1% and < 50%	4/61 (6.6)	NE (5.85, NE)	6/46 (13.0)	NE (NE, NE)		1.247 (0.287, 5.410)	0.74
≥ 50%	1/34 (2.9)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)		1.233 (0.145, 10.453)	0.86

Page 144 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first pruritus TEAE							
Overall	7/151 (4.6)	NE (15.90, NE)	15/169 (8.9)	NE (NE, NE)		1.503 (0.588, 3.838)	0.38
Age - at baseline (years)					0.11		
< 65	5/85 (5.9)	NE (15.90, NE)	5/91 (5.5)	NE (NE, NE)		0.624 (0.161, 2.418)	0.47
≥ 65	2/66 (3.0)	NE (NE, NE)	10/78 (12.8)	NE (16.56, NE)		3.737 (0.831, 16.800)	0.069

Page 145 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.63		
Male	3/86 (3.5)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.983 (0.506, 7.772)	0.30
Female	4/65 (6.2)	NE (15.90, NE)	6/62 (9.7)	NE (NE, NE)		1.188 (0.346, 4.081)	0.79

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.37		
Asian	2/19 (10.5)	NE (NE, NE)	2/21 (9.5)	NE (NE, NE)		0.805 (0.127, 5.108)	0.83
Non-Asian	5/131 (3.8)	NE (15.90, NE)	13/147 (8.8)	NE (NE, NE)		1.796 (0.602, 5.357)	0.27

Page 147 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.64		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.966 (0.189, 20.447)	0.57
Europe	4/110 (3.6)	NE (15.90, NE)	11/124 (8.9)	NE (NE, NE)		1.767 (0.517, 6.043)	0.33
Rest of world	2/22 (9.1)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.769 (0.122, 4.861)	0.79

Page 148 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.34		
North America and Europe	5/129 (3.9)	NE (15.90, NE)	13/144 (9.0)	NE (NE, NE)		1.816 (0.609, 5.415)	0.26
Rest of world	2/22 (9.1)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.769 (0.122, 4.861)	0.79
Baseline ECOG status (screening)					0.085		
0	4/53 (7.5)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.590 (0.127, 2.727)	0.49
1	3/98 (3.1)	15.90 (15.90, NE)	12/110 (10.9)	NE (16.56, NE)		2.630 (0.703, 9.838)	0.13

Page 149 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	3/67 (4.5)		6/76 (7.9)				
2	4/61 (6.6)		5/64 (7.8)				
> 2	0/23 (0.0)		4/29 (13.8)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.97		
Yes	2/50 (4.0)	NE (NE, NE)	5/57 (8.8)	NE (16.56, NE)		1.600 (0.315, 8.131)	0.58
No	5/101 (5.0)	NE (15.90, NE)	10/112 (8.9)	NE (NE, NE)		1.499 (0.485, 4.634)	0.46
Liver metastasis					0.99		
Yes	1/28 (3.6)	NE (NE, NE)	2/30 (6.7)	NE (6.90, NE)		1.279 (0.128, 12.832)	0.85
No	6/123 (4.9)	NE (15.90, NE)	13/139 (9.4)	NE (NE, NE)		1.511 (0.541, 4.224)	0.41

Page 151 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.49		
Yes	4/61 (6.6)	15.90 (15.90, NE)	7/80 (8.8)	NE (NE, NE)		1.006 (0.275, 3.688)	0.99
No	3/90 (3.3)	NE (NE, NE)	8/89 (9.0)	NE (NE, NE)		2.235 (0.601, 8.308)	0.23

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

Table 14-6.2.506. Summary of Time to First Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.79		
< 1%	4/47 (8.5)	15.90 (15.90, NE)	7/55 (12.7)	NE (NE, NE)		1.268 (0.356, 4.520)	0.71
≥ 1% and < 50%	2/61 (3.3)	NE (6.90, NE)	5/46 (10.9)	NE (16.56, NE)		2.120 (0.375, 11.980)	0.37
≥ 50%	1/34 (2.9)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)		1.566 (0.172, 14.239)	0.70

Page 153 of 153

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-506-teae-sum-soc-pref-10subj-1pct.rtf (Date Generated: 18JAN23:07:09:46) Source: adam.adsl, adam.adtts

4.10 Schwere UE (CTCAE Grad ≥ 3) nach SOC und PT, die bei ≥ 5 % bzw. ≥ 10 Studienteilnehmerinnen und Studienteilnehmer und ≥ 1 % der Studienteilnehmerinnen und Studienteilnehmer in einem Studienarm auftraten

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 blood and lymphatic system disorders TEAE							
Overall	27/151 (17.9)	NE (NE, NE)	10/169 (5.9)	NE (NE, NE)		0.250 (0.126, 0.497)	< 0.001
Age - at baseline (years)					0.37		
< 65	13/85 (15.3)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		0.363 (0.141, 0.934)	0.034
≥ 65	14/66 (21.2)	NE (NE, NE)	4/78 (5.1)	NE (NE, NE)		0.157 (0.059, 0.416)	< 0.001

Page 1 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.43		
Male	13/86 (15.1)	NE (NE, NE)	4/107 (3.7)	NE (NE, NE)		0.213 (0.073, 0.625)	0.003
Female	14/65 (21.5)	NE (NE, NE)	6/62 (9.7)	NE (NE, NE)		0.323 (0.133, 0.786)	0.016

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.17		
Asian	8/19 (42.1)	NE (0.33, NE)	1/21 (4.8)	NE (5.26, NE)		0.074 (0.011, 0.484)	0.002
Non-Asian	19/131 (14.5)	NE (NE, NE)	9/147 (6.1)	NE (NE, NE)		0.324 (0.152, 0.690)	0.004

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.65		
North America	2/19 (10.5)	NE (4.47, NE)	1/20 (5.0)	NE (10.41, NE)		0.391 (0.041, 3.742)	0.43
Europe	17/110 (15.5)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.302 (0.130, 0.706)	0.005
Rest of world	8/22 (36.4)	NE (0.36, NE)	2/25 (8.0)	NE (6.21, NE)		0.138 (0.036, 0.527)	0.005

Page 4 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.39		
North America and Europe	19/129 (14.7)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)		0.297 (0.134, 0.658)	0.003
Rest of world	8/22 (36.4)	NE (0.36, NE)	2/25 (8.0)	NE (6.21, NE)		0.138 (0.036, 0.527)	0.005
Baseline ECOG status (screening)					0.28		
0	11/53 (20.8)	NE (NE, NE)	2/59 (3.4)	NE (NE, NE)		0.140 (0.030, 0.642)	0.003
1	16/98 (16.3)	NE (NE, NE)	8/110 (7.3)	NE (NE, NE)		0.326 (0.151, 0.700)	0.008

Page 5 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	12/67 (17.9)	NE (NE, NE)	6/76 (7.9)	NE (NE, NE)		0.344 (0.136, 0.873)	0.028
2	10/61 (16.4)	NE (NE, NE)	0/64 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
> 2	5/23 (21.7)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		0.457 (0.139, 1.495)	0.24

Page 6 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.72		
Yes	9/50 (18.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		0.182 (0.058, 0.577)	0.007
No	18/101 (17.8)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)		0.289 (0.125, 0.668)	0.003
Liver metastasis					0.44		
Yes	6/28 (21.4)	NE (2.99, NE)	1/30 (3.3)	NE (NE, NE)		0.132 (0.015, 1.194)	0.029
No	21/123 (17.1)	NE (NE, NE)	9/139 (6.5)	NE (NE, NE)		0.283 (0.137, 0.588)	< 0.001

Page 7 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.16		
Yes	13/61 (21.3)	NE (NE, NE)	8/80 (10.0)	NE (NE, NE)		0.365 (0.158, 0.840)	0.021
No	14/90 (15.6)	NE (NE, NE)	2/89 (2.2)	NE (NE, NE)		0.114 (0.027, 0.481)	< 0.001

Page 8 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					1.00		
< 1%	10/47 (21.3)	NE (NE, NE)	4/55 (7.3)	NE (NE, NE)		0.267 (0.090, 0.791)	0.017
≥ 1% and < 50%	11/61 (18.0)	NE (NE, NE)	3/46 (6.5)	NE (NE, NE)		0.308 (0.087, 1.088)	0.057
≥ 50%	6/34 (17.6)	NE (NE, NE)	3/60 (5.0)	NE (NE, NE)		0.224 (0.061, 0.825)	0.023

Page 9 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 anaemia TEAE							
Overall	10/151 (6.6)	NE (NE, NE)	8/169 (4.7)	NE (NE, NE)		0.575 (0.236, 1.399)	0.24
Age - at baseline (years)					0.83		
< 65	7/85 (8.2)	NE (NE, NE)	5/91 (5.5)	NE (NE, NE)		0.565 (0.181, 1.758)	0.32
≥ 65	3/66 (4.5)	NE (NE, NE)	3/78 (3.8)	NE (NE, NE)		0.622 (0.152, 2.550)	0.56

Page 10 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.46		
Male	5/86 (5.8)	NE (NE, NE)	3/107 (2.8)	NE (NE, NE)		0.426 (0.109, 1.669)	0.23
Female	5/65 (7.7)	NE (NE, NE)	5/62 (8.1)	NE (NE, NE)		0.771 (0.236, 2.518)	0.68

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.41		
Asian	3/19 (15.8)	NE (3.68, NE)	1/21 (4.8)	NE (5.26, NE)		0.250 (0.028, 2.212)	0.20
Non-Asian	7/131 (5.3)	NE (NE, NE)	7/147 (4.8)	NE (NE, NE)		0.724 (0.266, 1.972)	0.55

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	6/110 (5.5)	NE (NE, NE)	6/124 (4.8)	NE (NE, NE)		0.740 (0.248, 2.210)	0.60
Rest of world	3/22 (13.6)	NE (NE, NE)	2/25 (8.0)	NE (6.21, NE)		0.469 (0.085, 2.591)	0.40

Page 13 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.79		
North America and Europe	7/129 (5.4)	NE (NE, NE)	6/144 (4.2)	NE (NE, NE)		0.654 (0.228, 1.877)	0.44
Rest of world	3/22 (13.6)	NE (NE, NE)	2/25 (8.0)	NE (6.21, NE)		0.469 (0.085, 2.591)	0.40
Baseline ECOG status (screening)					0.46		
0	3/53 (5.7)	NE (NE, NE)	1/59 (1.7)	NE (NE, NE)		0.268 (0.027, 2.608)	0.22
1	7/98 (7.1)	NE (NE, NE)	7/110 (6.4)	NE (NE, NE)		0.677 (0.257, 1.786)	0.47

Page 14 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	5/67 (7.5)		4/76 (5.3)				
2	4/61 (6.6)		0/64 (0.0)				
> 2	1/23 (4.3)		4/29 (13.8)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.20		
Yes	5/50 (10.0)	NE (NE, NE)	2/57 (3.5)	NE (NE, NE)		0.236 (0.051, 1.101)	0.067
No	5/101 (5.0)	NE (NE, NE)	6/112 (5.4)	NE (NE, NE)		0.919 (0.294, 2.878)	0.89
Liver metastasis					–		
Yes	4/28 (14.3)	NE (3.68, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	6/123 (4.9)	NE (NE, NE)	8/139 (5.8)	NE (NE, NE)		0.966 (0.349, 2.671)	0.95

Page 16 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.98		
Yes	7/61 (11.5)	NE (NE, NE)	6/80 (7.5)	NE (NE, NE)		0.527 (0.185, 1.502)	0.25
No	3/90 (3.3)	NE (NE, NE)	2/89 (2.2)	NE (NE, NE)		0.561 (0.101, 3.120)	0.52

Page 17 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		4/55 (7.3)				
≥ 1% and < 50%	6/61 (9.8)		2/46 (4.3)				
≥ 50%	1/34 (2.9)		2/60 (3.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 febrile neutropenia TEAE							
Overall	8/151 (5.3)	NE (NE, NE)	0/169 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Age - at baseline (years)					–		
< 65	4/85 (4.7)		0/91 (0.0)				
≥ 65	4/66 (6.1)		0/78 (0.0)				

Page 19 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	3/86 (3.5)		0/107 (0.0)				
Female	5/65 (7.7)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	3/19 (15.8)		0/21 (0.0)				
Non-Asian	5/131 (3.8)		0/147 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		0/20 (0.0)				
Europe	5/110 (4.5)		0/124 (0.0)				
Rest of world	3/22 (13.6)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	5/129 (3.9)		0/144 (0.0)				
Rest of world	3/22 (13.6)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	4/53 (7.5)		0/59 (0.0)				
1	4/98 (4.1)		0/110 (0.0)				

Page 23 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	3/67 (4.5)		0/76 (0.0)				
2	4/61 (6.6)		0/64 (0.0)				
> 2	1/23 (4.3)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	3/50 (6.0)		0/57 (0.0)				
No	5/101 (5.0)		0/112 (0.0)				
Liver metastasis					–		
Yes	0/28 (0.0)		0/30 (0.0)				
No	8/123 (6.5)		0/139 (0.0)				

Page 25 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	3/61 (4.9)		0/80 (0.0)				
No	5/90 (5.6)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		0/55 (0.0)				
≥ 1% and < 50%	3/61 (4.9)		0/46 (0.0)				
≥ 50%	2/34 (5.9)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 neutropenia TEAE							
Overall	13/151 (8.6)	NE (NE, NE)	0/169 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Age - at baseline (years)					–		
< 65	6/85 (7.1)		0/91 (0.0)				
≥ 65	7/66 (10.6)		0/78 (0.0)				

Page 28 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	4/86 (4.7)		0/107 (0.0)				
Female	9/65 (13.8)		0/62 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	3/19 (15.8)	NE (2.99, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	10/131 (7.6)	NE (NE, NE)	0/147 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 30 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		0/20 (0.0)				
Europe	9/110 (8.2)		0/124 (0.0)				
Rest of world	3/22 (13.6)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	10/129 (7.8)	NE (NE, NE)	0/144 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Rest of world	3/22 (13.6)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	5/53 (9.4)		0/59 (0.0)				
1	8/98 (8.2)		0/110 (0.0)				

Page 32 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	7/67 (10.4)		0/76 (0.0)				
2	3/61 (4.9)		0/64 (0.0)				
> 2	3/23 (13.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	4/50 (8.0)		0/57 (0.0)				
No	9/101 (8.9)		0/112 (0.0)				
Liver metastasis					–		
Yes	3/28 (10.7)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	10/123 (8.1)	NE (NE, NE)	0/139 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	7/61 (11.5)		0/80 (0.0)				
No	6/90 (6.7)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		0/55 (0.0)				
≥ 1% and < 50%	4/61 (6.6)		0/46 (0.0)				
≥ 50%	4/34 (11.8)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 gastrointestinal disorders TEAE							
Overall	11/151 (7.3)	NE (NE, NE)	35/169 (20.7)	NE (NE, NE)		2.487 (1.263, 4.896)	0.007
Age - at baseline (years)					0.12		
< 65	3/85 (3.5)	NE (NE, NE)	18/91 (19.8)	NE (NE, NE)		4.920 (1.452, 16.663)	0.005
≥ 65	8/66 (12.1)	NE (NE, NE)	17/78 (21.8)	NE (NE, NE)		1.549 (0.672, 3.572)	0.30

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.64		
Male	5/86 (5.8)	NE (NE, NE)	16/107 (15.0)	NE (NE, NE)		2.168 (0.799, 5.878)	0.12
Female	6/65 (9.2)	NE (NE, NE)	19/62 (30.6)	NE (12.19, NE)		3.065 (1.229, 7.647)	0.012

Page 38 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.98		
Asian	2/19 (10.5)	NE (NE, NE)	6/21 (28.6)	NE (3.55, NE)		2.586 (0.523, 12.799)	0.23
Non-Asian	9/131 (6.9)	NE (NE, NE)	29/147 (19.7)	NE (NE, NE)		2.481 (1.175, 5.239)	0.014

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.37		
North America	3/19 (15.8)	NE (NE, NE)	4/20 (20.0)	NE (12.19, NE)		1.082 (0.260, 4.508)	0.91
Europe	5/110 (4.5)	NE (NE, NE)	24/124 (19.4)	NE (NE, NE)		3.716 (1.412, 9.781)	0.004
Rest of world	3/22 (13.6)	NE (NE, NE)	7/25 (28.0)	NE (4.83, NE)		1.843 (0.488, 6.963)	0.37

Page 40 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.61		
North America and Europe	8/129 (6.2)	NE (NE, NE)	28/144 (19.4)	NE (NE, NE)		2.723 (1.238, 5.986)	0.010
Rest of world	3/22 (13.6)	NE (NE, NE)	7/25 (28.0)	NE (4.83, NE)		1.843 (0.488, 6.963)	0.37
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	11/59 (18.6)	NE (NE, NE)		NE (NE, NE)	NE
1	11/98 (11.2)	NE (NE, NE)	24/110 (21.8)	NE (15.51, NE)		1.527 (0.753, 3.099)	0.25

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	9/67 (13.4)	NE (NE, NE)	15/76 (19.7)	NE (NE, NE)		1.295 (0.567, 2.960)	0.54
2	0/61 (0.0)	NE (NE, NE)	16/64 (25.0)	NE (NE, NE)		NE (NE, NE)	NE
> 2	2/23 (8.7)	NE (4.63, NE)	4/29 (13.8)	NE (NE, NE)		1.420 (0.245, 8.242)	0.69

Page 42 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.28		
Yes	1/50 (2.0)	NE (NE, NE)	10/57 (17.5)	NE (NE, NE)		6.600 (0.852, 51.112)	0.040
No	10/101 (9.9)	NE (NE, NE)	25/112 (22.3)	NE (NE, NE)		2.084 (1.001, 4.342)	0.045
Liver metastasis					0.59		
Yes	4/28 (14.3)	NE (NE, NE)	9/30 (30.0)	15.51 (3.19, NE)		1.897 (0.598, 6.015)	0.28
No	7/123 (5.7)	NE (NE, NE)	26/139 (18.7)	NE (NE, NE)		2.867 (1.243, 6.612)	0.010

Page 43 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.31		
Yes	7/61 (11.5)	NE (NE, NE)	18/80 (22.5)	NE (NE, NE)		1.787 (0.744, 4.296)	0.19
No	4/90 (4.4)	NE (NE, NE)	17/89 (19.1)	NE (NE, NE)		3.593 (1.224, 10.547)	0.014

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.10		
< 1%	6/47 (12.8)	NE (NE, NE)	8/55 (14.5)	NE (NE, NE)		0.958 (0.334, 2.747)	0.94
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	12/46 (26.1)	NE (12.19, NE)		3.753 (1.211, 11.629)	0.014
≥ 50%	1/34 (2.9)	NE (NE, NE)	15/60 (25.0)	NE (5.98, NE)		8.883 (1.132, 69.688)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 diarrhoea TEAE							
Overall	4/151 (2.6)	NE (NE, NE)	23/169 (13.6)	NE (NE, NE)		4.750 (1.649, 13.686)	0.002
Age - at baseline (years)					0.53		
< 65	1/85 (1.2)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)		8.044 (1.021, 63.384)	0.019
≥ 65	3/66 (4.5)	NE (NE, NE)	14/78 (17.9)	NE (NE, NE)		3.546 (1.029, 12.225)	0.034

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.18		
Male	3/86 (3.5)	NE (NE, NE)	10/107 (9.3)	NE (NE, NE)		2.400 (0.673, 8.559)	0.17
Female	1/65 (1.5)	NE (NE, NE)	13/62 (21.0)	NE (NE, NE)		12.914 (1.683, 99.111)	0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.56		
Asian	1/19 (5.3)	NE (NE, NE)	3/21 (14.3)	NE (NE, NE)		2.558 (0.274, 23.869)	0.40
Non-Asian	3/131 (2.3)	NE (NE, NE)	20/147 (13.6)	NE (NE, NE)		5.524 (1.649, 18.512)	0.002

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.28		
North America	1/19 (5.3)	NE (NE, NE)	3/20 (15.0)	NE (NE, NE)		2.766 (0.292, 26.223)	0.36
Europe	1/110 (0.9)	NE (NE, NE)	16/124 (12.9)	NE (NE, NE)		13.004 (1.728, 97.853)	0.001
Rest of world	2/22 (9.1)	NE (NE, NE)	4/25 (16.0)	NE (NE, NE)		1.525 (0.289, 8.046)	0.62

Page 49 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.15		
North America and Europe	2/129 (1.6)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)		8.004 (1.861, 34.426)	< 0.001
Rest of world	2/22 (9.1)	NE (NE, NE)	4/25 (16.0)	NE (NE, NE)		1.525 (0.289, 8.046)	0.62
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	9/59 (15.3)	NE (NE, NE)		NE (NE, NE)	NE
1	4/98 (4.1)	NE (NE, NE)	14/110 (12.7)	NE (NE, NE)		2.642 (0.886, 7.878)	0.076

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	4/67 (6.0)	NE (NE, NE)	13/76 (17.1)	NE (NE, NE)		2.771 (0.901, 8.521)	0.063
2	0/61 (0.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)		NE (NE, NE)	NE
> 2	0/23 (0.0)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		NE (NE, NE)	NE

Page 51 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.45		
Yes	1/50 (2.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		2.347 (0.260, 21.214)	0.45
No	3/101 (3.0)	NE (NE, NE)	20/112 (17.9)	NE (NE, NE)		5.826 (1.729, 19.628)	0.001
Liver metastasis					0.94		
Yes	1/28 (3.6)	NE (NE, NE)	5/30 (16.7)	NE (NE, NE)		4.691 (0.570, 38.591)	0.12
No	3/123 (2.4)	NE (NE, NE)	18/139 (12.9)	NE (NE, NE)		4.850 (1.434, 16.399)	0.005

Page 52 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.24		
Yes	3/61 (4.9)	NE (NE, NE)	11/80 (13.8)	NE (NE, NE)		2.702 (0.757, 9.636)	0.11
No	1/90 (1.1)	NE (NE, NE)	12/89 (13.5)	NE (NE, NE)		10.683 (1.403, 81.367)	0.004

Page 53 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.50		
< 1%	2/47 (4.3)	NE (NE, NE)	5/55 (9.1)	NE (NE, NE)		2.007 (0.397, 10.137)	0.40
≥ 1% and < 50%	1/61 (1.6)	NE (NE, NE)	7/46 (15.2)	NE (NE, NE)		8.903 (1.100, 72.058)	0.013
≥ 50%	1/34 (2.9)	NE (NE, NE)	11/60 (18.3)	NE (NE, NE)		6.325 (0.795, 50.348)	0.043

Page 54 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 general disorders and administration site conditions TEAE							
Overall	22/151 (14.6)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		0.539 (0.287, 1.013)	0.053
Age - at baseline (years)					0.97		
< 65	15/85 (17.6)	NE (9.03, NE)	12/91 (13.2)	NE (NE, NE)		0.567 (0.264, 1.216)	0.14
≥ 65	7/66 (10.6)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		0.504 (0.170, 1.492)	0.22

Page 55 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.82		
Male	10/86 (11.6)	NE (9.03, NE)	10/107 (9.3)	NE (NE, NE)		0.539 (0.208, 1.395)	0.18
Female	12/65 (18.5)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		0.554 (0.234, 1.311)	0.19

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.67		
Asian	2/19 (10.5)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		0.394 (0.040, 3.902)	0.43
Non-Asian	19/131 (14.5)	NE (NE, NE)	17/147 (11.6)	NE (NE, NE)		0.579 (0.298, 1.126)	0.10

Page 57 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.90		
North America	4/19 (21.1)	NE (4.47, NE)	3/20 (15.0)	NE (11.70, NE)		0.593 (0.138, 2.558)	0.49
Europe	16/110 (14.5)	NE (9.03, NE)	14/124 (11.3)	NE (NE, NE)		0.559 (0.268, 1.165)	0.12
Rest of world	2/22 (9.1)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.390 (0.038, 3.956)	0.43

Page 58 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.67		
North America and Europe	20/129 (15.5)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)		0.556 (0.289, 1.070)	0.077
Rest of world	2/22 (9.1)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.390 (0.038, 3.956)	0.43
Baseline ECOG status (screening)					0.11		
0	9/53 (17.0)	NE (9.03, NE)	3/59 (5.1)	NE (NE, NE)		0.219 (0.058, 0.834)	0.016
1	13/98 (13.3)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		0.740 (0.350, 1.566)	0.43

Page 59 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.098		
1	4/67 (6.0)	NE (9.03, NE)	8/76 (10.5)	NE (NE, NE)		1.493 (0.424, 5.255)	0.51
2	14/61 (23.0)	NE (NE, NE)	9/64 (14.1)	NE (NE, NE)		0.439 (0.194, 0.997)	0.054
> 2	4/23 (17.4)	NE (4.27, NE)	1/29 (3.4)	NE (13.40, NE)		0.121 (0.016, 0.907)	0.027

Page 60 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.58		
Yes	7/50 (14.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		0.454 (0.157, 1.310)	0.18
No	15/101 (14.9)	NE (9.03, NE)	13/112 (11.6)	NE (NE, NE)		0.595 (0.276, 1.282)	0.17
Liver metastasis					0.22		
Yes	6/28 (21.4)	NE (3.68, NE)	2/30 (6.7)	NE (NE, NE)		0.242 (0.052, 1.133)	0.065
No	16/123 (13.0)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		0.649 (0.320, 1.316)	0.23

Page 61 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.80		
Yes	7/61 (11.5)	NE (NE, NE)	7/80 (8.8)	NE (NE, NE)		0.644 (0.222, 1.874)	0.41
No	15/90 (16.7)	NE (9.03, NE)	11/89 (12.4)	NE (NE, NE)		0.476 (0.215, 1.054)	0.068

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.90		
< 1%	7/47 (14.9)	NE (NE, NE)	7/55 (12.7)	NE (NE, NE)		0.657 (0.233, 1.852)	0.44
≥ 1% and < 50%	7/61 (11.5)	NE (NE, NE)	5/46 (10.9)	NE (NE, NE)		0.569 (0.185, 1.749)	0.36
≥ 50%	6/34 (17.6)	NE (9.03, NE)	6/60 (10.0)	NE (NE, NE)		0.497 (0.157, 1.574)	0.22

Page 63 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 fatigue TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	4/169 (2.4)	NE (NE, NE)		0.314 (0.095, 1.045)	0.043
Age - at baseline (years)					–		
< 65	6/85 (7.1)		3/91 (3.3)				
≥ 65	3/66 (4.5)		1/78 (1.3)				

Page 64 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	4/86 (4.7)		3/107 (2.8)				
Female	5/65 (7.7)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	1/19 (5.3)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	8/131 (6.1)	NE (NE, NE)	4/147 (2.7)	NE (NE, NE)		0.347 (0.101, 1.189)	0.072

Page 66 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	3/19 (15.8)		1/20 (5.0)				
Europe	4/110 (3.6)		3/124 (2.4)				
Rest of world	2/22 (9.1)		0/25 (0.0)				

Page 67 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	7/129 (5.4)	NE (NE, NE)	4/144 (2.8)	NE (NE, NE)		0.394 (0.111, 1.404)	0.13
Rest of world	2/22 (9.1)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	3/53 (5.7)	NE (NE, NE)	0/59 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
1	6/98 (6.1)	NE (NE, NE)	4/110 (3.6)	NE (NE, NE)		0.402 (0.104, 1.549)	0.15

Page 68 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		2/76 (2.6)				
2	6/61 (9.8)		2/64 (3.1)				
> 2	2/23 (8.7)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	3/50 (6.0)		1/57 (1.8)				
No	6/101 (5.9)		3/112 (2.7)				
Liver metastasis					–		
Yes	3/28 (10.7)		1/30 (3.3)				
No	6/123 (4.9)		3/139 (2.2)				

Page 70 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	2/61 (3.3)	NE (NE, NE)	1/80 (1.3)	NE (NE, NE)		0.313 (0.024, 4.145)	0.32
No	7/90 (7.8)	NE (NE, NE)	3/89 (3.4)	NE (NE, NE)		0.343 (0.090, 1.308)	0.11

Page 71 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	4/47 (8.5)		1/55 (1.8)				
≥ 1% and < 50%	3/61 (4.9)		1/46 (2.2)				
≥ 50%	1/34 (2.9)		2/60 (3.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 hepatobiliary disorders TEAE							
Overall	0/151 (0.0)	NE (NE, NE)	14/169 (8.3)	NE (NE, NE)		NE (NE, NE)	NE
Age - at baseline (years)					–		
< 65	0/85 (0.0)		7/91 (7.7)				
≥ 65	0/66 (0.0)		7/78 (9.0)				

Page 73 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)		7/107 (6.5)				
Female	0/65 (0.0)		7/62 (11.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	2/21 (9.5)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	0/131 (0.0)	NE (NE, NE)	12/147 (8.2)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		2/20 (10.0)				
Europe	0/110 (0.0)		9/124 (7.3)				
Rest of world	0/22 (0.0)		3/25 (12.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	0/129 (0.0)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)		NE (NE, NE)	NE
Rest of world	0/22 (0.0)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		7/59 (11.9)				
1	0/98 (0.0)		7/110 (6.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)		6/76 (7.9)				
2	0/61 (0.0)		6/64 (9.4)				
> 2	0/23 (0.0)		2/29 (6.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	2/57 (3.5)	NE (NE, NE)		NE (NE, NE)	NE
No	0/101 (0.0)	NE (NE, NE)	12/112 (10.7)	NE (NE, NE)		NE (NE, NE)	NE
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	0/123 (0.0)	NE (NE, NE)	14/139 (10.1)	NE (NE, NE)		NE (NE, NE)	NE

Page 79 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		5/80 (6.3)				
No	0/90 (0.0)		9/89 (10.1)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		4/55 (7.3)				
≥ 1% and < 50%	0/61 (0.0)		3/46 (6.5)				
≥ 50%	0/34 (0.0)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 infections and infestations TEAE							
Overall	27/151 (17.9)	18.37 (18.37, NE)	10/169 (5.9)	NE (NE, NE)		0.199 (0.099, 0.399)	< 0.001
Age - at baseline (years)					0.037		
< 65	12/85 (14.1)	NE (NE, NE)	8/91 (8.8)	NE (NE, NE)		0.428 (0.188, 0.975)	0.061
≥ 65	15/66 (22.7)	18.37 (7.10, NE)	2/78 (2.6)	NE (NE, NE)		0.053 (0.013, 0.215)	< 0.001

Page 82 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.23		
Male	15/86 (17.4)	NE (7.89, NE)	4/107 (3.7)	NE (NE, NE)		0.116 (0.039, 0.343)	< 0.001
Female	12/65 (18.5)	18.37 (18.37, NE)	6/62 (9.7)	NE (NE, NE)		0.320 (0.131, 0.785)	0.019

Page 83 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.95		
Asian	3/19 (15.8)	NE (7.10, NE)	1/21 (4.8)	NE (NE, NE)		0.244 (0.026, 2.308)	0.19
Non-Asian	24/131 (18.3)	18.37 (18.37, NE)	9/147 (6.1)	NE (NE, NE)		0.202 (0.099, 0.412)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.92		
North America	4/19 (21.1)	NE (7.89, NE)	1/20 (5.0)	NE (NE, NE)		0.193 (0.023, 1.615)	0.10
Europe	19/110 (17.3)	18.37 (18.37, NE)	7/124 (5.6)	NE (NE, NE)		0.187 (0.086, 0.409)	< 0.001
Rest of world	4/22 (18.2)	NE (7.10, NE)	2/25 (8.0)	NE (NE, NE)		0.365 (0.069, 1.940)	0.23

Page 85 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.70		
North America and Europe	23/129 (17.8)	18.37 (18.37, NE)	8/144 (5.6)	NE (NE, NE)		0.187 (0.088, 0.398)	< 0.001
Rest of world	4/22 (18.2)	NE (7.10, NE)	2/25 (8.0)	NE (NE, NE)		0.365 (0.069, 1.940)	0.23
Baseline ECOG status (screening)					0.65		
0	9/53 (17.0)	18.37 (NE, NE)	4/59 (6.8)	NE (NE, NE)		0.220 (0.068, 0.709)	0.009
1	18/98 (18.4)	NE (7.89, NE)	6/110 (5.5)	NE (NE, NE)		0.186 (0.078, 0.440)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.64		
1	16/67 (23.9)	18.37 (7.10, NE)	7/76 (9.2)	NE (NE, NE)		0.260 (0.110, 0.611)	0.002
2	6/61 (9.8)	NE (NE, NE)	2/64 (3.1)	NE (NE, NE)		0.175 (0.048, 0.645)	0.024
> 2	5/23 (21.7)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.108 (0.017, 0.677)	0.016

Page 87 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.29		
Yes	7/50 (14.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		0.357 (0.127, 1.003)	0.079
No	20/101 (19.8)	18.37 (18.37, NE)	5/112 (4.5)	NE (NE, NE)		0.143 (0.056, 0.364)	< 0.001
Liver metastasis					0.73		
Yes	7/28 (25.0)	NE (2.66, NE)	2/30 (6.7)	NE (8.84, NE)		0.092 (0.011, 0.768)	0.006
No	20/123 (16.3)	18.37 (18.37, NE)	8/139 (5.8)	NE (NE, NE)		0.217 (0.098, 0.481)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.89		
Yes	13/61 (21.3)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		0.208 (0.080, 0.540)	0.001
No	14/90 (15.6)	18.37 (7.89, NE)	5/89 (5.6)	NE (NE, NE)		0.171 (0.064, 0.460)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.83		
< 1%	6/47 (12.8)	18.37 (18.37, NE)	1/55 (1.8)	NE (NE, NE)		0.107 (0.013, 0.884)	0.012
≥ 1% and < 50%	13/61 (21.3)	NE (NE, NE)	4/46 (8.7)	NE (NE, NE)		0.209 (0.072, 0.606)	0.006
≥ 50%	6/34 (17.6)	NE (7.89, NE)	3/60 (5.0)	NE (NE, NE)		0.222 (0.057, 0.861)	0.022

Page 90 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 pneumonia TEAE							
Overall	9/151 (6.0)	18.37 (18.37, NE)	1/169 (0.6)	NE (NE, NE)		0.048 (0.007, 0.353)	< 0.001
Age - at baseline (years)					–		
< 65	6/85 (7.1)		1/91 (1.1)				
≥ 65	3/66 (4.5)		0/78 (0.0)				

Page 91 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	4/86 (4.7)		0/107 (0.0)				
Female	5/65 (7.7)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	1/19 (5.3)		0/21 (0.0)				
Non-Asian	8/131 (6.1)		1/147 (0.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)		0/20 (0.0)				
Europe	7/110 (6.4)		1/124 (0.8)				
Rest of world	1/22 (4.5)		0/25 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	8/129 (6.2)		1/144 (0.7)				
Rest of world	1/22 (4.5)		0/25 (0.0)				
Baseline ECOG status (screening)					–		
0	3/53 (5.7)		0/59 (0.0)				
1	6/98 (6.1)		1/110 (0.9)				

Page 95 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	4/67 (6.0)		1/76 (1.3)				
2	2/61 (3.3)		0/64 (0.0)				
> 2	3/23 (13.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	4/50 (8.0)		0/57 (0.0)				
No	5/101 (5.0)		1/112 (0.9)				
Liver metastasis					–		
Yes	2/28 (7.1)		1/30 (3.3)				
No	7/123 (5.7)		0/139 (0.0)				

Page 97 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	6/61 (9.8)		1/80 (1.3)				
No	3/90 (3.3)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	1/47 (2.1)		0/55 (0.0)				
≥ 1% and < 50%	6/61 (9.8)		1/46 (2.2)				
≥ 50%	2/34 (5.9)		0/60 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 investigations TEAE							
Overall	10/151 (6.6)	NE (NE, NE)	25/169 (14.8)	NE (NE, NE)		1.996 (0.956, 4.167)	0.060
Age - at baseline (years)					0.82		
< 65	5/85 (5.9)	NE (NE, NE)	11/91 (12.1)	NE (NE, NE)		1.868 (0.659, 5.295)	0.24
≥ 65	5/66 (7.6)	NE (NE, NE)	14/78 (17.9)	NE (NE, NE)		2.116 (0.752, 5.953)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.91		
Male	7/86 (8.1)	NE (NE, NE)	19/107 (17.8)	NE (NE, NE)		2.002 (0.826, 4.855)	0.11
Female	3/65 (4.6)	NE (NE, NE)	6/62 (9.7)	NE (NE, NE)		1.911 (0.492, 7.419)	0.35

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.037		
Asian	6/19 (31.6)	NE (0.23, NE)	6/21 (28.6)	NE (2.79, NE)		0.729 (0.244, 2.176)	0.59
Non-Asian	4/131 (3.1)	NE (NE, NE)	19/147 (12.9)	NE (NE, NE)		3.796 (1.269, 11.356)	0.009

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.084		
North America	1/19 (5.3)	NE (NE, NE)	5/20 (25.0)	NE (2.86, NE)		4.699 (0.539, 40.984)	0.12
Europe	3/110 (2.7)	NE (NE, NE)	14/124 (11.3)	NE (NE, NE)		3.698 (1.025, 13.343)	0.028
Rest of world	6/22 (27.3)	NE (0.46, NE)	6/25 (24.0)	NE (NE, NE)		0.687 (0.233, 2.021)	0.52

Page 103 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.028		
North America and Europe	4/129 (3.1)	NE (NE, NE)	19/144 (13.2)	NE (NE, NE)		3.857 (1.288, 11.548)	0.008
Rest of world	6/22 (27.3)	NE (0.46, NE)	6/25 (24.0)	NE (NE, NE)		0.687 (0.233, 2.021)	0.52
Baseline ECOG status (screening)					0.88		
0	4/53 (7.5)	NE (NE, NE)	10/59 (16.9)	NE (NE, NE)		2.170 (0.677, 6.961)	0.18
1	6/98 (6.1)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		1.828 (0.711, 4.699)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.57		
1	3/67 (4.5)	NE (NE, NE)	11/76 (14.5)	NE (NE, NE)		3.105 (0.860, 11.209)	0.067
2	5/61 (8.2)	NE (NE, NE)	11/64 (17.2)	NE (NE, NE)		1.839 (0.636, 5.314)	0.25
> 2	2/23 (8.7)	NE (NE, NE)	3/29 (10.3)	NE (NE, NE)		0.947 (0.177, 5.052)	0.95

Page 105 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.70		
Yes	3/50 (6.0)	NE (NE, NE)	10/57 (17.5)	NE (NE, NE)		2.504 (0.705, 8.897)	0.15
No	7/101 (6.9)	NE (NE, NE)	15/112 (13.4)	NE (NE, NE)		1.774 (0.717, 4.389)	0.21
Liver metastasis					0.36		
Yes	3/28 (10.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)		1.031 (0.247, 4.295)	0.97
No	7/123 (5.7)	NE (NE, NE)	21/139 (15.1)	NE (NE, NE)		2.392 (1.008, 5.675)	0.040

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.99		
Yes	5/61 (8.2)	NE (NE, NE)	14/80 (17.5)	NE (NE, NE)		1.965 (0.702, 5.501)	0.19
No	5/90 (5.6)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		1.904 (0.656, 5.525)	0.23

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)	NE (NE, NE)	10/55 (18.2)	NE (NE, NE)		2.621 (0.706, 9.730)	0.13
≥ 1% and < 50%	6/61 (9.8)	NE (NE, NE)	7/46 (15.2)	NE (NE, NE)		1.366 (0.477, 3.911)	0.57
≥ 50%	0/34 (0.0)	NE (NE, NE)	8/60 (13.3)	NE (NE, NE)		NE (NE, NE)	NE

Page 108 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 alanine aminotransferase increased TEAE							
Overall	0/151 (0.0)	NE (NE, NE)	14/169 (8.3)	NE (NE, NE)		NE (NE, NE)	NE
Age - at baseline (years)					–		
< 65	0/85 (0.0)		5/91 (5.5)				
≥ 65	0/66 (0.0)		9/78 (11.5)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)	NE (NE, NE)	11/107 (10.3)	NE (NE, NE)		NE (NE, NE)	NE
Female	0/65 (0.0)	NE (NE, NE)	3/62 (4.8)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	4/21 (19.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	0/131 (0.0)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		3/20 (15.0)				
Europe	0/110 (0.0)		7/124 (5.6)				
Rest of world	0/22 (0.0)		4/25 (16.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	0/129 (0.0)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)		NE (NE, NE)	NE
Rest of world	0/22 (0.0)	NE (NE, NE)	4/25 (16.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		6/59 (10.2)				
1	0/98 (0.0)		8/110 (7.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)		6/76 (7.9)				
2	0/61 (0.0)		7/64 (10.9)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		5/57 (8.8)				
No	0/101 (0.0)		9/112 (8.0)				
Liver metastasis					–		
Yes	0/28 (0.0)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		NE (NE, NE)	NE
No	0/123 (0.0)	NE (NE, NE)	12/139 (8.6)	NE (NE, NE)		NE (NE, NE)	NE

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		9/80 (11.3)				
No	0/90 (0.0)		5/89 (5.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		8/55 (14.5)				
≥ 1% and < 50%	0/61 (0.0)		2/46 (4.3)				
≥ 50%	0/34 (0.0)		4/60 (6.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 aspartate aminotransferase increased TEAE							
Overall	0/151 (0.0)	NE (NE, NE)	10/169 (5.9)	NE (NE, NE)		NE (NE, NE)	NE
Age - at baseline (years)					–		
< 65	0/85 (0.0)		4/91 (4.4)				
≥ 65	0/66 (0.0)		6/78 (7.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	0/86 (0.0)		8/107 (7.5)				
Female	0/65 (0.0)		2/62 (3.2)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)		2/21 (9.5)				
Non-Asian	0/131 (0.0)		8/147 (5.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)		2/20 (10.0)				
Europe	0/110 (0.0)		6/124 (4.8)				
Rest of world	0/22 (0.0)		2/25 (8.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	0/129 (0.0)		8/144 (5.6)				
Rest of world	0/22 (0.0)		2/25 (8.0)				
Baseline ECOG status (screening)					–		
0	0/53 (0.0)		4/59 (6.8)				
1	0/98 (0.0)		6/110 (5.5)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	0/67 (0.0)		6/76 (7.9)				
2	0/61 (0.0)		3/64 (4.7)				
> 2	0/23 (0.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)		3/57 (5.3)				
No	0/101 (0.0)		7/112 (6.3)				
Liver metastasis					–		
Yes	0/28 (0.0)		2/30 (6.7)				
No	0/123 (0.0)		8/139 (5.8)				

Page 124 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	0/61 (0.0)		7/80 (8.8)				
No	0/90 (0.0)		3/89 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		6/55 (10.9)				
≥ 1% and < 50%	0/61 (0.0)		1/46 (2.2)				
≥ 50%	0/34 (0.0)		3/60 (5.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 metabolism and nutrition disorders TEAE							
Overall	6/151 (4.0)	NE (NE, NE)	15/169 (8.9)	NE (NE, NE)		1.734 (0.688, 4.367)	0.25
Age - at baseline (years)					0.18		
< 65	1/85 (1.2)	NE (NE, NE)	7/91 (7.7)	NE (NE, NE)		5.432 (0.675, 43.710)	0.078
≥ 65	5/66 (7.6)	NE (NE, NE)	8/78 (10.3)	NE (NE, NE)		0.970 (0.336, 2.801)	0.96

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.87		
Male	3/86 (3.5)	NE (NE, NE)	8/107 (7.5)	NE (NE, NE)		1.381 (0.379, 5.036)	0.64
Female	3/65 (4.6)	NE (NE, NE)	7/62 (11.3)	NE (NE, NE)		2.123 (0.560, 8.049)	0.26

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.73		
Asian	1/19 (5.3)	NE (NE, NE)	4/21 (19.0)	NE (5.52, NE)		3.491 (0.404, 30.201)	0.23
Non-Asian	4/131 (3.1)	NE (NE, NE)	11/147 (7.5)	NE (NE, NE)		1.851 (0.605, 5.662)	0.29

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.61		
North America	2/19 (10.5)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		0.814 (0.125, 5.290)	0.84
Europe	3/110 (2.7)	NE (NE, NE)	8/124 (6.5)	NE (NE, NE)		1.715 (0.469, 6.274)	0.43
Rest of world	1/22 (4.5)	NE (NE, NE)	5/25 (20.0)	NE (5.52, NE)		4.022 (0.486, 33.290)	0.17

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.46		
North America and Europe	5/129 (3.9)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)		1.341 (0.476, 3.773)	0.60
Rest of world	1/22 (4.5)	NE (NE, NE)	5/25 (20.0)	NE (5.52, NE)		4.022 (0.486, 33.290)	0.17
Baseline ECOG status (screening)					0.53		
0	1/53 (1.9)	NE (NE, NE)	1/59 (1.7)	NE (NE, NE)		0.914 (0.059, 14.086)	0.95
1	5/98 (5.1)	NE (NE, NE)	14/110 (12.7)	NE (NE, NE)		1.753 (0.649, 4.734)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		6/76 (7.9)				
2	2/61 (3.3)		7/64 (10.9)				
> 2	2/23 (8.7)		2/29 (6.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.94		
Yes	2/50 (4.0)	NE (NE, NE)	6/57 (10.5)	NE (NE, NE)		1.570 (0.352, 6.996)	0.59
No	4/101 (4.0)	NE (NE, NE)	9/112 (8.0)	NE (NE, NE)		1.747 (0.547, 5.577)	0.35
Liver metastasis					0.36		
Yes	3/28 (10.7)	NE (NE, NE)	4/30 (13.3)	NE (NE, NE)		0.987 (0.241, 4.035)	0.99
No	3/123 (2.4)	NE (NE, NE)	11/139 (7.9)	NE (NE, NE)		2.407 (0.686, 8.445)	0.17

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.36		
Yes	3/61 (4.9)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		1.021 (0.261, 3.987)	0.98
No	3/90 (3.3)	NE (NE, NE)	10/89 (11.2)	NE (NE, NE)		2.504 (0.700, 8.951)	0.16

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	0/47 (0.0)		4/55 (7.3)				
≥ 1% and < 50%	4/61 (6.6)		5/46 (10.9)				
≥ 50%	2/34 (5.9)		5/60 (8.3)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 musculoskeletal and connective tissue disorders TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	8/169 (4.7)	NE (NE, NE)		0.542 (0.215, 1.368)	0.22
Age - at baseline (years)					0.99		
< 65	7/85 (8.2)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		0.580 (0.204, 1.645)	0.33
≥ 65	2/66 (3.0)	NE (NE, NE)	2/78 (2.6)	NE (NE, NE)		0.544 (0.079, 3.727)	0.56

Page 136 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.050		
Male	7/86 (8.1)	NE (NE, NE)	3/107 (2.8)	NE (NE, NE)		0.238 (0.062, 0.909)	0.031
Female	2/65 (3.1)	NE (NE, NE)	5/62 (8.1)	NE (NE, NE)		1.923 (0.406, 9.112)	0.43

Page 137 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	9/131 (6.9)	NE (NE, NE)	8/147 (5.4)	NE (NE, NE)		0.546 (0.217, 1.373)	0.22

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	1/20 (5.0)	NE (11.76, NE)		NE (NE, NE)	NE
Europe	8/110 (7.3)	NE (NE, NE)	7/124 (5.6)	NE (NE, NE)		0.533 (0.196, 1.452)	0.23
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 139 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	8/129 (6.2)	NE (NE, NE)	8/144 (5.6)	NE (NE, NE)		0.616 (0.238, 1.597)	0.34
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					0.42		
0	4/53 (7.5)	NE (NE, NE)	2/59 (3.4)	NE (NE, NE)		0.427 (0.076, 2.403)	0.31
1	5/98 (5.1)	NE (NE, NE)	6/110 (5.5)	NE (NE, NE)		0.603 (0.195, 1.859)	0.42

Page 140 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)		5/76 (6.6)				
2	4/61 (6.6)		2/64 (3.1)				
> 2	3/23 (13.0)		1/29 (3.4)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.28		
Yes	1/50 (2.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		1.784 (0.183, 17.358)	0.63
No	8/101 (7.9)	NE (NE, NE)	5/112 (4.5)	NE (NE, NE)		0.399 (0.140, 1.140)	0.10
Liver metastasis					0.80		
Yes	2/28 (7.1)	NE (NE, NE)	2/30 (6.7)	NE (6.47, NE)		0.754 (0.122, 4.658)	0.78
No	7/123 (5.7)	NE (NE, NE)	6/139 (4.3)	NE (NE, NE)		0.490 (0.171, 1.402)	0.21

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.91		
Yes	5/61 (8.2)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		0.568 (0.166, 1.935)	0.37
No	4/90 (4.4)	NE (NE, NE)	3/89 (3.4)	NE (NE, NE)		0.425 (0.106, 1.696)	0.28

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	3/47 (6.4)		1/55 (1.8)				
≥ 1% and < 50%	2/61 (3.3)		4/46 (8.7)				
≥ 50%	4/34 (11.8)		3/60 (5.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 neoplasms benign, malignant and unspecified (incl cysts and polyps) TEAE							
Overall	7/151 (4.6)	NE (NE, NE)	30/169 (17.8)	NE (NE, NE)		2.846 (1.263, 6.410)	0.010
Age - at baseline (years)					0.40		
< 65	6/85 (7.1)	NE (NE, NE)	20/91 (22.0)	NE (NE, NE)		2.477 (1.001, 6.128)	0.046
≥ 65	1/66 (1.5)	NE (NE, NE)	10/78 (12.8)	NE (NE, NE)		5.370 (0.715, 40.341)	0.076

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.32		
Male	5/86 (5.8)	NE (NE, NE)	17/107 (15.9)	NE (NE, NE)		1.999 (0.746, 5.352)	0.17
Female	2/65 (3.1)	NE (NE, NE)	13/62 (21.0)	NE (16.39, NE)		5.165 (1.184, 22.538)	0.017

Page 146 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	1/21 (4.8)	NE (9.10, NE)		NE (NE, NE)	NE
Non-Asian	7/131 (5.3)	NE (NE, NE)	29/147 (19.7)	NE (NE, NE)		2.805 (1.240, 6.346)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.69		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.650 (0.166, 16.396)	0.68
Europe	5/110 (4.5)	NE (NE, NE)	26/124 (21.0)	NE (NE, NE)		3.421 (1.323, 8.844)	0.008
Rest of world	1/22 (4.5)	NE (NE, NE)	2/25 (8.0)	NE (6.31, NE)		0.785 (0.059, 10.406)	0.86

Page 148 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.50		
North America and Europe	6/129 (4.7)	NE (NE, NE)	28/144 (19.4)	NE (NE, NE)		3.210 (1.339, 7.691)	0.007
Rest of world	1/22 (4.5)	NE (NE, NE)	2/25 (8.0)	NE (6.31, NE)		0.785 (0.059, 10.406)	0.86
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	5/59 (8.5)	NE (NE, NE)		NE (NE, NE)	NE
1	7/98 (7.1)	NE (NE, NE)	25/110 (22.7)	NE (16.13, NE)		2.160 (0.948, 4.920)	0.069

Page 149 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.23		
1	2/67 (3.0)	NE (NE, NE)	15/76 (19.7)	NE (NE, NE)		5.532 (1.273, 24.048)	0.011
2	4/61 (6.6)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)		1.191 (0.359, 3.953)	0.79
> 2	1/23 (4.3)	NE (NE, NE)	8/29 (27.6)	16.39 (7.13, NE)		5.088 (0.584, 44.305)	0.10

Page 150 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.27		
Yes	4/50 (8.0)	NE (NE, NE)	12/57 (21.1)	NE (16.13, NE)		1.659 (0.543, 5.065)	0.39
No	3/101 (3.0)	NE (NE, NE)	18/112 (16.1)	NE (NE, NE)		4.389 (1.306, 14.751)	0.010
Liver metastasis					0.36		
Yes	2/28 (7.1)	NE (NE, NE)	4/30 (13.3)	NE (16.13, NE)		1.149 (0.261, 5.065)	0.88
No	5/123 (4.1)	NE (NE, NE)	26/139 (18.7)	NE (NE, NE)		3.533 (1.366, 9.138)	0.006

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.98		
Yes	3/61 (4.9)	NE (NE, NE)	14/80 (17.5)	NE (16.13, NE)		2.568 (0.751, 8.776)	0.13
No	4/90 (4.4)	NE (NE, NE)	16/89 (18.0)	NE (NE, NE)		3.107 (1.056, 9.144)	0.034

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.48		
< 1%	1/47 (2.1)	NE (NE, NE)	12/55 (21.8)	NE (NE, NE)		8.406 (1.098, 64.355)	0.014
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	11/46 (23.9)	NE (16.13, NE)		2.517 (0.833, 7.601)	0.11
≥ 50%	2/34 (5.9)	NE (NE, NE)	7/60 (11.7)	NE (16.39, NE)		1.568 (0.323, 7.605)	0.58

Page 153 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 non-small cell lung cancer TEAE							
Overall	5/151 (3.3)	NE (NE, NE)	17/169 (10.1)	NE (NE, NE)		2.278 (0.865, 5.998)	0.099
Age - at baseline (years)					0.60		
< 65	4/85 (4.7)	NE (NE, NE)	11/91 (12.1)	NE (NE, NE)		1.940 (0.641, 5.870)	0.25
≥ 65	1/66 (1.5)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		3.868 (0.490, 30.552)	0.18

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.59		
Male	3/86 (3.5)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.800 (0.510, 6.346)	0.38
Female	2/65 (3.1)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		3.216 (0.711, 14.551)	0.12

Page 155 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	5/131 (3.8)	NE (NE, NE)	17/147 (11.6)	NE (NE, NE)		2.268 (0.861, 5.977)	0.10

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.650 (0.166, 16.396)	0.68
Europe	3/110 (2.7)	NE (NE, NE)	15/124 (12.1)	NE (NE, NE)		3.098 (0.922, 10.409)	0.062
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 157 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	4/129 (3.1)	NE (NE, NE)	17/144 (11.8)	NE (NE, NE)		2.831 (0.978, 8.199)	0.052
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	2/59 (3.4)	NE (NE, NE)		NE (NE, NE)	NE
1	5/98 (5.1)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		1.921 (0.721, 5.115)	0.20

Page 158 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)	NE (NE, NE)	9/76 (11.8)	NE (NE, NE)		6.460 (0.833, 50.111)	0.043
2	4/61 (6.6)	NE (NE, NE)	4/64 (6.3)	NE (NE, NE)		0.746 (0.205, 2.723)	0.68
> 2	0/23 (0.0)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		NE (NE, NE)	NE

Page 159 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.33		
Yes	2/50 (4.0)	NE (NE, NE)	4/57 (7.0)	NE (NE, NE)		1.162 (0.236, 5.729)	0.87
No	3/101 (3.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)		3.175 (0.924, 10.912)	0.058
Liver metastasis					0.084		
Yes	2/28 (7.1)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.369 (0.049, 2.783)	0.41
No	3/123 (2.4)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		3.558 (1.060, 11.941)	0.032

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.70		
Yes	2/61 (3.3)	NE (NE, NE)	6/80 (7.5)	NE (NE, NE)		1.660 (0.362, 7.612)	0.53
No	3/90 (3.3)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		2.843 (0.818, 9.879)	0.095

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.40		
< 1%	1/47 (2.1)	NE (NE, NE)	9/55 (16.4)	NE (NE, NE)		6.151 (0.793, 47.704)	0.049
≥ 1% and < 50%	2/61 (3.3)	NE (NE, NE)	4/46 (8.7)	NE (NE, NE)		1.872 (0.398, 8.810)	0.47
≥ 50%	2/34 (5.9)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)		0.943 (0.178, 5.008)	0.95

Page 162 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 nervous system disorders TEAE							
Overall	8/151 (5.3)	NE (NE, NE)	13/169 (7.7)	NE (NE, NE)		1.091 (0.441, 2.696)	0.85
Age - at baseline (years)					0.90		
< 65	5/85 (5.9)	NE (13.40, NE)	8/91 (8.8)	NE (NE, NE)		1.168 (0.363, 3.763)	0.79
≥ 65	3/66 (4.5)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		0.975 (0.245, 3.875)	0.97

Page 163 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.26		
Male	3/86 (3.5)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.755 (0.464, 6.644)	0.40
Female	5/65 (7.7)	NE (13.40, NE)	4/62 (6.5)	NE (NE, NE)		0.660 (0.177, 2.461)	0.54

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	7/131 (5.3)	NE (NE, NE)	12/147 (8.2)	NE (NE, NE)		1.154 (0.443, 3.008)	0.77

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.90		
North America	1/19 (5.3)	NE (NE, NE)	1/20 (5.0)	NE (NE, NE)		0.975 (0.065, 14.523)	0.99
Europe	6/110 (5.5)	NE (13.40, NE)	11/124 (8.9)	NE (NE, NE)		1.144 (0.404, 3.244)	0.79
Rest of world	1/22 (4.5)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.693 (0.050, 9.550)	0.79

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.70		
North America and Europe	7/129 (5.4)	NE (NE, NE)	12/144 (8.3)	NE (NE, NE)		1.157 (0.442, 3.027)	0.76
Rest of world	1/22 (4.5)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.693 (0.050, 9.550)	0.79
Baseline ECOG status (screening)					0.81		
0	3/53 (5.7)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		0.930 (0.210, 4.117)	0.93
1	5/98 (5.1)	NE (13.40, NE)	9/110 (8.2)	NE (NE, NE)		1.165 (0.382, 3.554)	0.79

Page 167 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	2/67 (3.0)	NE (NE, NE)	5/76 (6.6)	NE (NE, NE)		1.815 (0.375, 8.773)	0.47
2	6/61 (9.8)	NE (13.40, NE)	4/64 (6.3)	NE (NE, NE)		0.402 (0.099, 1.630)	0.17
> 2	0/23 (0.0)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		NE (NE, NE)	NE

Page 168 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.66		
Yes	2/50 (4.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		1.332 (0.246, 7.209)	0.74
No	6/101 (5.9)	NE (13.40, NE)	8/112 (7.1)	NE (NE, NE)		0.973 (0.322, 2.938)	0.96
Liver metastasis					0.51		
Yes	3/28 (10.7)	NE (NE, NE)	3/30 (10.0)	NE (NE, NE)		0.647 (0.139, 3.006)	0.60
No	5/123 (4.1)	NE (13.40, NE)	10/139 (7.2)	NE (NE, NE)		1.295 (0.417, 4.019)	0.64

Page 169 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.34		
Yes	5/61 (8.2)	NE (13.40, NE)	6/80 (7.5)	NE (NE, NE)		0.710 (0.217, 2.321)	0.57
No	3/90 (3.3)	NE (NE, NE)	7/89 (7.9)	NE (NE, NE)		1.701 (0.436, 6.631)	0.44

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		6/55 (10.9)				
≥ 1% and < 50%	2/61 (3.3)		6/46 (13.0)				
≥ 50%	3/34 (8.8)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first grade ≥ 3 respiratory, thoracic and mediastinal disorders TEAE							
Overall	22/151 (14.6)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		0.565 (0.298, 1.070)	0.074
Age - at baseline (years)					0.10		
< 65	11/85 (12.9)	NE (8.54, NE)	13/91 (14.3)	NE (NE, NE)		0.829 (0.369, 1.865)	0.65
≥ 65	11/66 (16.7)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		0.339 (0.115, 1.005)	0.036

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.44		
Male	12/86 (14.0)	NE (8.54, NE)	9/107 (8.4)	NE (NE, NE)		0.406 (0.166, 0.995)	0.044
Female	10/65 (15.4)	NE (NE, NE)	9/62 (14.5)	NE (NE, NE)		0.805 (0.323, 2.004)	0.64

Page 173 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.39		
Asian	3/19 (15.8)	NE (2.96, NE)	1/21 (4.8)	NE (9.69, NE)		< 0.001 (< 0.001, < 0.001)	0.048
Non-Asian	19/131 (14.5)	NE (NE, NE)	17/147 (11.6)	NE (NE, NE)		0.636 (0.325, 1.247)	0.18

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.74		
North America	5/19 (26.3)	NE (7.23, NE)	2/20 (10.0)	NE (NE, NE)		0.329 (0.064, 1.696)	0.16
Europe	15/110 (13.6)	NE (NE, NE)	14/124 (11.3)	NE (NE, NE)		0.644 (0.305, 1.358)	0.24
Rest of world	2/22 (9.1)	NE (NE, NE)	2/25 (8.0)	NE (9.69, NE)		0.376 (0.035, 4.064)	0.41

Page 175 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.87		
North America and Europe	20/129 (15.5)	NE (NE, NE)	16/144 (11.1)	NE (NE, NE)		0.572 (0.291, 1.121)	0.095
Rest of world	2/22 (9.1)	NE (NE, NE)	2/25 (8.0)	NE (9.69, NE)		0.376 (0.035, 4.064)	0.41
Baseline ECOG status (screening)					0.40		
0	4/53 (7.5)	NE (8.54, NE)	5/59 (8.5)	NE (NE, NE)		0.709 (0.175, 2.877)	0.62
1	18/98 (18.4)	NE (7.23, NE)	13/110 (11.8)	NE (NE, NE)		0.509 (0.246, 1.053)	0.061

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.51		
1	8/67 (11.9)	NE (8.54, NE)	6/76 (7.9)	NE (NE, NE)		0.522 (0.182, 1.499)	0.23
2	7/61 (11.5)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		0.914 (0.332, 2.513)	0.86
> 2	7/23 (30.4)	7.23 (5.16, NE)	4/29 (13.8)	NE (9.69, NE)		0.289 (0.082, 1.015)	0.043

Page 177 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.88		
Yes	7/50 (14.0)	NE (7.23, NE)	7/57 (12.3)	NE (NE, NE)		0.644 (0.223, 1.865)	0.42
No	15/101 (14.9)	NE (NE, NE)	11/112 (9.8)	NE (NE, NE)		0.537 (0.243, 1.188)	0.12
Liver metastasis					0.94		
Yes	7/28 (25.0)	7.23 (5.16, NE)	6/30 (20.0)	NE (8.08, NE)		0.494 (0.157, 1.552)	0.22
No	15/123 (12.2)	NE (NE, NE)	12/139 (8.6)	NE (NE, NE)		0.569 (0.263, 1.234)	0.15

Page 178 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.40		
Yes	6/61 (9.8)	NE (NE, NE)	8/80 (10.0)	NE (NE, NE)		0.824 (0.280, 2.423)	0.72
No	16/90 (17.8)	NE (8.54, NE)	10/89 (11.2)	NE (NE, NE)		0.483 (0.217, 1.073)	0.070

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

Table 14-6.2.507. Summary of Time to First Grade ≥ 3 Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.72		
< 1%	7/47 (14.9)	NE (NE, NE)	8/55 (14.5)	NE (NE, NE)		0.757 (0.280, 2.043)	0.59
≥ 1% and < 50%	9/61 (14.8)	NE (7.23, NE)	4/46 (8.7)	NE (NE, NE)		0.425 (0.119, 1.524)	0.16
≥ 50%	5/34 (14.7)	NE (8.54, NE)	5/60 (8.3)	NE (NE, NE)		0.504 (0.144, 1.762)	0.27

Page 180 of 180

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-507-teae-sum-grd3-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:10:28) Source: adam.adsl, adam.adtts

4.11 SUE nach SOC und PT, die bei ≥ 5 % bzw. ≥ 10 Studienteilnehmerinnen und Studienteilnehmer und ≥ 1 % der Studienteilnehmerinnen und Studienteilnehmer in einem Studienarm auftraten

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious blood and lymphatic system disorders TEAE							
Overall	12/151 (7.9)	NE (NE, NE)	2/169 (1.2)	NE (NE, NE)		0.130 (0.030, 0.563)	0.002
Age - at baseline (years)					–		
< 65	8/85 (9.4)		1/91 (1.1)				
≥ 65	4/66 (6.1)		1/78 (1.3)				

Page 1 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	5/86 (5.8)		1/107 (0.9)				
Female	7/65 (10.8)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	5/19 (26.3)		0/21 (0.0)				
Non-Asian	7/131 (5.3)		2/147 (1.4)				

Page 3 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	8/110 (7.3)	NE (NE, NE)	2/124 (1.6)	NE (NE, NE)		0.186 (0.041, 0.848)	0.018
Rest of world	4/22 (18.2)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 4 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	8/129 (6.2)	NE (NE, NE)	2/144 (1.4)	NE (NE, NE)		0.192 (0.042, 0.878)	0.020
Rest of world	4/22 (18.2)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	4/53 (7.5)		1/59 (1.7)				
1	8/98 (8.2)		1/110 (0.9)				

Page 5 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	5/67 (7.5)		1/76 (1.3)				
2	6/61 (9.8)		0/64 (0.0)				
> 2	1/23 (4.3)		1/29 (3.4)				

Page 6 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	6/50 (12.0)		0/57 (0.0)				
No	6/101 (5.9)		2/112 (1.8)				
Liver metastasis					0.17		
Yes	1/28 (3.6)	NE (NE, NE)	1/30 (3.3)	NE (NE, NE)		0.868 (0.051, 14.915)	0.92
No	11/123 (8.9)	NE (NE, NE)	1/139 (0.7)	NE (NE, NE)		0.070 (0.010, 0.505)	< 0.001

Page 7 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	5/61 (8.2)		1/80 (1.3)				
No	7/90 (7.8)		1/89 (1.1)				

Page 8 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	5/47 (10.6)		0/55 (0.0)				
≥ 1% and < 50%	4/61 (6.6)		1/46 (2.2)				
≥ 50%	3/34 (8.8)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious gastrointestinal disorders TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	14/169 (8.3)	NE (NE, NE)		1.077 (0.476, 2.437)	0.86
Age - at baseline (years)					0.019		
< 65	2/85 (2.4)	NE (NE, NE)	10/91 (11.0)	NE (NE, NE)		3.568 (0.800, 15.911)	0.083
≥ 65	7/66 (10.6)	NE (NE, NE)	4/78 (5.1)	NE (NE, NE)		0.410 (0.123, 1.372)	0.14

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.97		
Male	3/86 (3.5)	NE (NE, NE)	6/107 (5.6)	NE (NE, NE)		0.955 (0.244, 3.740)	0.95
Female	6/65 (9.2)	NE (NE, NE)	8/62 (12.9)	NE (NE, NE)		1.216 (0.432, 3.422)	0.72

Page 11 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.99		
Asian	2/19 (10.5)	NE (NE, NE)	3/21 (14.3)	NE (NE, NE)		1.249 (0.222, 7.024)	0.81
Non-Asian	7/131 (5.3)	NE (NE, NE)	11/147 (7.5)	NE (NE, NE)		1.041 (0.415, 2.613)	0.93

Page 12 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.67		
North America	2/19 (10.5)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		0.884 (0.136, 5.745)	0.91
Europe	4/110 (3.6)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		1.325 (0.418, 4.200)	0.65
Rest of world	3/22 (13.6)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		0.769 (0.165, 3.580)	0.75

Page 13 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.50		
North America and Europe	6/129 (4.7)	NE (NE, NE)	11/144 (7.6)	NE (NE, NE)		1.222 (0.463, 3.225)	0.70
Rest of world	3/22 (13.6)	NE (NE, NE)	3/25 (12.0)	NE (NE, NE)		0.769 (0.165, 3.580)	0.75
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		NE (NE, NE)	NE
1	9/98 (9.2)	NE (NE, NE)	10/110 (9.1)	NE (NE, NE)		0.689 (0.289, 1.647)	0.43

Page 14 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	7/67 (10.4)	NE (NE, NE)	5/76 (6.6)	NE (NE, NE)		0.451 (0.152, 1.337)	0.18
2	0/61 (0.0)	NE (NE, NE)	7/64 (10.9)	NE (NE, NE)		NE (NE, NE)	NE
> 2	2/23 (8.7)	NE (4.34, NE)	2/29 (6.9)	NE (NE, NE)		0.631 (0.079, 5.020)	0.64

Page 15 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	0/50 (0.0)	NE (NE, NE)	7/57 (12.3)	NE (NE, NE)		NE (NE, NE)	NE
No	9/101 (8.9)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)		0.569 (0.220, 1.473)	0.27
Liver metastasis					0.46		
Yes	4/28 (14.3)	NE (NE, NE)	4/30 (13.3)	NE (15.51, NE)		0.710 (0.192, 2.619)	0.63
No	5/123 (4.1)	NE (NE, NE)	10/139 (7.2)	NE (NE, NE)		1.401 (0.490, 4.003)	0.54

Page 16 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.72		
Yes	6/61 (9.8)	NE (NE, NE)	9/80 (11.3)	NE (NE, NE)		0.856 (0.311, 2.353)	0.77
No	3/90 (3.3)	NE (NE, NE)	5/89 (5.6)	NE (NE, NE)		1.451 (0.368, 5.712)	0.61

Page 17 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.40		
< 1%	5/47 (10.6)	NE (NE, NE)	5/55 (9.1)	NE (NE, NE)		0.599 (0.180, 1.987)	0.43
≥ 1% and < 50%	3/61 (4.9)	NE (NE, NE)	2/46 (4.3)	NE (NE, NE)		0.818 (0.142, 4.719)	0.83
≥ 50%	1/34 (2.9)	NE (NE, NE)	7/60 (11.7)	NE (NE, NE)		3.663 (0.450, 29.833)	0.19

Page 18 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious general disorders and administration site conditions TEAE							
Overall	9/151 (6.0)	NE (NE, NE)	11/169 (6.5)	NE (NE, NE)		0.821 (0.339, 1.987)	0.67
Age - at baseline (years)					0.67		
< 65	6/85 (7.1)	NE (NE, NE)	6/91 (6.6)	NE (NE, NE)		0.728 (0.230, 2.309)	0.58
≥ 65	3/66 (4.5)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		0.994 (0.244, 4.041)	0.99

Page 19 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.77		
Male	4/86 (4.7)	NE (NE, NE)	5/107 (4.7)	NE (NE, NE)		0.704 (0.181, 2.731)	0.61
Female	5/65 (7.7)	NE (NE, NE)	6/62 (9.7)	NE (NE, NE)		1.019 (0.321, 3.230)	0.98

Page 20 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.44		
Asian	2/19 (10.5)	NE (3.68, NE)	1/21 (4.8)	NE (NE, NE)		0.358 (0.032, 4.033)	0.38
Non-Asian	7/131 (5.3)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		0.948 (0.362, 2.481)	0.92

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.48		
North America	2/19 (10.5)	NE (NE, NE)	1/20 (5.0)	NE (NE, NE)		0.440 (0.045, 4.344)	0.49
Europe	4/110 (3.6)	NE (NE, NE)	8/124 (6.5)	NE (NE, NE)		1.166 (0.345, 3.940)	0.81
Rest of world	3/22 (13.6)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.509 (0.084, 3.086)	0.45

Page 22 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.42		
North America and Europe	6/129 (4.7)	NE (NE, NE)	9/144 (6.3)	NE (NE, NE)		0.972 (0.347, 2.722)	0.96
Rest of world	3/22 (13.6)	NE (NE, NE)	2/25 (8.0)	NE (NE, NE)		0.509 (0.084, 3.086)	0.45
Baseline ECOG status (screening)					0.82		
0	3/53 (5.7)	NE (NE, NE)	4/59 (6.8)	NE (NE, NE)		0.749 (0.160, 3.504)	0.71
1	6/98 (6.1)	NE (NE, NE)	7/110 (6.4)	NE (NE, NE)		0.864 (0.304, 2.456)	0.79

Page 23 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.85		
1	3/67 (4.5)	NE (NE, NE)	5/76 (6.6)	NE (NE, NE)		1.094 (0.271, 4.416)	0.90
2	5/61 (8.2)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)		0.671 (0.191, 2.366)	0.53
> 2	1/23 (4.3)	NE (NE, NE)	1/29 (3.4)	NE (NE, NE)		0.776 (0.051, 11.755)	0.86

Page 24 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.31		
Yes	4/50 (8.0)	NE (NE, NE)	3/57 (5.3)	NE (NE, NE)		0.492 (0.110, 2.193)	0.35
No	5/101 (5.0)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)		1.093 (0.357, 3.346)	0.88
Liver metastasis					–		
Yes	4/28 (14.3)	NE (3.68, NE)	0/30 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
No	5/123 (4.1)	NE (NE, NE)	11/139 (7.9)	NE (NE, NE)		1.467 (0.503, 4.277)	0.48

Page 25 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.69		
Yes	3/61 (4.9)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		1.074 (0.255, 4.532)	0.92
No	6/90 (6.7)	NE (NE, NE)	6/89 (6.7)	NE (NE, NE)		0.649 (0.207, 2.035)	0.47

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	4/47 (8.5)		5/55 (9.1)				
≥ 1% and < 50%	1/61 (1.6)		3/46 (6.5)				
≥ 50%	4/34 (11.8)		2/60 (3.3)				

Page 27 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious infections and infestations TEAE							
Overall	25/151 (16.6)	18.37 (9.03, NE)	11/169 (6.5)	NE (NE, NE)		0.211 (0.106, 0.418)	< 0.001
Age - at baseline (years)					0.55		
< 65	12/85 (14.1)	NE (9.03, NE)	6/91 (6.6)	NE (NE, NE)		0.266 (0.107, 0.666)	0.007
≥ 65	13/66 (19.7)	18.37 (7.89, NE)	5/78 (6.4)	NE (NE, NE)		0.161 (0.059, 0.440)	< 0.001

Page 28 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.44		
Male	17/86 (19.8)	9.03 (7.89, NE)	7/107 (6.5)	NE (NE, NE)		0.145 (0.057, 0.372)	< 0.001
Female	8/65 (12.3)	18.37 (18.37, NE)	4/62 (6.5)	NE (NE, NE)		0.307 (0.103, 0.919)	0.047

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					0.89		
Asian	4/19 (21.1)	NE (7.10, NE)	2/21 (9.5)	NE (NE, NE)		0.362 (0.072, 1.828)	0.22
Non-Asian	21/131 (16.0)	18.37 (9.03, NE)	9/147 (6.1)	NE (NE, NE)		0.201 (0.097, 0.417)	< 0.001

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	4/19 (21.1)	NE (7.89, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	16/110 (14.5)	18.37 (9.03, NE)	8/124 (6.5)	NE (NE, NE)		0.213 (0.097, 0.471)	< 0.001
Rest of world	5/22 (22.7)	NE (7.10, NE)	3/25 (12.0)	NE (6.24, NE)		0.413 (0.106, 1.612)	0.21

Page 31 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.70		
North America and Europe	20/129 (15.5)	18.37 (9.03, NE)	8/144 (5.6)	NE (NE, NE)		0.185 (0.086, 0.400)	< 0.001
Rest of world	5/22 (22.7)	NE (7.10, NE)	3/25 (12.0)	NE (6.24, NE)		0.413 (0.106, 1.612)	0.21
Baseline ECOG status (screening)					0.81		
0	10/53 (18.9)	18.37 (9.03, NE)	4/59 (6.8)	NE (NE, NE)		0.161 (0.052, 0.497)	0.001
1	15/98 (15.3)	NE (7.89, NE)	7/110 (6.4)	NE (NE, NE)		0.245 (0.105, 0.573)	0.002

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.94		
1	14/67 (20.9)	18.37 (7.89, NE)	6/76 (7.9)	NE (NE, NE)		0.229 (0.092, 0.572)	0.001
2	6/61 (9.8)	NE (NE, NE)	3/64 (4.7)	NE (NE, NE)		0.222 (0.072, 0.682)	0.034
> 2	5/23 (21.7)	NE (NE, NE)	2/29 (6.9)	NE (NE, NE)		0.233 (0.051, 1.064)	0.062

Page 33 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.56		
Yes	7/50 (14.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		0.298 (0.106, 0.839)	0.044
No	18/101 (17.8)	18.37 (9.03, NE)	6/112 (5.4)	NE (NE, NE)		0.173 (0.070, 0.426)	< 0.001
Liver metastasis					0.78		
Yes	6/28 (21.4)	NE (2.66, NE)	3/30 (10.0)	NE (8.84, NE)		0.105 (0.012, 0.908)	0.012
No	19/123 (15.4)	18.37 (9.03, NE)	8/139 (5.8)	NE (NE, NE)		0.207 (0.092, 0.467)	< 0.001

Page 34 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.95		
Yes	11/61 (18.0)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		0.218 (0.084, 0.566)	0.003
No	14/90 (15.6)	18.37 (7.89, NE)	6/89 (6.7)	NE (NE, NE)		0.195 (0.073, 0.520)	< 0.001

Page 35 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.86		
< 1%	5/47 (10.6)	18.37 (18.37, NE)	1/55 (1.8)	NE (NE, NE)		0.138 (0.015, 1.244)	0.035
≥ 1% and < 50%	11/61 (18.0)	NE (NE, NE)	4/46 (8.7)	NE (15.34, NE)		0.201 (0.067, 0.602)	0.008
≥ 50%	7/34 (20.6)	NE (7.89, NE)	4/60 (6.7)	NE (NE, NE)		0.220 (0.065, 0.745)	0.010

Page 36 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

Endpoint	Docetaxel 75 mg/m^2 Q3W Events/Subjects (%)	Docetaxel 75 mg/m^2 Q3W Median (95% CI) (months)[a]	AMG 510 960 mg QD Events/Subjects (%)	AMG 510 960 mg QD Median (95% CI) (months)[a]	p-value[b] Interaction with Treatment	Hazard Ratio (AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious pneumonia TEAE							
Overall	10/151 (6.6)	18.37 (18.37, NE)	1/169 (0.6)	NE (NE, NE)		0.039 (0.005, 0.294)	< 0.001
Age - at baseline (years)					–		
< 65	7/85 (8.2)		1/91 (1.1)				
≥ 65	3/66 (4.5)		0/78 (0.0)				

Page 37 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					–		
Male	5/86 (5.8)		0/107 (0.0)				
Female	5/65 (7.7)		1/62 (1.6)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	1/19 (5.3)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	9/131 (6.9)	18.37 (18.37, NE)	1/147 (0.7)	NE (NE, NE)		0.044 (0.006, 0.337)	< 0.001

Page 39 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (9.23, NE)	0/20 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	8/110 (7.3)	18.37 (9.03, NE)	1/124 (0.8)	NE (NE, NE)		0.050 (0.007, 0.352)	< 0.001
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 40 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	9/129 (7.0)	18.37 (18.37, NE)	1/144 (0.7)	NE (NE, NE)		0.044 (0.006, 0.338)	< 0.001
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	4/53 (7.5)		0/59 (0.0)				
1	6/98 (6.1)		1/110 (0.9)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	5/67 (7.5)		1/76 (1.3)				
2	2/61 (3.3)		0/64 (0.0)				
> 2	3/23 (13.0)		0/29 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					–		
Yes	4/50 (8.0)		0/57 (0.0)				
No	6/101 (5.9)		1/112 (0.9)				
Liver metastasis					–		
Yes	2/28 (7.1)		1/30 (3.3)				
No	8/123 (6.5)		0/139 (0.0)				

Page 43 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					–		
Yes	6/61 (9.8)		1/80 (1.3)				
No	4/90 (4.4)		0/89 (0.0)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	1/47 (2.1)		0/55 (0.0)				
≥ 1% and < 50%	6/61 (9.8)		1/46 (2.2)				
≥ 50%	3/34 (8.8)		0/60 (0.0)				

Page 45 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious neoplasms benign, malignant and unspecified (incl cysts and polyps) TEAE							
Overall	7/151 (4.6)	NE (NE, NE)	31/169 (18.3)	NE (NE, NE)		2.996 (1.329, 6.751)	0.006
Age - at baseline (years)					0.51		
< 65	6/85 (7.1)	NE (NE, NE)	22/91 (24.2)	NE (NE, NE)		2.792 (1.135, 6.871)	0.021
≥ 65	1/66 (1.5)	NE (NE, NE)	9/78 (11.5)	NE (NE, NE)		4.717 (0.625, 35.590)	0.11

Page 46 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.22		
Male	5/86 (5.8)	NE (NE, NE)	16/107 (15.0)	NE (NE, NE)		1.870 (0.694, 5.041)	0.22
Female	2/65 (3.1)	NE (NE, NE)	15/62 (24.2)	NE (16.39, NE)		6.184 (1.424, 26.846)	0.006

Page 47 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	2/21 (9.5)	NE (9.10, NE)		NE (NE, NE)	NE
Non-Asian	7/131 (5.3)	NE (NE, NE)	29/147 (19.7)	NE (NE, NE)		2.829 (1.249, 6.406)	0.011

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.80		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.650 (0.166, 16.396)	0.68
Europe	5/110 (4.5)	NE (NE, NE)	26/124 (21.0)	NE (NE, NE)		3.466 (1.339, 8.972)	0.007
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (9.10, NE)		1.528 (0.156, 14.996)	0.73

Page 49 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.71		
North America and Europe	6/129 (4.7)	NE (NE, NE)	28/144 (19.4)	NE (NE, NE)		3.242 (1.351, 7.778)	0.006
Rest of world	1/22 (4.5)	NE (NE, NE)	3/25 (12.0)	NE (9.10, NE)		1.528 (0.156, 14.996)	0.73
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	6/59 (10.2)	NE (NE, NE)		NE (NE, NE)	NE
1	7/98 (7.1)	NE (NE, NE)	25/110 (22.7)	NE (16.13, NE)		2.187 (0.958, 4.993)	0.065

Page 50 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.29		
1	2/67 (3.0)	NE (NE, NE)	15/76 (19.7)	NE (NE, NE)		5.617 (1.288, 24.497)	0.010
2	4/61 (6.6)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		1.411 (0.433, 4.599)	0.58
> 2	1/23 (4.3)	NE (NE, NE)	8/29 (27.6)	16.39 (7.13, NE)		5.088 (0.584, 44.305)	0.10

Page 51 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.25		
Yes	4/50 (8.0)	NE (NE, NE)	12/57 (21.1)	NE (16.13, NE)		1.710 (0.555, 5.263)	0.36
No	3/101 (3.0)	NE (NE, NE)	19/112 (17.0)	NE (NE, NE)		4.692 (1.400, 15.725)	0.006
Liver metastasis					0.50		
Yes	2/28 (7.1)	NE (NE, NE)	5/30 (16.7)	NE (16.13, NE)		1.707 (0.364, 8.012)	0.53
No	5/123 (4.1)	NE (NE, NE)	26/139 (18.7)	NE (NE, NE)		3.533 (1.366, 9.138)	0.006

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.82		
Yes	3/61 (4.9)	NE (NE, NE)	16/80 (20.0)	NE (16.13, NE)		3.083 (0.906, 10.496)	0.062
No	4/90 (4.4)	NE (NE, NE)	15/89 (16.9)	NE (NE, NE)		2.905 (0.981, 8.599)	0.049

Page 53 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.49		
< 1%	1/47 (2.1)	NE (NE, NE)	12/55 (21.8)	NE (NE, NE)		8.406 (1.098, 64.355)	0.014
≥ 1% and < 50%	4/61 (6.6)	NE (NE, NE)	12/46 (26.1)	NE (16.13, NE)		2.957 (0.969, 9.022)	0.054
≥ 50%	2/34 (5.9)	NE (NE, NE)	7/60 (11.7)	NE (16.39, NE)		1.568 (0.323, 7.605)	0.58

Page 54 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious non-small cell lung cancer TEAE							
Overall	5/151 (3.3)	NE (NE, NE)	18/169 (10.7)	NE (NE, NE)		2.449 (0.932, 6.436)	0.070
Age - at baseline (years)					0.65		
< 65	4/85 (4.7)	NE (NE, NE)	12/91 (13.2)	NE (NE, NE)		2.161 (0.717, 6.508)	0.18
≥ 65	1/66 (1.5)	NE (NE, NE)	6/78 (7.7)	NE (NE, NE)		3.868 (0.490, 30.552)	0.18

Page 55 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.51		
Male	3/86 (3.5)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.800 (0.510, 6.346)	0.38
Female	2/65 (3.1)	NE (NE, NE)	9/62 (14.5)	NE (NE, NE)		3.717 (0.828, 16.697)	0.073

Page 56 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	5/131 (3.8)	NE (NE, NE)	18/147 (12.2)	NE (NE, NE)		2.438 (0.927, 6.414)	0.071

Page 57 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	1/19 (5.3)	NE (NE, NE)	2/20 (10.0)	NE (NE, NE)		1.650 (0.166, 16.396)	0.68
Europe	3/110 (2.7)	NE (NE, NE)	16/124 (12.9)	NE (NE, NE)		3.385 (1.008, 11.362)	0.042
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE

Page 58 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					–		
North America and Europe	4/129 (3.1)	NE (NE, NE)	18/144 (12.5)	NE (NE, NE)		3.048 (1.054, 8.815)	0.035
Rest of world	1/22 (4.5)	NE (NE, NE)	0/25 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Baseline ECOG status (screening)					–		
0	0/53 (0.0)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		NE (NE, NE)	NE
1	5/98 (5.1)	NE (NE, NE)	15/110 (13.6)	NE (NE, NE)		1.921 (0.721, 5.115)	0.20

Page 59 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)	NE (NE, NE)	9/76 (11.8)	NE (NE, NE)		6.460 (0.833, 50.111)	0.043
2	4/61 (6.6)	NE (NE, NE)	5/64 (7.8)	NE (NE, NE)		0.957 (0.273, 3.350)	0.95
> 2	0/23 (0.0)	NE (NE, NE)	4/29 (13.8)	NE (NE, NE)		NE (NE, NE)	NE

Page 60 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.44		
Yes	2/50 (4.0)	NE (NE, NE)	5/57 (8.8)	NE (NE, NE)		1.547 (0.318, 7.518)	0.61
No	3/101 (3.0)	NE (NE, NE)	13/112 (11.6)	NE (NE, NE)		3.175 (0.924, 10.912)	0.058
Liver metastasis					0.16		
Yes	2/28 (7.1)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.806 (0.132, 4.930)	0.83
No	3/123 (2.4)	NE (NE, NE)	16/139 (11.5)	NE (NE, NE)		3.558 (1.060, 11.941)	0.032

Page 61 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.81		
Yes	2/61 (3.3)	NE (NE, NE)	7/80 (8.8)	NE (NE, NE)		2.026 (0.444, 9.243)	0.37
No	3/90 (3.3)	NE (NE, NE)	11/89 (12.4)	NE (NE, NE)		2.843 (0.818, 9.879)	0.095

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.40		
< 1%	1/47 (2.1)	NE (NE, NE)	9/55 (16.4)	NE (NE, NE)		6.151 (0.793, 47.704)	0.049
≥ 1% and < 50%	2/61 (3.3)	NE (NE, NE)	5/46 (10.9)	NE (NE, NE)		2.478 (0.526, 11.688)	0.27
≥ 50%	2/34 (5.9)	NE (NE, NE)	4/60 (6.7)	NE (NE, NE)		0.943 (0.178, 5.008)	0.95

Page 63 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious nervous system disorders TEAE							
Overall	6/151 (4.0)	NE (NE, NE)	11/169 (6.5)	NE (NE, NE)		1.258 (0.474, 3.342)	0.65
Age - at baseline (years)					0.98		
< 65	4/85 (4.7)	NE (NE, NE)	7/91 (7.7)	NE (NE, NE)		1.353 (0.405, 4.515)	0.63
≥ 65	2/66 (3.0)	NE (NE, NE)	4/78 (5.1)	NE (NE, NE)		1.088 (0.210, 5.646)	0.92

Page 64 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.27		
Male	3/86 (3.5)	NE (NE, NE)	9/107 (8.4)	NE (NE, NE)		1.768 (0.467, 6.701)	0.39
Female	3/65 (4.6)	NE (NE, NE)	2/62 (3.2)	NE (NE, NE)		0.573 (0.112, 2.921)	0.54

Page 65 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	0/19 (0.0)	NE (NE, NE)	1/21 (4.8)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	5/131 (3.8)	NE (NE, NE)	10/147 (6.8)	NE (NE, NE)		1.375 (0.478, 3.956)	0.56

Page 66 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					–		
North America	0/19 (0.0)	NE (NE, NE)	1/20 (5.0)	NE (NE, NE)		NE (NE, NE)	NE
Europe	5/110 (4.5)	NE (NE, NE)	9/124 (7.3)	NE (NE, NE)		1.152 (0.391, 3.393)	0.80
Rest of world	1/22 (4.5)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.693 (0.050, 9.550)	0.79

Page 67 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.63		
North America and Europe	5/129 (3.9)	NE (NE, NE)	10/144 (6.9)	NE (NE, NE)		1.381 (0.477, 3.997)	0.56
Rest of world	1/22 (4.5)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.693 (0.050, 9.550)	0.79
Baseline ECOG status (screening)					0.88		
0	2/53 (3.8)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		0.952 (0.163, 5.556)	0.96
1	4/98 (4.1)	NE (NE, NE)	8/110 (7.3)	NE (NE, NE)		1.383 (0.439, 4.357)	0.60

Page 68 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					–		
1	1/67 (1.5)		5/76 (6.6)				
2	5/61 (8.2)		3/64 (4.7)				
> 2	0/23 (0.0)		3/29 (10.3)				

Page 69 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.93		
Yes	2/50 (4.0)	NE (NE, NE)	4/57 (7.0)	NE (NE, NE)		0.964 (0.176, 5.294)	0.97
No	4/101 (4.0)	NE (NE, NE)	7/112 (6.3)	NE (NE, NE)		1.374 (0.414, 4.566)	0.61
Liver metastasis					0.16		
Yes	3/28 (10.7)	NE (NE, NE)	2/30 (6.7)	NE (NE, NE)		0.377 (0.079, 1.802)	0.28
No	3/123 (2.4)	NE (NE, NE)	9/139 (6.5)	NE (NE, NE)		2.054 (0.556, 7.585)	0.28

Page 70 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.29		
Yes	4/61 (6.6)	NE (NE, NE)	5/80 (6.3)	NE (NE, NE)		0.774 (0.221, 2.712)	0.70
No	2/90 (2.2)	NE (NE, NE)	6/89 (6.7)	NE (NE, NE)		2.074 (0.410, 10.504)	0.37

Page 71 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					–		
< 1%	2/47 (4.3)		5/55 (9.1)				
≥ 1% and < 50%	2/61 (3.3)		5/46 (10.9)				
≥ 50%	1/34 (2.9)		1/60 (1.7)				

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Time to first serious respiratory, thoracic and mediastinal disorders TEAE							
Overall	19/151 (12.6)	NE (NE, NE)	14/169 (8.3)	NE (NE, NE)		0.541 (0.268, 1.091)	0.081
Age - at baseline (years)					0.42		
< 65	10/85 (11.8)	NE (NE, NE)	9/91 (9.9)	NE (NE, NE)		0.665 (0.268, 1.650)	0.38
≥ 65	9/66 (13.6)	NE (NE, NE)	5/78 (6.4)	NE (NE, NE)		0.431 (0.142, 1.304)	0.12

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Sex					0.090		
Male	11/86 (12.8)	NE (NE, NE)	5/107 (4.7)	NE (NE, NE)		0.270 (0.093, 0.781)	0.014
Female	8/65 (12.3)	NE (NE, NE)	9/62 (14.5)	NE (NE, NE)		1.032 (0.393, 2.715)	0.95

Page 74 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Race category 2					–		
Asian	3/19 (15.8)	NE (2.96, NE)	0/21 (0.0)	NE (NE, NE)		NE (NE, NE)	NE
Non-Asian	16/131 (12.2)	NE (NE, NE)	14/147 (9.5)	NE (NE, NE)		0.641 (0.309, 1.330)	0.23

Page 75 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 1					0.54		
North America	4/19 (21.1)	NE (7.23, NE)	1/20 (5.0)	NE (NE, NE)		0.206 (0.024, 1.770)	0.12
Europe	13/110 (11.8)	NE (NE, NE)	12/124 (9.7)	NE (NE, NE)		0.678 (0.308, 1.493)	0.34
Rest of world	2/22 (9.1)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.376 (0.035, 4.064)	0.41

Page 76 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Region category 2					0.74		
North America and Europe	17/129 (13.2)	NE (NE, NE)	13/144 (9.0)	NE (NE, NE)		0.563 (0.270, 1.172)	0.12
Rest of world	2/22 (9.1)	NE (NE, NE)	1/25 (4.0)	NE (NE, NE)		0.376 (0.035, 4.064)	0.41
Baseline ECOG status (screening)					0.35		
0	2/53 (3.8)	NE (NE, NE)	3/59 (5.1)	NE (NE, NE)		1.038 (0.178, 6.064)	0.97
1	17/98 (17.3)	NE (NE, NE)	11/110 (10.0)	NE (NE, NE)		0.465 (0.215, 1.007)	0.044

Page 77 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Number of prior lines of therapy in advanced disease					0.26		
1	6/67 (9.0)	NE (NE, NE)	3/76 (3.9)	NE (NE, NE)		0.332 (0.084, 1.308)	0.12
2	6/61 (9.8)	NE (NE, NE)	8/64 (12.5)	NE (NE, NE)		1.096 (0.386, 3.114)	0.87
> 2	7/23 (30.4)	7.23 (5.16, NE)	3/29 (10.3)	NE (NE, NE)		0.251 (0.062, 1.015)	0.034

Page 78 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
History of CNS involvement					0.81		
Yes	8/50 (16.0)	NE (7.23, NE)	6/57 (10.5)	NE (NE, NE)		0.434 (0.141, 1.338)	0.14
No	11/101 (10.9)	NE (NE, NE)	8/112 (7.1)	NE (NE, NE)		0.594 (0.237, 1.490)	0.26
Liver metastasis					0.34		
Yes	7/28 (25.0)	7.23 (5.16, NE)	3/30 (10.0)	NE (NE, NE)		0.300 (0.076, 1.183)	0.067
No	12/123 (9.8)	NE (NE, NE)	11/139 (7.9)	NE (NE, NE)		0.685 (0.304, 1.545)	0.37

Page 79 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger amnog 202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
Bone metastasis at baseline					0.44		
Yes	6/61 (9.8)	NE (NE, NE)	7/80 (8.8)	NE (NE, NE)		0.709 (0.225, 2.235)	0.55
No	13/90 (14.4)	NE (NE, NE)	7/89 (7.9)	NE (NE, NE)		0.468 (0.191, 1.150)	0.098

Page 80 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

Table 14-6.2.509. Summary of Time to First Serious Treatment Emergent Adverse Event by MedDRA SOC and PT (Most Frequent TEAEs (≥ 5% Subjects or ≥ 10 Subjects and ≥ 1% Subjects in at least One Treatment Arm))
(Safety Analysis Set)
(20190009 PFS Primary Analysis)

	Docetaxel 75 mg/m^2 Q3W		AMG 510 960 mg QD		p-value[b]	Hazard Ratio	
Endpoint	Events/Subjects (%)	Median (95% CI) (months)[a]	Events/Subjects (%)	Median (95% CI) (months)[a]	Interaction with Treatment	(AMG 510/Docetaxel) (95% CI)	p-value (2-sided)[c]
PD-L1 protein expression					0.39		
< 1%	7/47 (14.9)	NE (NE, NE)	7/55 (12.7)	NE (NE, NE)		0.708 (0.249, 2.013)	0.52
≥ 1% and < 50%	7/61 (11.5)	NE (7.23, NE)	1/46 (2.2)	NE (NE, NE)		0.134 (0.014, 1.291)	0.035
≥ 50%	4/34 (11.8)	NE (NE, NE)	5/60 (8.3)	NE (NE, NE)		0.667 (0.183, 2.427)	0.54

Page 81 of 81

KM = Kaplan-Meier, CI = Confidence Interval, TEAE = Treatment Emergent Adverse Event, NE = Not Estimable.
Unstratified analysis was conducted overall and for subgroups.
[a] 95% CI is based on the estimated variance for log-log transformation of the Kaplan-Meier survival estimate.
[b] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[c] 2-sided p-values were calculated using the unstratified log-rank test.
TEAEs in this table are events with onset after the administration of the first dose of any study treatment and within the end of study, or 30 days of the last dose of any study treatment, or before the first dose of AMG 510 if subjects cross over from docetaxel to AMG 510, whichever occurs earlier.
Data cut-off date: 02AUG2022.

Program: /userdata/stat/amg510/onc/20190009/analysis/ger_amnog_202208/tables/output/t-teae-sum-soc-pref-subgroup.sas
Output: t14-06-002-509-teae-sum-ser-soc-pref-5pct.rtf (Date Generated: 18JAN23:07:11:14) Source: adam.adsl, adam.adtts

4.12 PRO-CTCAE

4.12.1 Verlaufskurve für den Endpunkt PRO-CTCAE

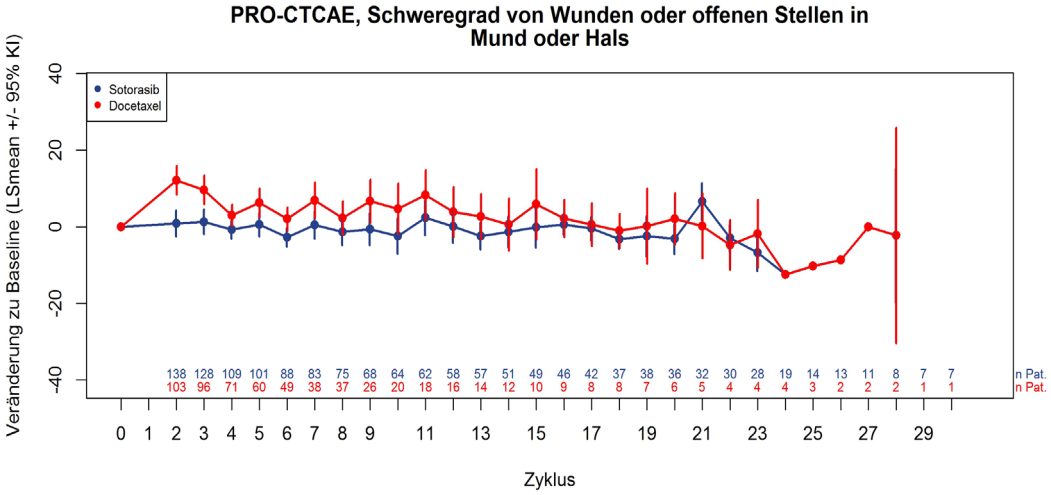

Abbildung 32: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

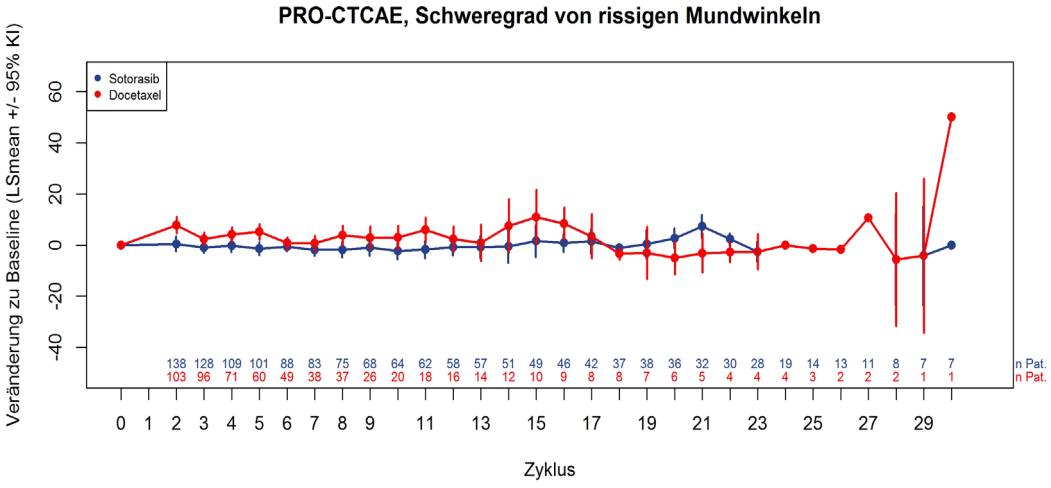

Abbildung 33: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von rissigen Mundwinkeln, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

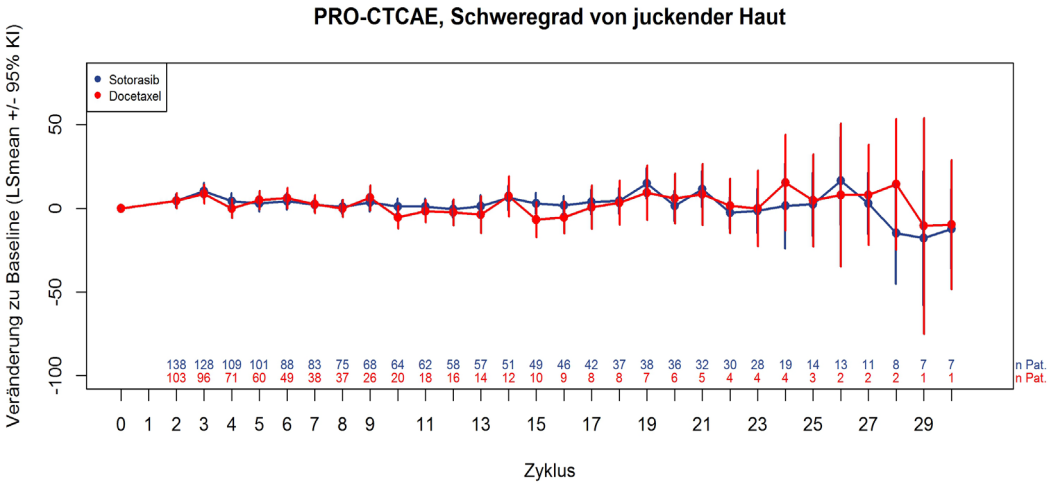

Abbildung 34: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von juckender Haut, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

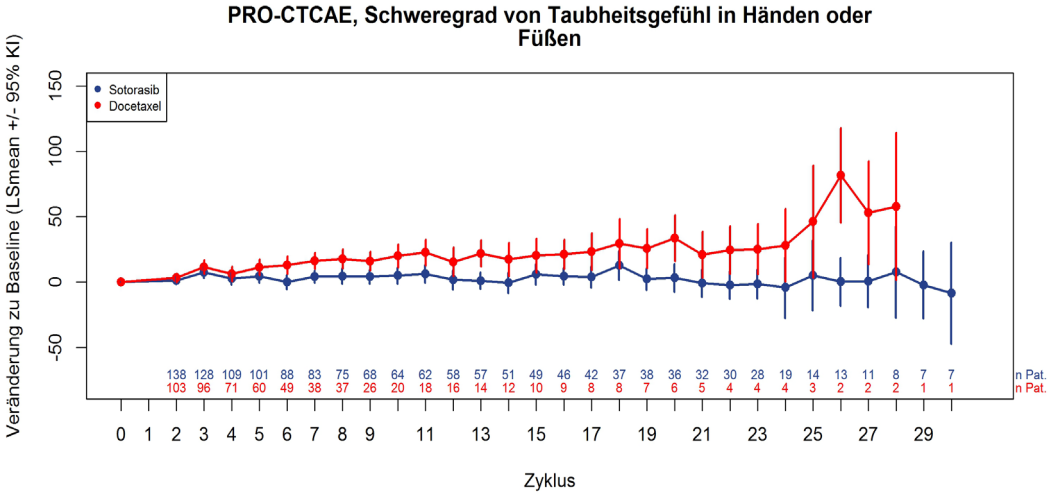

Abbildung 35: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

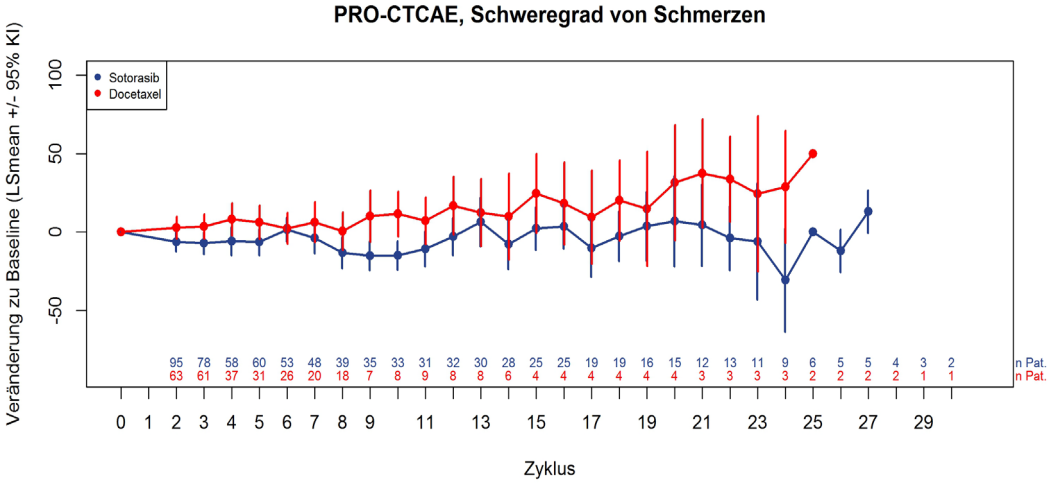

Abbildung 36: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von Schmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

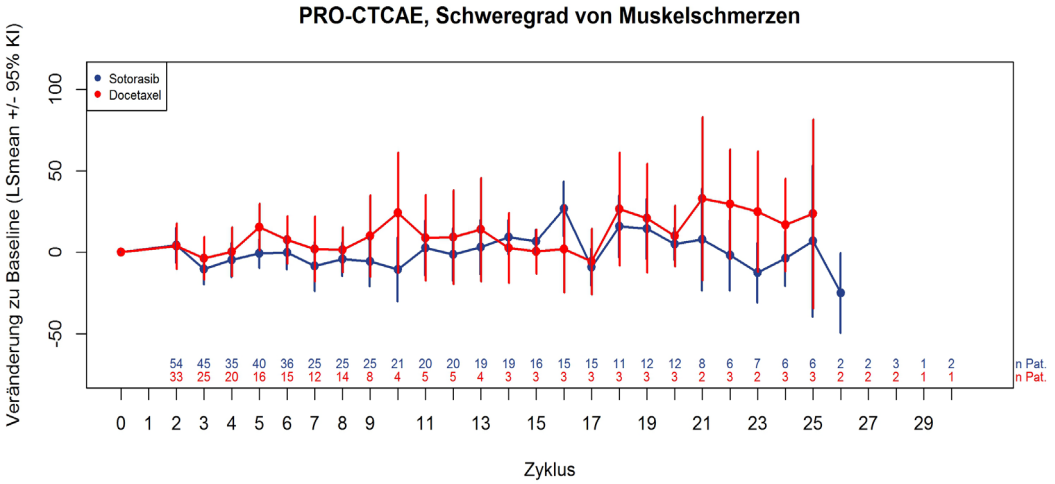

Abbildung 37: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von Muskelschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

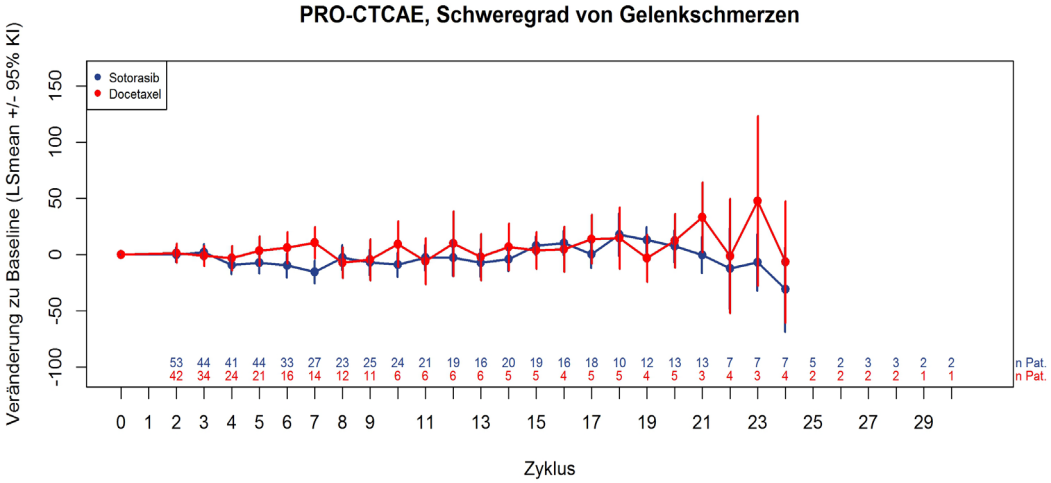

Abbildung 38: Verlaufskurve für den Endpunkt PRO-CTCAE, Schweregrad von Gelenkschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

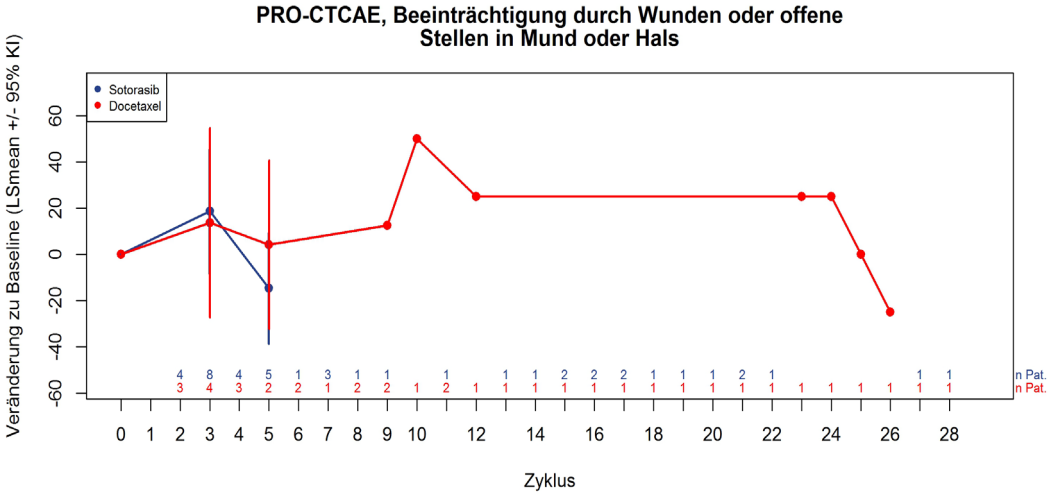

Abbildung 39: Verlaufskurve für den Endpunkt PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

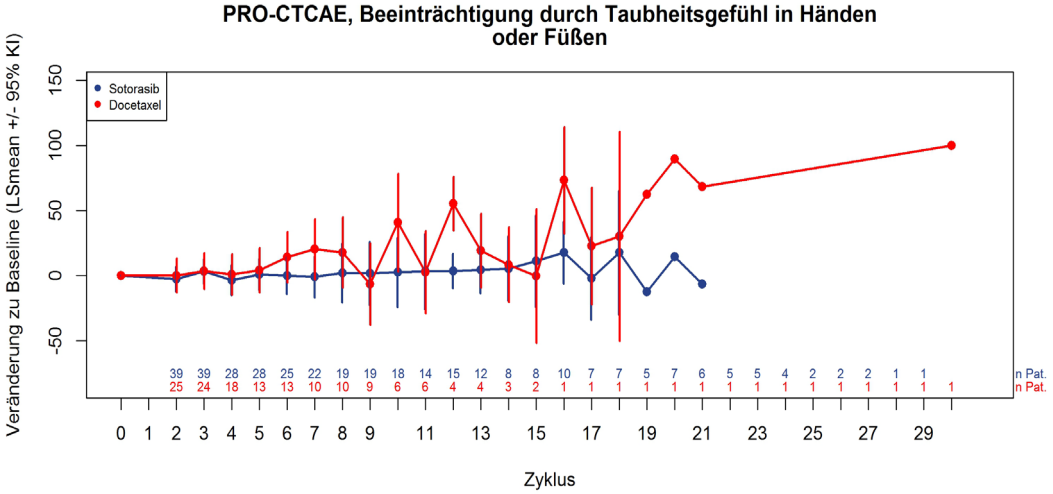

Abbildung 40: Verlaufskurve für den Endpunkt PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

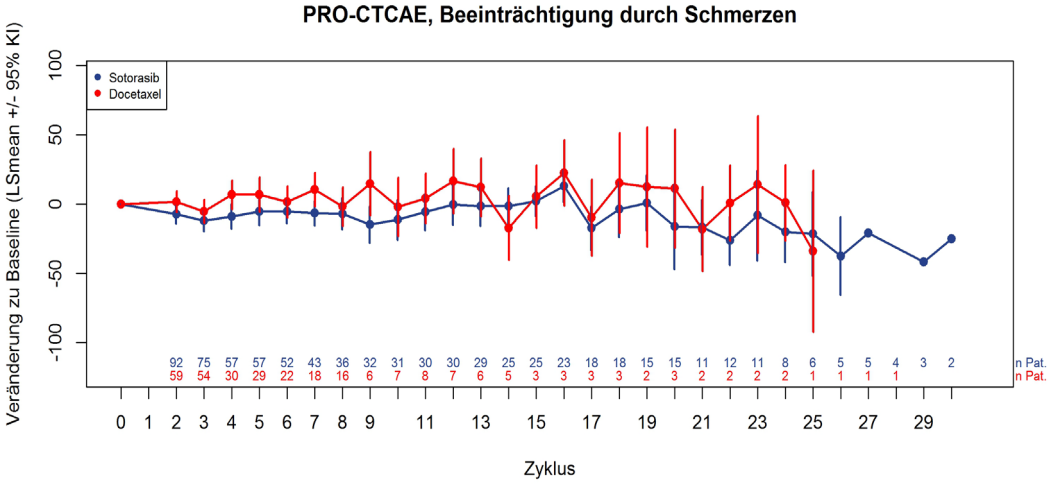

Abbildung 41: Verlaufskurve für den Endpunkt PRO-CTCAE, Beeinträchtigung durch Schmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

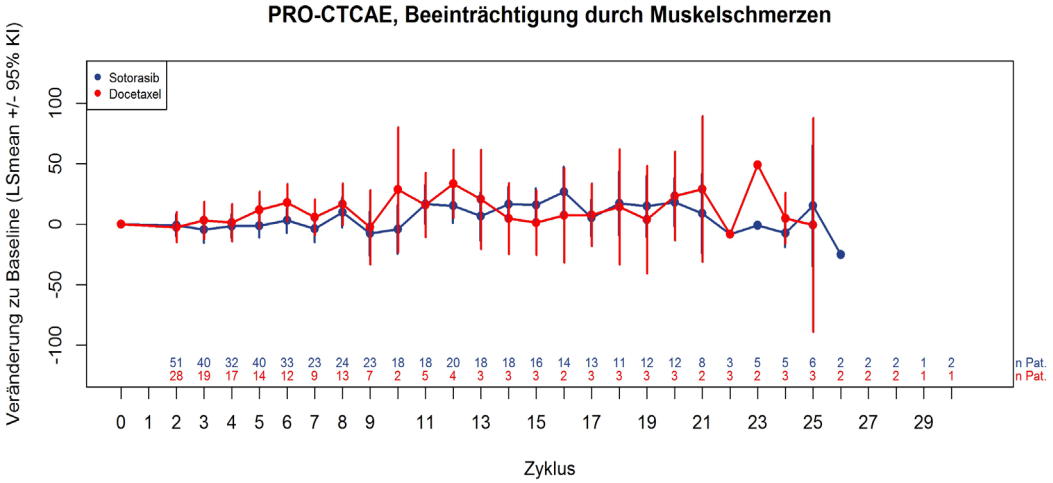

Abbildung 42: Verlaufskurve für den Endpunkt PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

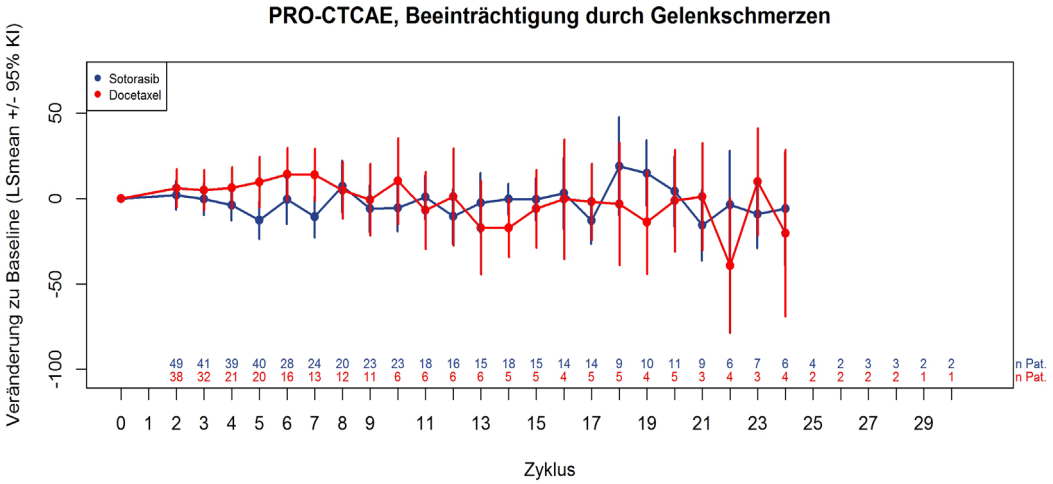

Abbildung 43: Verlaufskurve für den Endpunkt PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

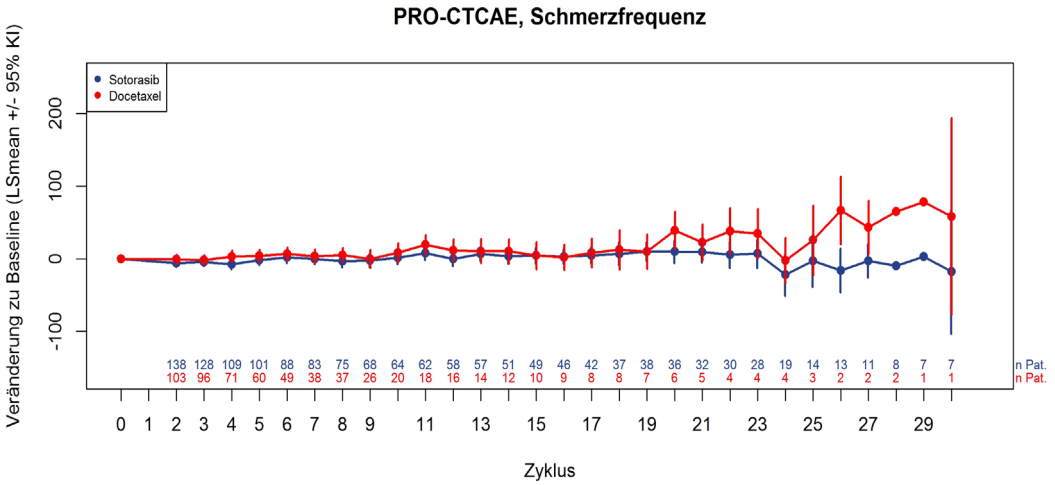

Abbildung 44: Verlaufskurve für den Endpunkt PRO-CTCAE, Schmerzfrequenz, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

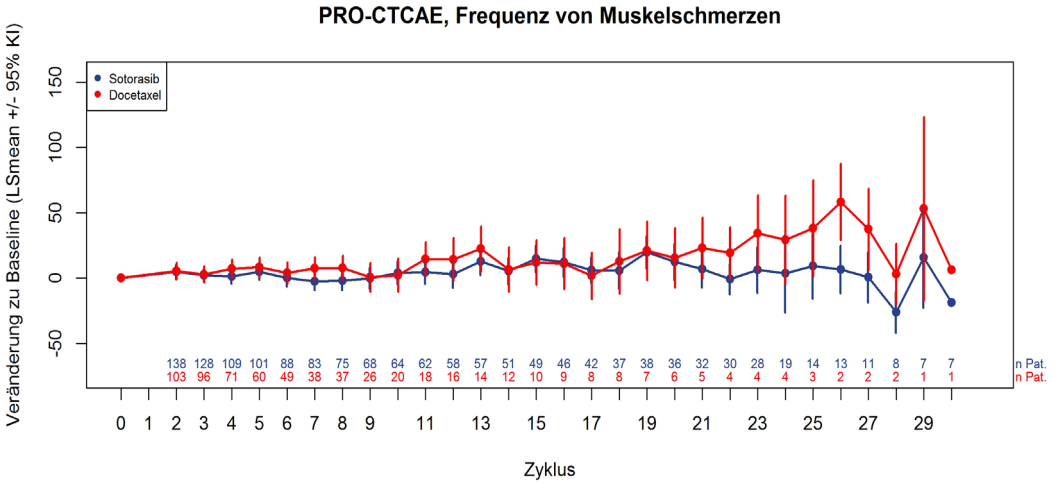

Abbildung 45: Verlaufskurve für den Endpunkt PRO-CTCAE, Frequenz von Muskelschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

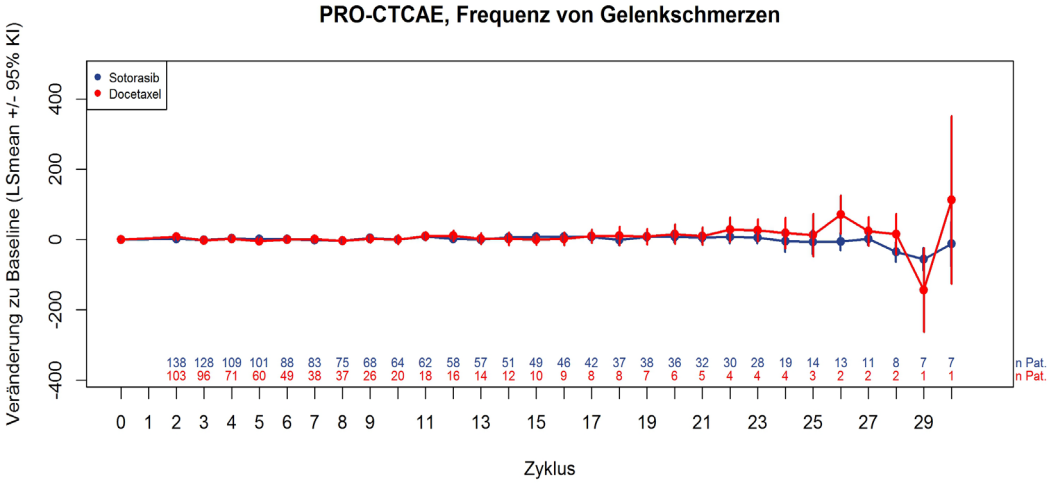

Abbildung 46: Verlaufskurve für den Endpunkt PRO-CTCAE, Frequenz von Gelenkschmerzen, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

4.12.2 Subgruppenanalysen für den Endpunkt PRO-CTCAE (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Alter bei Studienbeginn							
<65 Jahre	19/85 (22,4)	n.b. [13,8; n.b.]	29/69 (42,0)	8,1 [2,4; n.b.]	0,3 [0,2; 0,6]	0,0001	0,0897
≥65 Jahre	12/78 (15,4)	n.b. [n.b.; n.b.]	31/59 (52,5)	2,8 [1,4; n.b.]	0,2 [0,1; 0,4]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Geschlecht							
Weiblich	14/60 (23,3)	n.b. [13,8; n.b.]	24/51 (47,1)	5,8 [1,6; n.b.]	0,4 [0,2; 0,8]	0,0083	0,1544
Männlich	17/103 (16,5)	n.b. [n.b.; n.b.]	36/77 (46,8)	4,4 [1,5; n.b.]	0,2 [0,1; 0,3]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Region 2							
Nordamerika und Europa	22/138 (15,9)	n.b. [n.b.; n.b.]	43/109 (39,4)	8,4 [3,4; n.b.]	0,3 [0,1; 0,5]	<,0001	0,7782
Rest der Welt	9/25 (36,0)	n.b. [2,1; n.b.]	17/19 (89,5)	1,3 [0,7; 1,5]	0,2 [0,1; 0,7]	0,0031	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Region 1							
Nordamerika	2/19 (10,5)	n.b. [n.b.; n.b.]	5/16 (31,2)	n.b. [1,6; n.b.]	0,7 [0,1; 4,4]	0,7315	0,8875
Europa	20/119 (16,8)	n.b. [n.b.; n.b.]	38/93 (40,9)	8,4 [2,8; n.b.]	0,2 [0,1; 0,4]	<,0001	
Rest der Welt	9/25 (36,0)	n.b. [2,1; n.b.]	17/19 (89,5)	1,3 [0,7; 1,5]	0,2 [0,1; 0,7]	0,0031	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; ECOG Performance-Status							
0	15/57 (26,3)	n.b. [13,8; n.b.]	22/52 (42,3)	8,4 [2,4; n.b.]	0,5 [0,2; 1,0]	0,0327	0,0399
1	16/106 (15,1)	n.b. [15,2; n.b.]	38/76 (50,0)	2,8 [1,5; n.b.]	0,2 [0,1; 0,3]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Lebermetastasen bei Studienbeginn							
Nein	25/135 (18,5)	n.b. [n.b.; n.b.]	50/107 (46,7)	5,8 [2,4; n.b.]	0,2 [0,1; 0,4]	<,0001	0,9735
Ja	6/28 (21,4)	n.b. [7,0; n.b.]	10/21 (47,6)	8,1 [1,4; 8,1]	0,3 [0,1; 1,1]	0,0515	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Knochenmetastasen bei Studienbeginn							
Nein	21/86 (24,4)	n.b. [13,8; n.b.]	37/77 (48,1)	3,4 [1,5; n.b.]	0,4 [0,2; 0,6]	0,0004	0,2959
Ja	10/77 (13,0)	n.b. [n.b.; n.b.]	23/51 (45,1)	5,8 [2,8; 8,4]	0,2 [0,1; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; PD-L1-Proteinexpression							
<1%	10/54 (18,5)	n.b. [13,8; n.b.]	19/41 (46,3)	5,8 [1,5; n.b.]	0,3 [0,1; 0,6]	0,0015	0,8526
≥1% und <50%	7/44 (15,9)	n.b. [n.b.; n.b.]	22/49 (44,9)	4,4 [1,9; n.b.]	0,2 [0,1; 0,5]	0,0004	
≥50%	11/58 (19,0)	n.b. [15,2; n.b.]	14/30 (46,7)	4,2 [1,4; n.b.]	0,3 [0,1; 0,8]	0,0066	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Ethnie-2							
Asiatisch	7/21 (33,3)	n.b. [2,1; n.b.]	15/18 (83,3)	1,1 [0,7; 1,5]	0,3 [0,1; 0,7]	0,0070	0,8922
Nicht asiatisch	24/141 (17,0)	n.b. [n.b.; n.b.]	45/109 (41,3)	8,4 [2,8; n.b.]	0,3 [0,2; 0,4]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Vorgeschichte einer Beteiligung des ZNS							
Nein	19/108 (17,6)	n.b. [15,2; n.b.]	39/88 (44,3)	5,8 [1,9; n.b.]	0,2 [0,1; 0,4]	<,0001	0,9996
Ja	12/55 (21,8)	n.b. [n.b.; n.b.]	21/40 (52,5)	2,8 [1,4; n.b.]	0,3 [0,1; 0,7]	0,0013	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Anzahl an vorherigen Therapielinien							
1	13/71 (18,3)	n.b. [n.b.; n.b.]	34/58 (58,6)	1,9 [1,4; 4,4]	0,2 [0,1; 0,4]	<,0001	0,0539
2	11/63 (17,5)	n.b. [15,2; n.b.]	23/51 (45,1)	8,1 [1,4; n.b.]	0,2 [0,1; 0,5]	0,0002	
>2	7/29 (24,1)	13,8 [7,0; n.b.]	3/19 (15,8)	n.b. [n.b.; n.b.]	0,8 [0,2; 3,5]	0,7825	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Alter bei Studienbeginn							
<65 Jahre	15/85 (17,6)	n.b. [n.b.; n.b.]	22/69 (31,9)	n.b. [4,6; n.b.]	0,4 [0,2; 0,9]	0,0171	0,3101
≥65 Jahre	16/78 (20,5)	n.b. [n.b.; n.b.]	22/59 (37,3)	n.b. [3,5; n.b.]	0,2 [0,1; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Geschlecht							
Weiblich	13/60 (21,7)	n.b. [13,8; n.b.]	15/51 (29,4)	n.b. [4,6; n.b.]	0,5 [0,2; 1,2]	0,1277	0,1062
Männlich	18/103 (17,5)	n.b. [n.b.; n.b.]	29/77 (37,7)	n.b. [3,5; n.b.]	0,3 [0,1; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Region 2							
Nordamerika und Europa	23/138 (16,7)	n.b. [n.b.; n.b.]	34/109 (31,2)	n.b. [5,0; n.b.]	0,4 [0,2; 0,6]	0,0003	0,8943
Rest der Welt	8/25 (32,0)	n.b. [4,3; n.b.]	10/19 (52,6)	2,0 [0,8; n.b.]	0,3 [0,1; 0,9]	0,0313	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Region 1							
Nordamerika	2/19 (10,5)	n.b. [5,5; n.b.]	3/16 (18,8)	n.b. [5,1; n.b.]	0,0 [0,0; n.b.]	0,2660	0,9420
Europa	21/119 (17,6)	n.b. [n.b.; n.b.]	31/93 (33,3)	n.b. [4,6; n.b.]	0,4 [0,2; 0,7]	0,0008	
Rest der Welt	8/25 (32,0)	n.b. [4,3; n.b.]	10/19 (52,6)	2,0 [0,8; n.b.]	0,3 [0,1; 0,9]	0,0313	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; ECOG Performance-Status							
0	12/57 (21,1)	n.b. [n.b.; n.b.]	18/52 (34,6)	n.b. [4,6; n.b.]	0,4 [0,2; 0,9]	0,0188	0,6900
1	19/106 (17,9)	n.b. [n.b.; n.b.]	26/76 (34,2)	n.b. [4,2; n.b.]	0,3 [0,1; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Lebermetastasen bei Studienbeginn							
Nein	26/135 (19,3)	n.b. [n.b.; n.b.]	37/107 (34,6)	n.b. [5,0; n.b.]	0,4 [0,2; 0,6]	0,0001	0,9320
Ja	5/28 (17,9)	n.b. [n.b.; n.b.]	7/21 (33,3)	n.b. [1,4; n.b.]	0,3 [0,0; 1,7]	0,1426	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Knochenmetastasen bei Studienbeginn							
Nein	17/86 (19,8)	n.b. [n.b.; n.b.]	27/77 (35,1)	n.b. [5,0; n.b.]	0,4 [0,2; 0,7]	0,0011	0,6342
Ja	14/77 (18,2)	n.b. [8,7; n.b.]	17/51 (33,3)	n.b. [2,8; n.b.]	0,4 [0,2; 0,8]	0,0124	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; PD-L1-Proteinexpression							
<1%	8/54 (14,8)	n.b. [n.b.; n.b.]	16/41 (39,0)	n.b. [2,8; n.b.]	0,2 [0,0; 0,5]	0,0002	0,2268
≥1% und <50%	11/44 (25,0)	n.b. [6,2; n.b.]	15/49 (30,6)	n.b. [2,8; n.b.]	0,5 [0,2; 1,1]	0,0920	
≥50%	9/58 (15,5)	n.b. [n.b.; n.b.]	10/30 (33,3)	n.b. [4,6; n.b.]	0,4 [0,1; 1,0]	0,0530	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Ethnie-2							
Asiatisch	6/21 (28,6)	n.b. [4,3; n.b.]	9/18 (50,0)	2,0 [0,7; n.b.]	0,3 [0,1; 1,0]	0,0458	0,9822
Nicht asiatisch	25/141 (17,7)	n.b. [n.b.; n.b.]	35/109 (32,1)	n.b. [5,0; n.b.]	0,4 [0,2; 0,7]	0,0003	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Vorgeschichte einer Beteiligung des ZNS							
Nein	21/108 (19,4)	n.b. [13,8; n.b.]	31/88 (35,2)	n.b. [4,6; n.b.]	0,3 [0,2; 0,6]	0,0002	0,8958
Ja	10/55 (18,2)	n.b. [n.b.; n.b.]	13/40 (32,5)	n.b. [2,1; n.b.]	0,4 [0,2; 0,9]	0,0284	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Anzahl an vorherigen Therapielinien							
1	12/71 (16,9)	n.b. [n.b.; n.b.]	19/58 (32,8)	n.b. [2,8; n.b.]	0,4 [0,2; 0,8]	0,0133	0,6678
2	12/63 (19,0)	n.b. [13,8; n.b.]	20/51 (39,2)	5,8 [4,2; n.b.]	0,3 [0,1; 0,6]	0,0005	
>2	7/29 (24,1)	n.b. [7,6; n.b.]	5/19 (26,3)	n.b. [5,0; n.b.]	0,7 [0,2; 2,1]	0,4828	
PRO-CTCAE, Schweregrad von juckender Haut; Alter bei Studienbeginn							
<65 Jahre	35/85 (41,2)	9,7 [3,5; n.b.]	28/69 (40,6)	5,6 [2,1; n.b.]	1,0 [0,6; 1,8]	0,9710	0,4334
≥65 Jahre	42/78 (53,8)	3,5 [2,1; 7,6]	28/59 (47,5)	3,1 [1,5; n.b.]	1,4 [0,8; 2,3]	0,2592	
PRO-CTCAE, Schweregrad von juckender Haut; Geschlecht							
Weiblich	28/60 (46,7)	4,2 [2,1; n.b.]	23/51 (45,1)	4,2 [1,9; n.b.]	0,9 [0,5; 1,7]	0,8348	0,9676
Männlich	49/103 (47,6)	6,3 [2,8; 15,2]	33/77 (42,9)	8,9 [2,1; n.b.]	0,9 [0,6; 1,5]	0,7880	
PRO-CTCAE, Schweregrad von juckender Haut; Region 2							
Nordamerika und Europa	64/138 (46,4)	6,3 [3,5; 11,3]	42/109 (38,5)	8,9 [3,0; n.b.]	1,1 [0,8; 1,7]	0,5404	0,1342
Rest der Welt	13/25 (52,0)	3,4 [0,8; n.b.]	14/19 (73,7)	1,5 [1,0; 3,5]	0,4 [0,1; 0,9]	0,0307	
PRO-CTCAE, Schweregrad von juckender Haut; Region 1							
Nordamerika	10/19 (52,6)	4,4 [0,7; n.b.]	7/16 (43,8)	n.b. [1,4; n.b.]	1,1 [0,3; 3,7]	0,9002	0,2977
Europa	54/119 (45,4)	6,3 [3,5; 11,3]	35/93 (37,6)	8,9 [2,8; n.b.]	1,1 [0,7; 1,7]	0,7419	
Rest der Welt	13/25 (52,0)	3,4 [0,8; n.b.]	14/19 (73,7)	1,5 [1,0; 3,5]	0,4 [0,1; 0,9]	0,0307	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von juckender Haut; ECOG Performance-Status							
0	26/57 (45,6)	7,7 [3,5; n.b.]	19/52 (36,5)	8,9 [4,2; n.b.]	1,1 [0,6; 2,1]	0,7340	0,3280
1	51/106 (48,1)	4,1 [2,1; 15,2]	37/76 (48,7)	2,8 [1,5; n.b.]	0,9 [0,6; 1,5]	0,7531	
PRO-CTCAE, Schweregrad von juckender Haut; Lebermetastasen bei Studienbeginn							
Nein	63/135 (46,7)	7,5 [3,4; 11,3]	43/107 (40,2)	8,9 [3,0; n.b.]	1,1 [0,7; 1,7]	0,6110	0,2404
Ja	14/28 (50,0)	4,4 [1,2; n.b.]	13/21 (61,9)	1,4 [1,4; 3,5]	0,5 [0,2; 1,4]	0,1762	
PRO-CTCAE, Schweregrad von juckender Haut; Knochenmetastasen bei Studienbeginn							
Nein	45/86 (52,3)	4,2 [2,1; 11,3]	32/77 (41,6)	8,9 [2,8; n.b.]	1,2 [0,8; 2,0]	0,4041	0,1829
Ja	32/77 (41,6)	7,6 [2,8; n.b.]	24/51 (47,1)	3,0 [1,4; n.b.]	0,7 [0,4; 1,3]	0,3050	
PRO-CTCAE, Schweregrad von juckender Haut; PD-L1-Proteinexpression							
<1%	25/54 (46,3)	6,3 [2,1; n.b.]	18/41 (43,9)	n.b. [1,5; n.b.]	1,1 [0,6; 2,2]	0,7081	0,6510
≥1% und <50%	21/44 (47,7)	4,4 [2,1; n.b.]	18/49 (36,7)	4,9 [3,0; n.b.]	1,5 [0,7; 2,9]	0,2736	
≥50%	26/58 (44,8)	7,5 [2,8; n.b.]	14/30 (46,7)	8,9 [1,4; n.b.]	0,9 [0,4; 1,8]	0,7215	
PRO-CTCAE, Schweregrad von juckender Haut; Ethnie-2							
Asiatisch	11/21 (52,4)	3,4 [1,3; n.b.]	12/18 (66,7)	1,5 [1,4; 5,6]	0,6 [0,3; 1,6]	0,3190	0,3268
Nicht asiatisch	66/141 (46,8)	4,4 [3,4; 11,3]	44/109 (40,4)	8,9 [2,8; n.b.]	1,2 [0,8; 1,7]	0,4718	
PRO-CTCAE, Schweregrad von juckender Haut; Vorgeschichte einer Beteiligung des ZNS							
Nein	47/108 (43,5)	7,6 [3,4; 15,2]	37/88 (42,0)	8,9 [2,1; n.b.]	1,1 [0,7; 1,7]	0,7402	0,7161
Ja	30/55 (54,5)	4,1 [2,1; n.b.]	19/40 (47,5)	3,0 [2,1; n.b.]	1,1 [0,6; 1,9]	0,8623	
PRO-CTCAE, Schweregrad von juckender Haut; Anzahl an vorherigen Therapielinien							
1	24/71 (33,8)	11,3 [4,1; n.b.]	32/58 (55,2)	2,1 [1,4; n.b.]	0,5 [0,3; 0,9]	0,0220	0,0030
2	33/63 (52,4)	4,4 [2,1; 15,2]	19/51 (37,3)	n.b. [3,5; n.b.]	1,5 [0,8; 2,7]	0,1960	
>2	20/29 (69,0)	2,1 [0,7; 3,5]	5/19 (26,3)	8,9 [n.b.; n.b.]	3,2 [1,1; 9,6]	0,0266	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Alter bei Studienbeginn							
<65 Jahre	35/85 (41,2)	7,6 [2,8; n.b.]	36/69 (52,2)	3,5 [2,1; 4,9]	0,8 [0,5; 1,3]	0,2810	0,4998
≥65 Jahre	33/78 (42,3)	8,5 [4,3; n.b.]	34/59 (57,6)	2,8 [2,1; 5,1]	0,5 [0,3; 0,9]	0,0185	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Geschlecht							
Weiblich	24/60 (40,0)	13,4 [2,8; n.b.]	31/51 (60,8)	3,1 [1,6; 4,9]	0,6 [0,3; 1,1]	0,0769	0,7411
Männlich	44/103 (42,7)	7,6 [5,3; 14,2]	39/77 (50,6)	3,5 [2,1; 5,1]	0,6 [0,4; 1,0]	0,0339	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Region 2							
Nordamerika und Europa	55/138 (39,9)	10,4 [5,6; n.b.]	59/109 (54,1)	3,5 [2,3; 4,9]	0,6 [0,4; 0,9]	0,0223	0,6970
Rest der Welt	13/25 (52,0)	4,3 [1,4; 8,5]	11/19 (57,9)	1,9 [1,4; n.b.]	0,5 [0,2; 1,3]	0,1521	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Region 1							
Nordamerika	9/19 (47,4)	4,2 [0,7; n.b.]	11/16 (68,8)	3,4 [2,1; 8,5]	0,7 [0,3; 2,0]	0,5498	0,9169
Europa	46/119 (38,7)	10,4 [5,6; n.b.]	48/93 (51,6)	3,5 [2,1; 5,1]	0,6 [0,4; 0,9]	0,0224	
Rest der Welt	13/25 (52,0)	4,3 [1,4; 8,5]	11/19 (57,9)	1,9 [1,4; n.b.]	0,5 [0,2; 1,3]	0,1521	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; ECOG Performance-Status							
0	29/57 (50,9)	7,6 [4,2; 13,4]	28/52 (53,8)	4,2 [2,1; 9,9]	0,7 [0,4; 1,2]	0,1762	0,1874
1	39/106 (36,8)	n.b. [3,0; n.b.]	42/76 (55,3)	2,8 [1,6; 3,7]	0,6 [0,4; 0,9]	0,0184	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Lebermetastasen bei Studienbeginn							
Nein	59/135 (43,7)	7,7 [4,2; 14,2]	57/107 (53,3)	3,5 [2,8; 4,9]	0,7 [0,5; 1,0]	0,0442	0,0918
Ja	9/28 (32,1)	n.b. [2,9; n.b.]	13/21 (61,9)	1,5 [1,4; 8,5]	0,6 [0,2; 1,8]	0,4006	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Knochenmetastasen bei Studienbeginn							
Nein	45/86 (52,3)	5,7 [2,8; 9,0]	45/77 (58,4)	3,1 [2,1; 4,4]	0,8 [0,5; 1,3]	0,3627	0,1028
Ja	23/77 (29,9)	n.b. [5,6; n.b.]	25/51 (49,0)	3,5 [1,4; n.b.]	0,5 [0,3; 0,9]	0,0202	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; PD-L1-Proteinexpression							
<1%	19/54 (35,2)	13,4 [5,3; n.b.]	26/41 (63,4)	3,5 [1,5; 3,7]	0,4 [0,2; 0,7]	0,0023	0,0422
≥1% und <50%	22/44 (50,0)	5,6 [1,4; n.b.]	20/49 (40,8)	4,4 [2,1; n.b.]	1,3 [0,7; 2,4]	0,4904	
≥50%	22/58 (37,9)	9,0 [3,3; n.b.]	16/30 (53,3)	2,8 [1,4; n.b.]	0,6 [0,3; 1,1]	0,1095	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Ethnie-2							
Asiatisch	9/21 (42,9)	7,5 [2,2; n.b.]	9/18 (50,0)	2,8 [1,4; n.b.]	0,5 [0,2; 1,4]	0,1690	0,9251
Nicht asiatisch	59/141 (41,8)	8,5 [5,3; n.b.]	61/109 (56,0)	3,5 [2,1; 4,4]	0,6 [0,4; 0,9]	0,0152	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Vorgeschichte einer Beteiligung des ZNS							
Nein	45/108 (41,7)	6,3 [3,7; 14,2]	52/88 (59,1)	2,8 [2,0; 3,5]	0,6 [0,4; 0,9]	0,0075	0,6138
Ja	23/55 (41,8)	10,4 [2,8; n.b.]	18/40 (45,0)	4,4 [2,1; n.b.]	0,7 [0,4; 1,3]	0,2576	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Anzahl an vorherigen Therapielinien							
1	28/71 (39,4)	8,5 [4,2; 14,2]	32/58 (55,2)	2,8 [2,1; 3,5]	0,5 [0,3; 0,9]	0,0230	0,2378
2	24/63 (38,1)	n.b. [5,7; n.b.]	29/51 (56,9)	3,7 [1,5; 4,9]	0,5 [0,3; 0,9]	0,0179	
>2	16/29 (55,2)	2,8 [1,4; n.b.]	9/19 (47,4)	8,5 [1,4; n.b.]	1,3 [0,5; 2,9]	0,5853	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Schmerzen; Alter bei Studienbeginn							
<65 Jahre	29/84 (34,5)	12,2 [5,6; n.b.]	30/63 (47,6)	4,9 [2,1; n.b.]	0,5 [0,3; 0,9]	0,0188	0,4409
≥65 Jahre	26/73 (35,6)	15,4 [4,8; n.b.]	20/53 (37,7)	n.b. [2,1; n.b.]	0,8 [0,4; 1,5]	0,4745	
PRO-CTCAE, Schweregrad von Schmerzen; Geschlecht							
Weiblich	22/57 (38,6)	n.b. [3,6; n.b.]	28/46 (60,9)	2,1 [1,4; 4,9]	0,5 [0,3; 0,9]	0,0194	0,2111
Männlich	33/100 (33,0)	12,5 [9,1; n.b.]	22/70 (31,4)	8,7 [3,5; n.b.]	0,7 [0,4; 1,3]	0,2598	
PRO-CTCAE, Schweregrad von Schmerzen; Region 2							
Nordamerika und Europa	45/134 (33,6)	n.b. [9,1; n.b.]	44/99 (44,4)	4,9 [2,7; n.b.]	0,6 [0,4; 1,0]	0,0393	0,6659
Rest der Welt	10/23 (43,5)	12,5 [4,2; 15,4]	6/17 (35,3)	n.b. [1,4; n.b.]	0,5 [0,1; 2,0]	0,3254	
PRO-CTCAE, Schweregrad von Schmerzen; Region 1							
Nordamerika	6/18 (33,3)	12,2 [3,3; n.b.]	8/14 (57,1)	3,0 [1,5; n.b.]	0,6 [0,1; 2,5]	0,4732	0,7471
Europa	39/116 (33,6)	n.b. [8,3; n.b.]	36/85 (42,4)	7,3 [2,1; n.b.]	0,7 [0,4; 1,1]	0,0889	
Rest der Welt	10/23 (43,5)	12,5 [4,2; 15,4]	6/17 (35,3)	n.b. [1,4; n.b.]	0,5 [0,1; 2,0]	0,3254	
PRO-CTCAE, Schweregrad von Schmerzen; ECOG Performance-Status							
0	21/55 (38,2)	15,4 [4,9; n.b.]	16/45 (35,6)	8,7 [4,2; n.b.]	1,0 [0,5; 2,3]	0,9065	0,0897
1	34/102 (33,3)	12,5 [5,6; n.b.]	34/71 (47,9)	2,7 [2,1; n.b.]	0,5 [0,3; 0,8]	0,0046	
PRO-CTCAE, Schweregrad von Schmerzen; Lebermetastasen bei Studienbeginn							
Nein	43/130 (33,1)	15,4 [9,7; n.b.]	42/95 (44,2)	7,3 [2,1; n.b.]	0,6 [0,3; 0,9]	0,0099	0,2188
Ja	12/27 (44,4)	4,8 [2,0; n.b.]	8/21 (38,1)	4,9 [1,4; n.b.]	1,2 [0,4; 3,7]	0,7957	
PRO-CTCAE, Schweregrad von Schmerzen; Knochenmetastasen bei Studienbeginn							
Nein	26/83 (31,3)	15,4 [12,2; n.b.]	30/67 (44,8)	4,9 [2,1; n.b.]	0,5 [0,3; 0,9]	0,0297	0,4031
Ja	29/74 (39,2)	9,7 [4,2; n.b.]	20/49 (40,8)	8,7 [2,1; 8,7]	0,7 [0,3; 1,2]	0,1959	
PRO-CTCAE, Schweregrad von Schmerzen; PD-L1-Proteinexpression							
<1%	18/51 (35,3)	n.b. [5,6; n.b.]	12/39 (30,8)	n.b. [3,5; n.b.]	0,9 [0,4; 1,9]	0,7668	0,3275
≥1% und <50%	14/43 (32,6)	15,4 [3,5; n.b.]	19/44 (43,2)	4,2 [2,1; n.b.]	0,7 [0,3; 1,5]	0,4056	
≥50%	20/56 (35,7)	12,5 [3,6; n.b.]	14/25 (56,0)	2,8 [1,4; 7,3]	0,5 [0,2; 1,0]	0,0470	
PRO-CTCAE, Schweregrad von Schmerzen; Ethnie-2							
Asiatisch	7/19 (36,8)	12,5 [2,1; n.b.]	6/16 (37,5)	n.b. [0,8; n.b.]	0,6 [0,2; 1,9]	0,3385	0,9922
Nicht asiatisch	48/137 (35,0)	15,4 [8,3; n.b.]	43/99 (43,4)	7,3 [2,8; n.b.]	0,6 [0,4; 1,0]	0,0389	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Schmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	36/103 (35,0)	15,4 [4,8; n.b.]	38/80 (47,5)	4,2 [2,1; n.b.]	0,6 [0,4; 1,0]	0,0522	0,9798
Ja	19/54 (35,2)	12,5 [4,9; n.b.]	12/36 (33,3)	n.b. [2,7; n.b.]	0,5 [0,2; 1,2]	0,1283	
PRO-CTCAE, Schweregrad von Schmerzen; Anzahl an vorherigen Therapielinien							
1	25/69 (36,2)	9,1 [4,3; n.b.]	23/54 (42,6)	2,8 [2,1; n.b.]	0,7 [0,4; 1,2]	0,1857	0,3085
2	17/61 (27,9)	n.b. [12,2; n.b.]	20/43 (46,5)	7,3 [2,1; n.b.]	0,4 [0,2; 0,9]	0,0162	
>2	13/27 (48,1)	4,8 [2,1; n.b.]	7/19 (36,8)	8,7 [1,6; 8,7]	1,0 [0,4; 2,6]	0,9682	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	23/67 (34,3)	16,6 [6,2; n.b.]	12/53 (22,6)	14,5 [5,3; n.b.]	1,6 [0,8; 3,3]	0,2166	0,3086
≥65 Jahre	20/62 (32,3)	n.b. [7,8; n.b.]	11/46 (23,9)	8,5 [5,2; n.b.]	1,0 [0,4; 2,2]	0,9656	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Geschlecht							
Weiblich	19/48 (39,6)	16,6 [3,6; n.b.]	6/40 (15,0)	n.b. [14,5; n.b.]	1,9 [0,7; 5,1]	0,1843	0,0725
Männlich	24/81 (29,6)	n.b. [12,5; n.b.]	17/59 (28,8)	8,5 [4,6; n.b.]	0,8 [0,4; 1,6]	0,5328	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Region 2							
Nordamerika und Europa	37/108 (34,3)	n.b. [10,4; n.b.]	21/87 (24,1)	14,5 [5,3; n.b.]	1,1 [0,6; 2,0]	0,6740	0,5396
Rest der Welt	6/21 (28,6)	12,5 [3,5; n.b.]	2/12 (16,7)	n.b. [0,7; n.b.]	1,0 [0,2; 6,4]	0,9631	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Region 1							
Nordamerika	10/15 (66,7)	2,9 [0,7; 10,4]	1/12 (8,3)	n.b. [8,5; n.b.]	227160000,0 [0,0; n.b.]	0,0101	0,0624
Europa	27/93 (29,0)	n.b. [16,6; n.b.]	20/75 (26,7)	14,5 [5,2; n.b.]	0,8 [0,4; 1,5]	0,4625	
Rest der Welt	6/21 (28,6)	12,5 [3,5; n.b.]	2/12 (16,7)	n.b. [0,7; n.b.]	1,0 [0,2; 6,4]	0,9631	
PRO-CTCAE, Schweregrad von Muskelschmerzen; ECOG Performance-Status							
0	12/47 (25,5)	n.b. [13,1; n.b.]	9/41 (22,0)	n.b. [5,3; n.b.]	0,7 [0,3; 1,9]	0,5279	0,4671
1	31/82 (37,8)	12,5 [3,7; n.b.]	14/58 (24,1)	14,5 [5,0; n.b.]	1,4 [0,7; 2,7]	0,3178	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	38/114 (33,3)	n.b. [12,5; n.b.]	21/82 (25,6)	14,5 [5,3; n.b.]	1,0 [0,6; 1,7]	0,9617	0,1516
Ja	5/15 (33,3)	n.b. [2,1; n.b.]	2/17 (11,8)	n.b. [n.b.; n.b.]	1,3 [0,2; 7,0]	0,7982	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	21/72 (29,2)	n.b. [13,1; n.b.]	13/56 (23,2)	n.b. [5,3; n.b.]	1,0 [0,5; 2,0]	0,9151	0,5003
Ja	22/57 (38,6)	12,5 [3,6; n.b.]	10/43 (23,3)	14,5 [4,6; n.b.]	1,2 [0,5; 2,7]	0,6493	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Muskelschmerzen; PD-L1-Proteinexpression							
<1%	14/42 (33,3)	n.b. [3,7; n.b.]	8/32 (25,0)	14,5 [5,0; n.b.]	1,0 [0,4; 2,5]	0,9976	0,9027
≥1% und <50%	11/34 (32,4)	n.b. [6,2; n.b.]	7/36 (19,4)	n.b. [4,6; n.b.]	1,7 [0,6; 4,6]	0,2745	
≥50%	16/46 (34,8)	16,6 [4,0; n.b.]	6/23 (26,1)	8,5 [5,2; n.b.]	1,1 [0,4; 3,3]	0,8058	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Ethnie-2							
Asiatisch	5/17 (29,4)	10,4 [3,4; n.b.]	1/11 (9,1)	n.b. [n.b.; n.b.]	3,1 [0,3; 28,6]	0,2892	0,4348
Nicht asiatisch	38/111 (34,2)	16,6 [12,5; n.b.]	22/87 (25,3)	14,5 [5,3; n.b.]	1,1 [0,7; 1,9]	0,6699	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	27/82 (32,9)	n.b. [7,8; n.b.]	20/67 (29,9)	14,5 [5,2; n.b.]	0,9 [0,5; 1,6]	0,7516	0,0842
Ja	16/47 (34,0)	16,6 [6,2; n.b.]	3/32 (9,4)	n.b. [n.b.; n.b.]	3,3 [0,9; 11,7]	0,0489	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	17/57 (29,8)	n.b. [4,0; n.b.]	8/44 (18,2)	14,5 [8,5; n.b.]	1,6 [0,7; 3,7]	0,2940	0,1784
2	15/48 (31,2)	n.b. [10,4; n.b.]	13/41 (31,7)	n.b. [4,6; n.b.]	0,7 [0,3; 1,5]	0,2992	
>2	11/24 (45,8)	5,2 [2,1; n.b.]	2/14 (14,3)	n.b. [n.b.; n.b.]	2,9 [0,6; 13,3]	0,1602	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	23/64 (35,9)	11,8 [9,0; n.b.]	16/50 (32,0)	16,6 [2,8; 17,5]	0,9 [0,4; 1,9]	0,8084	0,6977
≥65 Jahre	14/64 (21,9)	n.b. [n.b.; n.b.]	9/47 (19,1)	n.b. [5,2; n.b.]	0,8 [0,3; 1,9]	0,5902	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Geschlecht							
Weiblich	18/48 (37,5)	n.b. [2,1; n.b.]	8/38 (21,1)	17,5 [16,6; n.b.]	1,9 [0,7; 5,0]	0,1788	0,0326
Männlich	19/80 (23,8)	n.b. [10,0; n.b.]	17/59 (28,8)	n.b. [5,0; n.b.]	0,5 [0,3; 1,1]	0,0926	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Region 2							
Nordamerika und Europa	28/108 (25,9)	n.b. [n.b.; n.b.]	23/80 (28,8)	16,6 [5,2; n.b.]	0,7 [0,4; 1,3]	0,2923	0,1737
Rest der Welt	9/20 (45,0)	9,7 [1,4; n.b.]	2/17 (11,8)	n.b. [1,3; n.b.]	1,2 [0,2; 6,5]	0,8649	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Region 1							
Nordamerika	4/13 (30,8)	n.b. [2,1; n.b.]	1/10 (10,0)	16,6 [n.b.; n.b.]	367600000,0 [0,0; n.b.]	0,1086	0,3051
Europa	24/95 (25,3)	n.b. [n.b.; n.b.]	22/70 (31,4)	17,5 [5,0; n.b.]	0,6 [0,3; 1,1]	0,1060	
Rest der Welt	9/20 (45,0)	9,7 [1,4; n.b.]	2/17 (11,8)	n.b. [1,3; n.b.]	1,2 [0,2; 6,5]	0,8649	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; ECOG Performance-Status							
0	11/46 (23,9)	n.b. [10,0; n.b.]	9/39 (23,1)	n.b. [n.b.; n.b.]	0,6 [0,2; 1,7]	0,3443	0,7982
1	26/82 (31,7)	n.b. [9,7; n.b.]	16/58 (27,6)	16,6 [5,0; 17,5]	1,0 [0,5; 1,9]	0,9334	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	34/109 (31,2)	n.b. [10,0; n.b.]	21/80 (26,2)	17,5 [5,2; n.b.]	0,9 [0,5; 1,6]	0,7686	0,6239
Ja	3/19 (15,8)	n.b. [n.b.; n.b.]	4/17 (23,5)	16,6 [1,6; 16,6]	0,3 [0,0; 3,4]	0,3173	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	23/69 (33,3)	n.b. [9,0; n.b.]	15/53 (28,3)	n.b. [5,0; n.b.]	0,7 [0,3; 1,5]	0,3519	0,9761
Ja	14/59 (23,7)	n.b. [10,0; n.b.]	10/44 (22,7)	16,6 [16,6; 17,5]	0,9 [0,4; 2,4]	0,8999	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	12/44 (27,3)	n.b. [9,0; n.b.]	3/31 (9,7)	17,5 [17,5; n.b.]	2,4 [0,5; 11,1]	0,2545	0,2383
≥1% und <50%	7/32 (21,9)	n.b. [11,8; n.b.]	8/36 (22,2)	16,6 [16,6; n.b.]	0,7 [0,2; 2,2]	0,5544	
≥50%	14/45 (31,1)	n.b. [9,7; n.b.]	9/22 (40,9)	5,2 [1,4; n.b.]	0,7 [0,3; 1,7]	0,4333	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Ethnie-2							
Asiatisch	7/17 (41,2)	10,0 [1,5; n.b.]	1/16 (6,2)	n.b. [n.b.; n.b.]	3,8 [0,4; 33,2]	0,1974	0,1140
Nicht asiatisch	30/110 (27,3)	n.b. [n.b.; n.b.]	23/80 (28,8)	16,6 [5,2; n.b.]	0,8 [0,5; 1,4]	0,4454	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	19/80 (23,8)	n.b. [n.b.; n.b.]	16/65 (24,6)	17,5 [5,2; n.b.]	0,8 [0,4; 1,6]	0,4663	0,4462
Ja	18/48 (37,5)	n.b. [3,0; n.b.]	9/32 (28,1)	16,6 [2,4; 16,6]	1,2 [0,5; 2,7]	0,7496	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	12/57 (21,1)	n.b. [n.b.; n.b.]	7/45 (15,6)	17,5 [17,5; n.b.]	1,3 [0,5; 3,6]	0,5773	0,0533
2	13/47 (27,7)	n.b. [11,8; n.b.]	16/39 (41,0)	5,0 [2,4; n.b.]	0,5 [0,2; 1,0]	0,0542	
>2	12/24 (50,0)	6,9 [1,4; n.b.]	2/13 (15,4)	16,6 [0,8; 16,6]	5,1 [0,6; 40,5]	0,0844	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Alter bei Studienbeginn							
<65 Jahre	1/24 (4,2)		4/36 (11,1)				n. a.
≥65 Jahre	6/19 (31,6)		2/32 (6,2)				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Geschlecht							
Weiblich	5/19 (26,3)		4/29 (13,8)				n. a.
Männlich	2/24 (8,3)		2/39 (5,1)				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Region 2							
Nordamerika und Europa	5/31 (16,1)	n.b. [11,0; n.b.]	5/51 (9,8)	n.b. [n.b.; n.b.]	0,7 [0,1; 3,1]	0,6260	0,3431
Rest der Welt	2/12 (16,7)	n.b. [0,7; n.b.]	1/17 (5,9)	n.b. [n.b.; n.b.]	1,0 [0,1; 18,9]	1,0000	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Region 1							
Nordamerika	2/4 (50,0)		1/6 (16,7)	-	-	-	n. a.
Europa	3/27 (11,1)		4/45 (8,9)				
Rest der Welt	2/12 (16,7)		1/17 (5,9)				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; ECOG Performance-Status							
0	1/19 (5,3)	n.b. [n.b.; n.b.]	2/28 (7,1)	n.b. [n.b.; n.b.]	0,6 [0,1; 6,3]	0,6419	0,5754
1	6/24 (25,0)	n.b. [11,0; n.b.]	4/40 (10,0)	n.b. [3,5; n.b.]	1,5 [0,3; 7,4]	0,5979	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Lebermetastasen bei Studienbeginn							
Nein	5/35 (14,3)	n.b. [n.b.; n.b.]	6/58 (10,3)	n.b. [n.b.; n.b.]	0,5 [0,1; 2,1]	0,3189	n. b.
Ja	2/8 (25,0)		0/10				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Knochenmetastasen bei Studienbeginn							
Nein	4/28 (14,3)		3/42 (7,1)				n. a.
Ja	3/15 (20,0)		3/26 (11,5)				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; PD-L1-Proteinexpression							
<1%	2/13 (15,4)		1/22 (4,5)				n. a.
≥1% und <50%	1/10 (10,0)		3/24 (12,5)				
≥50%	3/17 (17,6)		1/16 (6,2)				
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Ethnie-2							
Asiatisch	2/11 (18,2)	n.b. [1,3; n.b.]	1/15 (6,7)	n.b. [n.b.; n.b.]	2,7 [0,2; 33,0]	0,4142	0,4704
Nicht asiatisch	5/32 (15,6)	n.b. [n.b.; n.b.]	5/53 (9,4)	n.b. [n.b.; n.b.]	0,8 [0,2; 3,3]	0,7663	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Vorgeschichte einer Beteiligung des ZNS							
Nein	5/28 (17,9)	n.b. [11,0; n.b.]	5/44 (11,4)	n.b. [5,1; n.b.]	0,8 [0,2; 3,1]	0,7277	0,7036
Ja	2/15 (13,3)	n.b. [n.b.; n.b.]	1/24 (4,2)	n.b. [n.b.; n.b.]	3,0 [0,2; 36,7]	0,3751	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Anzahl an vorherigen Therapielinien							
1	1/19 (5,3)		2/35 (5,7)				n. a.
2	3/15 (20,0)		4/27 (14,8)				
>2	3/9 (33,3)		0/6	-	-	-	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Alter bei Studienbeginn							
<65 Jahre	12/54 (22,2)	n.b. [n.b.; n.b.]	10/50 (20,0)	n.b. [7,4; n.b.]	1,2 [0,5; 2,9]	0,7194	0,9704
≥65 Jahre	14/52 (26,9)	n.b. [10,3; n.b.]	10/43 (23,3)	n.b. [4,9; n.b.]	1,2 [0,5; 3,0]	0,6857	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Geschlecht							
Weiblich	10/38 (26,3)	n.b. [n.b.; n.b.]	7/38 (18,4)	n.b. [7,4; n.b.]	1,4 [0,5; 3,9]	0,4715	0,4575
Männlich	16/68 (23,5)	n.b. [n.b.; n.b.]	13/55 (23,6)	n.b. [5,6; n.b.]	1,0 [0,5; 2,2]	0,9464	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Region 2							
Nordamerika und Europa	23/88 (26,1)	n.b. [n.b.; n.b.]	18/81 (22,2)	n.b. [7,4; n.b.]	1,1 [0,6; 2,1]	0,6871	0,8374
Rest der Welt	3/18 (16,7)	n.b. [4,1; n.b.]	2/12 (16,7)	n.b. [2,8; n.b.]	1,9 [0,2; 21,9]	0,6076	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Region 1							
Nordamerika	6/14 (42,9)	n.b. [0,7; n.b.]	2/12 (16,7)	n.b. [2,0; n.b.]	2,0 [0,3; 13,1]	0,4587	0,2815
Europa	17/74 (23,0)	n.b. [n.b.; n.b.]	16/69 (23,2)	n.b. [5,6; n.b.]	0,9 [0,4; 1,8]	0,7728	
Rest der Welt	3/18 (16,7)	n.b. [4,1; n.b.]	2/12 (16,7)	n.b. [2,8; n.b.]	1,9 [0,2; 21,9]	0,6076	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; ECOG Performance-Status							
0	9/39 (23,1)	n.b. [10,3; n.b.]	10/34 (29,4)	n.b. [4,9; n.b.]	0,7 [0,3; 1,7]	0,4082	0,2367
1	17/67 (25,4)	n.b. [n.b.; n.b.]	10/59 (16,9)	n.b. [n.b.; n.b.]	1,5 [0,7; 3,4]	0,2822	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Lebermetastasen bei Studienbeginn							
Nein	18/89 (20,2)	n.b. [n.b.; n.b.]	14/75 (18,7)	n.b. [7,4; n.b.]	1,1 [0,5; 2,3]	0,7648	0,8824
Ja	8/17 (47,1)	3,4 [1,5; n.b.]	6/18 (33,3)	n.b. [1,4; n.b.]	0,9 [0,2; 3,8]	0,8759	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Knochenmetastasen bei Studienbeginn							
Nein	13/63 (20,6)	n.b. [n.b.; n.b.]	10/56 (17,9)	n.b. [7,4; n.b.]	1,2 [0,5; 3,0]	0,6161	0,4707
Ja	13/43 (30,2)	n.b. [3,4; n.b.]	10/37 (27,0)	n.b. [3,5; n.b.]	0,8 [0,3; 2,1]	0,6834	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; PD-L1-Proteinexpression							
<1%	8/32 (25,0)	n.b. [4,6; n.b.]	6/32 (18,8)	n.b. [7,4; n.b.]	1,4 [0,5; 4,4]	0,5270	0,8379
≥1% und <50%	9/30 (30,0)	n.b. [3,4; n.b.]	8/31 (25,8)	n.b. [4,9; n.b.]	0,9 [0,3; 2,5]	0,8986	
≥50%	8/38 (21,1)	n.b. [10,3; n.b.]	4/22 (18,2)	n.b. [3,0; n.b.]	1,4 [0,4; 5,6]	0,5989	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Ethnie-2							
Asiatisch	2/14 (14,3)		1/9 (11,1)				n. a.
Nicht asiatisch	24/92 (26,1)		19/84 (22,6)				

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Vorgeschichte einer Beteiligung des ZNS							
Nein	14/71 (19,7)	n.b. [n.b.; n.b.]	14/65 (21,5)	n.b. [5,6; n.b.]	1,0 [0,5; 2,1]	0,9666	0,4081
Ja	12/35 (34,3)	n.b. [3,4; n.b.]	6/28 (21,4)	n.b. [7,4; n.b.]	1,6 [0,6; 4,3]	0,3886	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Anzahl an vorherigen Therapielinien							
1	11/42 (26,2)	n.b. [n.b.; n.b.]	9/39 (23,1)	n.b. [4,9; n.b.]	1,1 [0,5; 2,8]	0,7858	0,3593
2	8/41 (19,5)	n.b. [10,3; n.b.]	10/39 (25,6)	n.b. [5,6; n.b.]	0,8 [0,3; 2,0]	0,5935	
>2	7/23 (30,4)	n.b. [4,1; n.b.]	1/15 (6,7)	n.b. [n.b.; n.b.]	4,3 [0,5; 35,6]	0,1428	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Alter bei Studienbeginn							
<65 Jahre	31/82 (37,8)	9,1 [3,6; n.b.]	25/63 (39,7)	8,7 [2,8; n.b.]	0,9 [0,5; 1,6]	0,7100	0,5105
≥65 Jahre	29/72 (40,3)	11,8 [3,7; n.b.]	14/53 (26,4)	n.b. [4,6; n.b.]	1,2 [0,6; 2,4]	0,6105	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Geschlecht							
Weiblich	24/55 (43,6)	n.b. [2,1; n.b.]	20/46 (43,5)	4,9 [2,1; n.b.]	0,9 [0,5; 1,8]	0,8266	0,5686
Männlich	36/99 (36,4)	9,7 [5,6; n.b.]	19/70 (27,1)	8,7 [5,7; n.b.]	1,0 [0,6; 1,9]	0,9492	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Region 2							
Nordamerika und Europa	49/131 (37,4)	n.b. [5,6; n.b.]	38/99 (38,4)	8,7 [4,6; n.b.]	0,9 [0,6; 1,4]	0,7054	0,0855
Rest der Welt	11/23 (47,8)	4,1 [2,4; n.b.]	1/17 (5,9)	n.b. [2,8; n.b.]	2,9 [0,3; 24,9]	0,3212	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Region 1							
Nordamerika	7/17 (41,2)	5,6 [0,7; n.b.]	5/14 (35,7)	5,6 [2,1; n.b.]	2,3 [0,5; 10,6]	0,2620	0,1811
Europa	42/114 (36,8)	n.b. [5,6; n.b.]	33/85 (38,8)	8,7 [3,5; n.b.]	0,9 [0,5; 1,4]	0,5497	
Rest der Welt	11/23 (47,8)	4,1 [2,4; n.b.]	1/17 (5,9)	n.b. [2,8; n.b.]	2,9 [0,3; 24,9]	0,3212	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; ECOG Performance-Status							
0	18/54 (33,3)	n.b. [5,6; n.b.]	15/45 (33,3)	8,7 [5,6; n.b.]	1,0 [0,5; 2,0]	0,8972	0,9325
1	42/100 (42,0)	5,6 [2,9; n.b.]	24/71 (33,8)	n.b. [2,8; n.b.]	1,0 [0,6; 1,6]	0,8664	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Lebermetastasen bei Studienbeginn							
Nein	48/128 (37,5)	11,8 [4,1; n.b.]	30/95 (31,6)	n.b. [5,6; n.b.]	1,0 [0,6; 1,6]	0,9354	0,9828
Ja	12/26 (46,2)	9,1 [1,4; n.b.]	9/21 (42,9)	4,9 [1,4; n.b.]	1,0 [0,3; 2,7]	0,9406	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Knochenmetastasen bei Studienbeginn							
Nein	32/80 (40,0)	9,7 [4,1; n.b.]	20/67 (29,9)	n.b. [n.b.; n.b.]	1,2 [0,6; 2,2]	0,5761	0,5406
Ja	28/74 (37,8)	11,8 [3,5; n.b.]	19/49 (38,8)	5,7 [3,0; n.b.]	0,8 [0,5; 1,6]	0,5964	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Schmerzen; PD-L1-Proteinexpression							
<1%	17/51 (33,3)	n.b. [3,7; n.b.]	8/39 (20,5)	n.b. [n.b.; n.b.]	1,4 [0,6; 3,4]	0,3987	0,4348
≥1% und <50%	15/43 (34,9)	n.b. [2,8; n.b.]	16/44 (36,4)	5,6 [3,0; n.b.]	0,9 [0,4; 1,9]	0,8156	
≥50%	23/53 (43,4)	4,1 [2,8; n.b.]	11/25 (44,0)	3,3 [1,4; n.b.]	0,8 [0,4; 1,7]	0,5509	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Ethnie-2							
Asiatisch	8/19 (42,1)	4,1 [2,1; n.b.]	2/16 (12,5)	n.b. [2,8; n.b.]	1,8 [0,4; 9,2]	0,4656	0,2248
Nicht asiatisch	51/134 (38,1)	11,8 [5,6; n.b.]	36/99 (36,4)	8,7 [4,9; n.b.]	1,0 [0,6; 1,5]	0,8973	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	36/100 (36,0)	11,8 [3,7; n.b.]	26/80 (32,5)	8,7 [4,9; n.b.]	1,1 [0,6; 1,8]	0,7936	0,5884
Ja	24/54 (44,4)	5,6 [3,5; n.b.]	13/36 (36,1)	n.b. [2,8; n.b.]	0,9 [0,4; 1,7]	0,6834	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Anzahl an vorherigen Therapielinien							
1	26/68 (38,2)	9,2 [2,9; n.b.]	15/54 (27,8)	n.b. [4,6; n.b.]	1,3 [0,7; 2,5]	0,4201	0,5628
2	21/59 (35,6)	n.b. [4,1; n.b.]	17/43 (39,5)	n.b. [2,8; n.b.]	0,8 [0,4; 1,6]	0,5295	
>2	13/27 (48,1)	4,1 [2,8; n.b.]	7/19 (36,8)	8,7 [3,3; 8,7]	1,0 [0,4; 2,6]	0,9689	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	23/65 (35,4)	16,6 [3,6; n.b.]	14/51 (27,5)	n.b. [5,3; n.b.]	1,1 [0,6; 2,3]	0,7408	0,7915
≥65 Jahre	20/60 (33,3)	n.b. [4,8; n.b.]	10/45 (22,2)	6,2 [5,6; n.b.]	1,2 [0,5; 2,7]	0,6954	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Geschlecht							
Weiblich	18/46 (39,1)	16,6 [3,5; n.b.]	7/38 (18,4)	n.b. [5,6; n.b.]	1,7 [0,7; 4,2]	0,2740	0,1411
Männlich	25/79 (31,6)	n.b. [4,8; n.b.]	17/58 (29,3)	6,2 [3,5; n.b.]	0,8 [0,4; 1,6]	0,5612	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Region 2							
Nordamerika und Europa	37/105 (35,2)	n.b. [9,7; n.b.]	22/84 (26,2)	n.b. [5,6; n.b.]	1,1 [0,6; 1,9]	0,7230	0,6077
Rest der Welt	6/20 (30,0)	n.b. [3,5; n.b.]	2/12 (16,7)	n.b. [0,7; n.b.]	1,4 [0,2; 7,8]	0,7283	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Region 1							
Nordamerika	7/14 (50,0)	4,8 [1,4; n.b.]	2/12 (16,7)	n.b. [6,2; n.b.]	2,2 [0,4; 12,7]	0,3565	0,3858
Europa	30/91 (33,0)	n.b. [9,7; n.b.]	20/72 (27,8)	n.b. [5,0; n.b.]	0,9 [0,5; 1,7]	0,8382	
Rest der Welt	6/20 (30,0)	n.b. [3,5; n.b.]	2/12 (16,7)	n.b. [0,7; n.b.]	1,4 [0,2; 7,8]	0,7283	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; ECOG Performance-Status							
0	13/45 (28,9)	n.b. [9,7; n.b.]	12/39 (30,8)	n.b. [5,3; n.b.]	0,7 [0,3; 1,6]	0,3987	0,2644
1	30/80 (37,5)	n.b. [3,6; n.b.]	12/57 (21,1)	n.b. [6,2; n.b.]	1,5 [0,8; 3,1]	0,2308	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	37/110 (33,6)	n.b. [9,7; n.b.]	21/79 (26,6)	n.b. [5,6; n.b.]	1,0 [0,6; 1,8]	0,9527	0,4050
Ja	6/15 (40,0)	4,8 [1,4; n.b.]	3/17 (17,6)	n.b. [1,5; n.b.]	0,4 [0,1; 2,2]	0,2456	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	20/69 (29,0)	n.b. [9,7; n.b.]	14/53 (26,4)	n.b. [5,3; n.b.]	1,0 [0,5; 2,0]	0,9194	0,5195
Ja	23/56 (41,1)	10,4 [3,5; n.b.]	10/43 (23,3)	n.b. [3,5; n.b.]	1,3 [0,6; 2,8]	0,5404	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; PD-L1-Proteinexpression							
<1%	11/41 (26,8)	n.b. [4,8; n.b.]	7/32 (21,9)	n.b. [5,6; n.b.]	0,8 [0,3; 2,3]	0,7295	0,8284
≥1% und <50%	11/32 (34,4)	n.b. [2,8; n.b.]	6/34 (17,6)	n.b. [n.b.; n.b.]	1,7 [0,6; 5,1]	0,3549	
≥50%	19/45 (42,2)	10,4 [3,5; n.b.]	7/22 (31,8)	6,2 [3,5; n.b.]	1,0 [0,4; 2,6]	0,9454	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Ethnie-2							
Asiatisch	6/16 (37,5)	10,4 [2,4; n.b.]	1/11 (9,1)	n.b. [n.b.; n.b.]	3,8 [0,4; 33,8]	0,1981	0,3302
Nicht asiatisch	37/108 (34,3)	n.b. [7,1; n.b.]	23/84 (27,4)	n.b. [5,6; n.b.]	1,1 [0,6; 1,9]	0,7469	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	25/78 (32,1)	n.b. [4,8; n.b.]	19/66 (28,8)	n.b. [5,3; n.b.]	1,0 [0,5; 1,8]	0,9763	0,2399
Ja	18/47 (38,3)	16,6 [3,6; n.b.]	5/30 (16,7)	n.b. [3,5; n.b.]	1,8 [0,7; 5,0]	0,2429	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	16/54 (29,6)	n.b. [4,8; n.b.]	10/41 (24,4)	n.b. [5,6; n.b.]	1,1 [0,5; 2,4]	0,8691	0,4822
2	16/47 (34,0)	n.b. [4,7; n.b.]	12/41 (29,3)	n.b. [3,5; n.b.]	0,9 [0,4; 1,9]	0,7562	
>2	11/24 (45,8)	n.b. [2,1; n.b.]	2/14 (14,3)	n.b. [n.b.; n.b.]	2,6 [0,6; 12,1]	0,2021	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	19/62 (30,6)	n.b. [7,6; n.b.]	19/50 (38,0)	5,3 [2,6; 18,2]	0,6 [0,3; 1,2]	0,1698	0,3424
≥65 Jahre	17/63 (27,0)	n.b. [n.b.; n.b.]	8/45 (17,8)	n.b. [5,2; n.b.]	1,3 [0,5; 3,2]	0,6165	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Geschlecht							
Weiblich	16/46 (34,8)	n.b. [3,9; n.b.]	11/37 (29,7)	18,2 [5,3; n.b.]	0,9 [0,4; 2,1]	0,8061	0,3986
Männlich	20/79 (25,3)	n.b. [n.b.; n.b.]	16/58 (27,6)	n.b. [3,4; n.b.]	0,6 [0,3; 1,3]	0,1908	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Region 2							
Nordamerika und Europa	29/105 (27,6)	n.b. [n.b.; n.b.]	23/78 (29,5)	18,2 [5,2; n.b.]	0,7 [0,4; 1,3]	0,2814	0,7322
Rest der Welt	7/20 (35,0)	12,5 [3,0; n.b.]	4/17 (23,5)	n.b. [1,3; n.b.]	0,7 [0,2; 2,7]	0,5698	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Region 1							
Nordamerika	6/13 (46,2)	-	1/9 (11,1)				n. a.
Europa	23/92 (25,0)		22/69 (31,9)				
Rest der Welt	7/20 (35,0)		4/17 (23,5)				
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; ECOG Performance-Status							
0	10/44 (22,7)	n.b. [n.b.; n.b.]	12/38 (31,6)	n.b. [3,4; n.b.]	0,4 [0,2; 1,1]	0,0599	0,4217
1	26/81 (32,1)	n.b. [10,4; n.b.]	15/57 (26,3)	18,2 [5,2; 18,2]	1,0 [0,5; 1,9]	0,9393	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	32/106 (30,2)	n.b. [12,5; n.b.]	23/78 (29,5)	18,2 [5,2; n.b.]	0,8 [0,4; 1,4]	0,4315	0,4754
Ja	4/19 (21,1)	n.b. [n.b.; n.b.]	4/17 (23,5)	n.b. [1,4; n.b.]	0,4 [0,1; 2,4]	0,2944	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	20/68 (29,4)	n.b. [12,5; n.b.]	16/51 (31,4)	n.b. [2,8; n.b.]	0,7 [0,3; 1,4]	0,2929	0,8440
Ja	16/57 (28,1)	n.b. [8,6; n.b.]	11/44 (25,0)	18,2 [3,4; 18,2]	0,8 [0,3; 1,7]	0,5087	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	12/42 (28,6)	n.b. [7,6; n.b.]	9/30 (30,0)	18,2 [3,5; n.b.]	0,6 [0,2; 1,7]	0,3369	0,9658
≥1% und <50%	8/32 (25,0)	n.b. [n.b.; n.b.]	7/35 (20,0)	n.b. [3,4; n.b.]	0,8 [0,3; 2,4]	0,7498	
≥50%	14/44 (31,8)	12,5 [3,9; n.b.]	7/22 (31,8)	n.b. [2,1; n.b.]	0,8 [0,3; 2,1]	0,6177	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Ethnie-2							
Asiatisch	7/17 (41,2)	10,4 [3,0; n.b.]	1/16 (6,2)	n.b. [n.b.; n.b.]	3,2 [0,3; 29,8]	0,2835	0,1009
Nicht asiatisch	29/107 (27,1)	n.b. [n.b.; n.b.]	26/78 (33,3)	18,2 [3,5; n.b.]	0,7 [0,4; 1,2]	0,1592	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	22/77 (28,6)	n.b. [n.b.; n.b.]	19/63 (30,2)	18,2 [3,5; n.b.]	0,7 [0,4; 1,4]	0,3730	0,9832
Ja	14/48 (29,2)	n.b. [8,6; n.b.]	8/32 (25,0)	n.b. [2,8; n.b.]	0,8 [0,3; 1,9]	0,5650	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	13/55 (23,6)	n.b. [n.b.; n.b.]	12/43 (27,9)	18,2 [2,8; n.b.]	0,8 [0,3; 1,7]	0,5220	0,1554
2	13/47 (27,7)	n.b. [10,4; n.b.]	14/39 (35,9)	5,3 [2,8; n.b.]	0,5 [0,2; 1,1]	0,1009	
>2	10/23 (43,5)	8,6 [3,2; n.b.]	1/13 (7,7)	n.b. [n.b.; n.b.]	4,1 [0,5; 33,2]	0,1483	
PRO-CTCAE, Schmerzfrequenz; Alter bei Studienbeginn							
<65 Jahre	46/85 (54,1)	4,5 [2,8; 8,4]	33/69 (47,8)	3,9 [2,4; 15,2]	0,9 [0,6; 1,5]	0,7794	0,6339
≥65 Jahre	43/78 (55,1)	4,8 [2,1; 6,2]	28/59 (47,5)	4,6 [2,8; 6,1]	1,1 [0,6; 1,8]	0,7354	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schmerzfrequenz; Geschlecht							
Weiblich	34/60 (56,7)	2,8 [2,1; 8,4]	24/51 (47,1)	7,4 [2,4; 15,2]	1,1 [0,6; 1,9]	0,7000	0,3064
Männlich	55/103 (53,4)	4,9 [3,6; 9,1]	37/77 (48,1)	3,7 [2,7; 5,6]	0,8 [0,5; 1,2]	0,2936	
PRO-CTCAE, Schmerzfrequenz; Region 2							
Nordamerika und Europa	74/138 (53,6)	4,5 [2,8; 8,4]	52/109 (47,7)	4,6 [2,8; 7,4]	1,0 [0,7; 1,4]	0,9996	0,9016
Rest der Welt	15/25 (60,0)	4,2 [2,1; 7,3]	9/19 (47,4)	3,5 [1,4; 8,1]	0,8 [0,3; 2,0]	0,6080	
PRO-CTCAE, Schmerzfrequenz; Region 1							
Nordamerika	11/19 (57,9)	4,8 [2,1; 11,8]	11/16 (68,8)	2,8 [1,4; n.b.]	1,2 [0,5; 3,2]	0,7124	0,9778
Europa	63/119 (52,9)	4,5 [2,8; 9,1]	41/93 (44,1)	5,2 [2,8; 7,4]	0,9 [0,6; 1,4]	0,7977	
Rest der Welt	15/25 (60,0)	4,2 [2,1; 7,3]	9/19 (47,4)	3,5 [1,4; 8,1]	0,8 [0,3; 2,0]	0,6080	
PRO-CTCAE, Schmerzfrequenz; ECOG Performance-Status							
0	37/57 (64,9)	4,5 [2,1; 7,3]	28/52 (53,8)	4,6 [1,4; 8,1]	1,0 [0,6; 1,6]	0,8624	0,8554
1	52/106 (49,1)	4,3 [3,5; 8,4]	33/76 (43,4)	3,5 [2,8; n.b.]	0,9 [0,6; 1,5]	0,7837	
PRO-CTCAE, Schmerzfrequenz; Lebermetastasen bei Studienbeginn							
Nein	75/135 (55,6)	4,3 [3,4; 5,6]	51/107 (47,7)	4,6 [3,0; 7,4]	1,0 [0,7; 1,5]	0,8917	0,6248
Ja	14/28 (50,0)	4,8 [1,5; n.b.]	10/21 (47,6)	2,8 [1,4; n.b.]	0,6 [0,2; 1,8]	0,3303	
PRO-CTCAE, Schmerzfrequenz; Knochenmetastasen bei Studienbeginn							
Nein	52/86 (60,5)	3,6 [2,7; 5,3]	42/77 (54,5)	3,5 [2,1; 5,6]	0,9 [0,6; 1,4]	0,7357	0,5232
Ja	37/77 (48,1)	6,2 [4,2; 9,4]	19/51 (37,3)	8,1 [2,8; n.b.]	1,1 [0,6; 1,9]	0,8339	
PRO-CTCAE, Schmerzfrequenz; PD-L1-Proteinexpression							
<1%	26/54 (48,1)	7,3 [3,6; n.b.]	19/41 (46,3)	7,4 [2,7; 15,2]	0,9 [0,5; 1,6]	0,6801	0,9740
≥1% und <50%	23/44 (52,3)	2,8 [1,4; 11,8]	21/49 (42,9)	3,0 [1,9; n.b.]	0,9 [0,5; 1,8]	0,8270	
≥50%	33/58 (56,9)	4,2 [2,7; 5,4]	16/30 (53,3)	3,5 [1,4; n.b.]	1,0 [0,5; 2,1]	0,9402	
PRO-CTCAE, Schmerzfrequenz; Ethnie-2							
Asiatisch	11/21 (52,4)	4,2 [2,1; n.b.]	9/18 (50,0)	3,5 [1,5; 8,1]	0,8 [0,3; 2,2]	0,6997	0,7352
Nicht asiatisch	77/141 (54,6)	4,5 [2,8; 8,4]	51/109 (46,8)	4,6 [2,8; 7,4]	1,0 [0,7; 1,5]	0,8919	
PRO-CTCAE, Schmerzfrequenz; Vorgeschichte einer Beteiligung des ZNS							
Nein	52/108 (48,1)	5,3 [3,6; 9,7]	43/88 (48,9)	3,9 [2,8; 6,1]	0,8 [0,5; 1,2]	0,3610	0,1820
Ja	37/55 (67,3)	3,5 [2,7; 5,1]	18/40 (45,0)	7,4 [2,7; n.b.]	1,3 [0,7; 2,4]	0,3447	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schmerzfrequenz; Anzahl an vorherigen Therapielinien							
1	33/71 (46,5)	4,9 [2,8; 9,4]	32/58 (55,2)	2,8 [2,0; 5,2]	0,7 [0,4; 1,2]	0,1624	0,1326
2	39/63 (61,9)	4,3 [2,1; 5,6]	21/51 (41,2)	8,1 [2,8; n.b.]	1,4 [0,8; 2,4]	0,2571	
>2	17/29 (58,6)	4,2 [1,4; 7,3]	8/19 (42,1)	6,1 [1,4; n.b.]	1,2 [0,5; 2,9]	0,6938	
PRO-CTCAE, Frequenz von Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	48/85 (56,5)	3,5 [2,1; 7,7]	36/69 (52,2)	3,4 [1,4; 17,5]	1,0 [0,6; 1,6]	0,9310	0,7876
≥65 Jahre	45/78 (57,7)	4,2 [2,7; 7,8]	30/59 (50,8)	5,0 [2,8; 5,6]	0,8 [0,5; 1,4]	0,4296	
PRO-CTCAE, Frequenz von Muskelschmerzen; Geschlecht							
Weiblich	33/60 (55,0)	5,3 [2,8; 11,1]	30/51 (58,8)	3,1 [1,4; 5,6]	0,8 [0,4; 1,3]	0,3566	0,4476
Männlich	60/103 (58,3)	3,7 [2,2; 6,1]	36/77 (46,8)	5,0 [2,8; 5,7]	1,0 [0,7; 1,6]	0,8579	
PRO-CTCAE, Frequenz von Muskelschmerzen; Region 2							
Nordamerika und Europa	75/138 (54,3)	5,3 [2,8; 8,3]	56/109 (51,4)	4,6 [2,8; 5,6]	0,9 [0,7; 1,3]	0,7235	0,4358
Rest der Welt	18/25 (72,0)	2,4 [1,4; 4,1]	10/19 (52,6)	1,9 [0,7; n.b.]	1,3 [0,5; 3,3]	0,5801	
PRO-CTCAE, Frequenz von Muskelschmerzen; Region 1							
Nordamerika	10/19 (52,6)	2,8 [0,7; n.b.]	8/16 (50,0)	5,6 [1,4; n.b.]	1,4 [0,4; 4,1]	0,5878	0,6027
Europa	65/119 (54,6)	5,6 [2,8; 8,3]	48/93 (51,6)	4,3 [2,8; 5,2]	0,9 [0,6; 1,3]	0,4605	
Rest der Welt	18/25 (72,0)	2,4 [1,4; 4,1]	10/19 (52,6)	1,9 [0,7; n.b.]	1,3 [0,5; 3,3]	0,5801	
PRO-CTCAE, Frequenz von Muskelschmerzen; ECOG Performance-Status							
0	38/57 (66,7)	4,2 [2,8; 7,2]	28/52 (53,8)	5,0 [2,1; 17,5]	1,0 [0,6; 1,8]	0,8821	0,5715
1	55/106 (51,9)	3,7 [2,1; 7,7]	38/76 (50,0)	3,7 [1,9; 5,2]	0,9 [0,6; 1,4]	0,5591	
PRO-CTCAE, Frequenz von Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	85/135 (63,0)	3,5 [2,4; 5,6]	55/107 (51,4)	4,6 [2,8; 5,6]	1,1 [0,8; 1,6]	0,5256	0,0329
Ja	8/28 (28,6)	n.b. [2,2; n.b.]	11/21 (52,4)	2,1 [0,9; n.b.]	0,4 [0,1; 1,3]	0,1228	
PRO-CTCAE, Frequenz von Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	54/86 (62,8)	4,1 [2,8; 6,2]	38/77 (49,4)	5,0 [3,1; 17,5]	1,1 [0,7; 1,7]	0,6008	0,2386
Ja	39/77 (50,6)	2,8 [2,1; 10,4]	28/51 (54,9)	2,8 [1,4; 5,6]	0,7 [0,4; 1,2]	0,2347	
PRO-CTCAE, Frequenz von Muskelschmerzen; PD-L1-Proteinexpression							
<1%	30/54 (55,6)	5,9 [2,7; 11,1]	23/41 (56,1)	3,5 [1,4; 5,6]	0,6 [0,4; 1,2]	0,1563	0,2458
≥1% und <50%	27/44 (61,4)	3,5 [0,7; 6,2]	23/49 (46,9)	4,6 [2,8; 5,7]	1,4 [0,7; 2,5]	0,3344	
≥50%	29/58 (50,0)	4,1 [2,1; 16,6]	15/30 (50,0)	3,1 [1,4; n.b.]	0,9 [0,5; 1,8]	0,7850	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Frequenz von Muskelschmerzen; Ethnie-2							
Asiatisch	14/21 (66,7)	2,7 [1,4; 6,1]	11/18 (61,1)	1,4 [0,7; n.b.]	0,8 [0,3; 1,8]	0,5718	0,4983
Nicht asiatisch	78/141 (55,3)	4,2 [2,8; 7,8]	54/109 (49,5)	4,9 [2,8; 5,6]	1,0 [0,7; 1,4]	0,9677	
PRO-CTCAE, Frequenz von Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	55/108 (50,9)	5,9 [2,8; 9,1]	46/88 (52,3)	4,3 [2,8; 5,2]	0,8 [0,6; 1,2]	0,3446	0,3072
Ja	38/55 (69,1)	2,8 [1,4; 4,1]	20/40 (50,0)	2,8 [1,4; n.b.]	1,2 [0,7; 2,1]	0,5818	
PRO-CTCAE, Frequenz von Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	36/71 (50,7)	4,1 [2,1; 9,1]	31/58 (53,4)	3,1 [1,9; 5,6]	0,8 [0,5; 1,4]	0,4559	0,5870
2	39/63 (61,9)	5,3 [2,7; 8,3]	27/51 (52,9)	4,6 [2,8; 17,5]	1,0 [0,6; 1,7]	0,9071	
>2	18/29 (62,1)	2,8 [2,1; 5,9]	8/19 (42,1)	n.b. [0,7; n.b.]	1,2 [0,5; 2,9]	0,6127	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	46/85 (54,1)	2,8 [2,1; 8,3]	25/69 (36,2)	11,5 [4,9; n.b.]	1,7 [1,0; 2,9]	0,0363	0,0133
≥65 Jahre	38/78 (48,7)	7,1 [3,4; 9,7]	30/59 (50,8)	4,6 [2,1; 13,4]	0,7 [0,4; 1,2]	0,1832	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Geschlecht							
Weiblich	33/60 (55,0)	2,8 [1,4; 7,8]	23/51 (45,1)	7,6 [2,8; 17,5]	1,4 [0,8; 2,6]	0,2154	0,2739
Männlich	51/103 (49,5)	7,0 [2,8; 9,7]	32/77 (41,6)	5,2 [2,1; n.b.]	1,0 [0,6; 1,6]	0,8743	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Region 2							
Nordamerika und Europa	73/138 (52,9)	5,1 [2,8; 8,3]	42/109 (38,5)	7,6 [4,9; 17,5]	1,4 [0,9; 2,0]	0,1205	0,0371
Rest der Welt	11/25 (44,0)	5,4 [1,4; n.b.]	13/19 (68,4)	1,5 [0,8; 3,5]	0,4 [0,2; 1,1]	0,0721	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Region 1							
Nordamerika	8/19 (42,1)	n.b. [0,8; n.b.]	7/16 (43,8)	7,6 [2,1; n.b.]	0,9 [0,3; 3,3]	0,9100	0,0954
Europa	65/119 (54,6)	5,1 [2,8; 8,3]	35/93 (37,6)	6,1 [4,6; 17,5]	1,4 [0,9; 2,2]	0,0987	
Rest der Welt	11/25 (44,0)	5,4 [1,4; n.b.]	13/19 (68,4)	1,5 [0,8; 3,5]	0,4 [0,2; 1,1]	0,0721	
PRO-CTCAE, Frequenz von Gelenkschmerzen; ECOG Performance-Status							
0	36/57 (63,2)	2,8 [2,1; 8,3]	24/52 (46,2)	6,1 [2,1; n.b.]	1,3 [0,7; 2,2]	0,4311	0,4730
1	48/106 (45,3)	7,0 [3,3; 14,5]	31/76 (40,8)	11,5 [2,8; 17,5]	1,0 [0,6; 1,6]	0,9612	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	73/135 (54,1)	4,5 [2,8; 7,8]	44/107 (41,1)	7,6 [4,3; 17,5]	1,3 [0,9; 1,9]	0,2067	0,0797
Ja	11/28 (39,3)	7,7 [2,2; n.b.]	11/21 (52,4)	2,1 [1,6; 11,5]	0,2 [0,1; 1,0]	0,0318	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Frequenz von Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	48/86 (55,8)	4,2 [2,2; 9,0]	34/77 (44,2)	4,9 [3,5; n.b.]	1,2 [0,7; 1,9]	0,4568	0,6998
Ja	36/77 (46,8)	7,0 [2,8; 9,7]	21/51 (41,2)	11,5 [2,1; 17,5]	1,1 [0,6; 1,9]	0,8100	
PRO-CTCAE, Frequenz von Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	30/54 (55,6)	4,5 [2,1; 9,7]	16/41 (39,0)	13,4 [4,9; 17,5]	1,5 [0,8; 2,9]	0,1942	0,1168
≥1% und <50%	19/44 (43,2)	8,3 [2,1; n.b.]	16/49 (32,7)	7,6 [4,3; n.b.]	1,3 [0,6; 2,6]	0,5181	
≥50%	29/58 (50,0)	4,2 [2,1; 9,0]	18/30 (60,0)	2,8 [1,4; 6,1]	0,6 [0,3; 1,2]	0,1414	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Ethnie-2							
Asiatisch	9/21 (42,9)	5,4 [1,4; n.b.]	13/18 (72,2)	1,5 [0,8; 3,5]	0,4 [0,2; 1,0]	0,0523	0,0190
Nicht asiatisch	74/141 (52,5)	5,1 [2,8; 9,0]	41/109 (37,6)	11,5 [4,9; 17,5]	1,3 [0,9; 2,0]	0,1441	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	47/108 (43,5)	7,8 [4,5; 9,7]	37/88 (42,0)	6,1 [4,3; 17,5]	1,0 [0,6; 1,5]	0,8494	0,3920
Ja	37/55 (67,3)	2,8 [1,4; 4,2]	18/40 (45,0)	11,5 [1,4; n.b.]	1,3 [0,7; 2,4]	0,3376	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	32/71 (45,1)	7,7 [2,8; 11,8]	28/58 (48,3)	4,9 [2,1; 17,5]	0,9 [0,5; 1,5]	0,5977	0,3544
2	34/63 (54,0)	3,6 [2,1; 9,0]	21/51 (41,2)	7,6 [2,8; n.b.]	1,2 [0,7; 2,1]	0,4754	
>2	18/29 (62,1)	2,8 [0,8; 9,7]	6/19 (31,6)	11,5 [2,1; 11,5]	1,8 [0,7; 4,7]	0,2138	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; PRO-CTCAE = Patient-Reported Outcome Version der Common Technology Criteria for Adverse Events; ZNS = Zentrales Nervensystem

4.12.3 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt PRO-CTCAE (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	N	Patienten mit Ereignis n (%)	Median (Monate) [95% KI]	Hazard Ratio [95% KI]	p(Cox)[1]	p(logrank)[2]
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals								
165	60 (36,4)	13,8 [9,2; n.b.]	139	77 (55,4)	2,7 [1,5; 5,8]	0,38 [0,26; 0,55]	<,0001	<,0001
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln								
165	58 (35,2)	13,8 [7,6; n.b.]	139	64 (46,0)	5,0 [2,8; n.b.]	0,44 [0,30; 0,64]	<,0001	<,0001
PRO-CTCAE, Schweregrad von juckender Haut								
165	98 (59,4)	3,5 [2,4; 6,3]	139	74 (53,2)	2,8 [2,1; 5,1]	0,98 [0,72; 1,34]	0,8991	0,8992
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen								
165	92 (55,8)	5,3 [3,0; 6,9]	139	85 (61,2)	2,5 [2,0; 3,5]	0,67 [0,49; 0,91]	0,0114	0,0109
PRO-CTCAE, Schweregrad von Schmerzen								
159	78 (49,1)	6,3 [4,2; 12,2]	125	66 (52,8)	3,0 [2,1; 4,9]	0,64 [0,46; 0,91]	0,0133	0,0127
PRO-CTCAE, Schweregrad von Muskelschmerzen								
130	55 (42,3)	12,5 [6,3; n.b.]	107	38 (35,5)	8,5 [4,8; n.b.]	0,92 [0,60; 1,41]	0,7021	0,7020
PRO-CTCAE, Schweregrad von Gelenkschmerzen								
129	53 (41,1)	11,7 [6,9; n.b.]	103	35 (34,0)	16,6 [5,0; n.b.]	0,91 [0,58; 1,44]	0,6925	0,6924
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals								
43	10 (23,3)	n.b. [11,0; n.b.]	68	10 (14,7)	n.b. [n.b.; n.b.]	0,84 [0,31; 2,32]	0,7401	0,7399
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen								
106	33 (31,1)	n.b. [10,2; n.b.]	99	33 (33,3)	n.b. [5,1; n.b.]	0,87 [0,53; 1,43]	0,5786	0,5785
PRO-CTCAE, Beeinträchtigung durch Schmerzen								
156	84 (53,8)	4,1 [3,3; 9,2]	125	55 (44,0)	5,6 [2,8; n.b.]	0,97 [0,68; 1,38]	0,8765	0,8768
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen								
125	55 (44,0)	11,4 [4,0; n.b.]	104	37 (35,6)	n.b. [5,0; n.b.]	0,96 [0,62; 1,48]	0,8413	0,8418
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen								
127	51 (40,2)	12,5 [6,9; n.b.]	100	38 (38,0)	18,2 [2,8; n.b.]	0,71 [0,46; 1,12]	0,1422	0,1405
PRO-CTCAE, Schmerzfrequenz								
165	106 (64,2)	3,6 [2,8; 4,9]	139	78 (56,1)	3,0 [2,2; 4,7]	0,93 [0,69; 1,26]	0,6362	0,6361
PRO-CTCAE, Frequenz von Muskelschmerzen								
165	112 (67,9)	2,8 [2,2; 3,7]	139	83 (59,7)	2,8 [1,9; 4,8]	0,94 [0,70; 1,26]	0,6814	0,6826

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**N**	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**Hazard Ratio [95% KI]**	**p(Cox)[1]**	**p(logrank)[2]**
PRO-CTCAE, Frequenz von Gelenkschmerzen								
165	101 (61,2)	3,3 [2,7; 5,4]	139	71 (51,1)	4,6 [2,1; 11,2]	1,03 [0,76; 1,41]	0,8444	0,8441
1) p-Wert des Cox-Modells 2) p-Wert des Logrank-Tests Die Auswertung erfolgte auf Grundlage der ITT-Population.								
KI = Konfidenzintervall; n.b. = nicht berechenbar; PRO-CTCAE = Patient-Reported Outcome Version der Common Technology Criteria for Adverse Events								

4.12.4 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt PRO-CTCAE (präspezifizierte Analyse inkl. Tod als Ereignis)

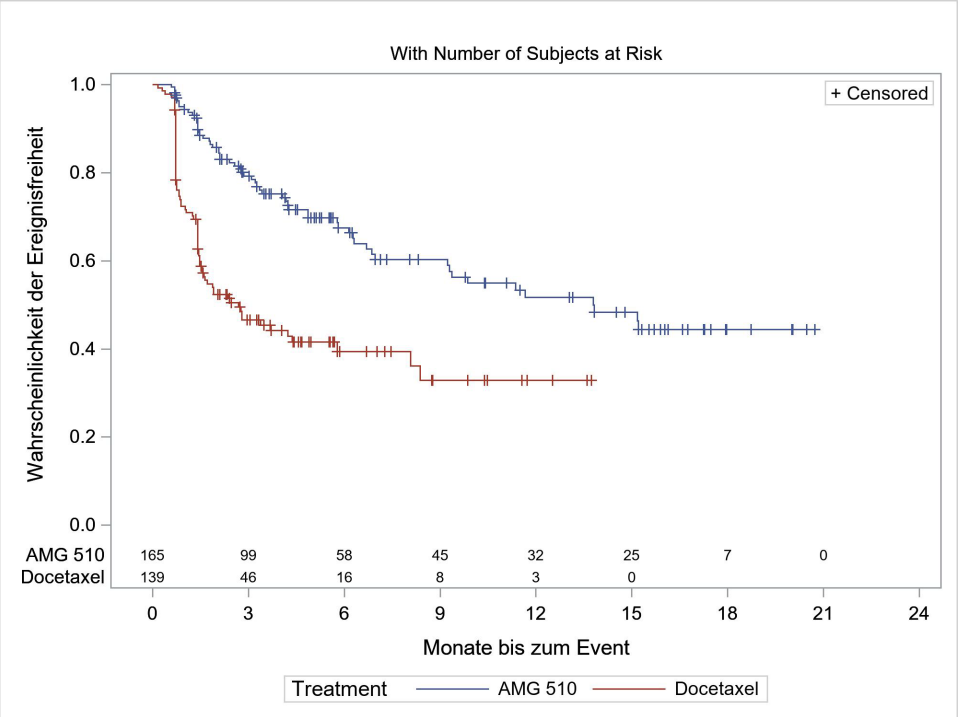

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von Wunden oder offenen Stellen in Mund oder Hals, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

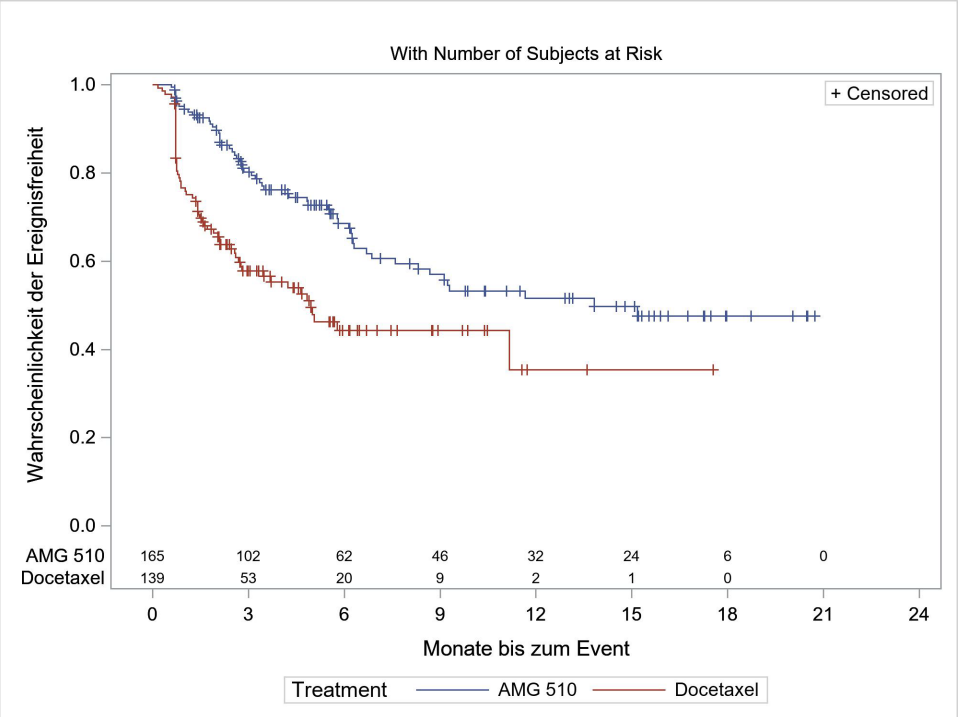

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von rissigen Mundwinkeln, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

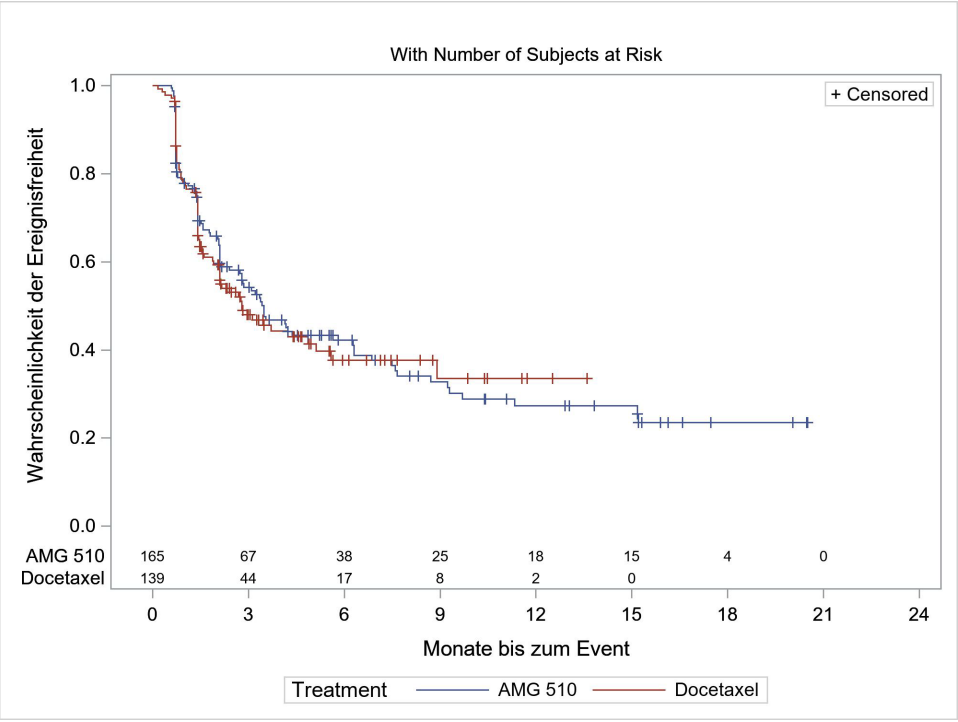

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von juckender Haut, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

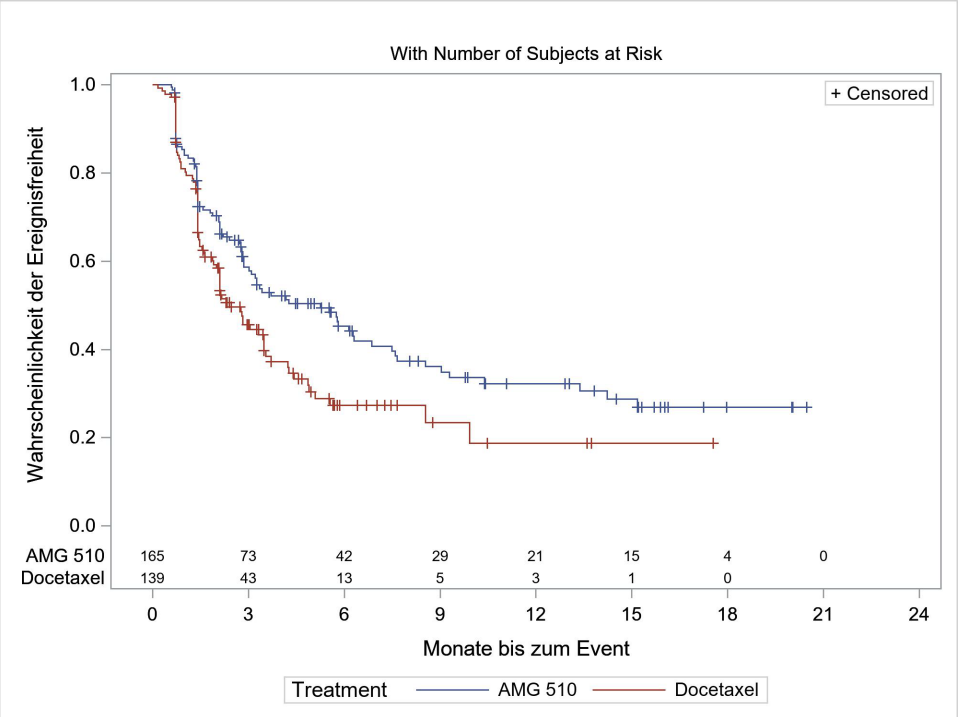

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von Taubheitsgefühl in Händen oder Füßen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

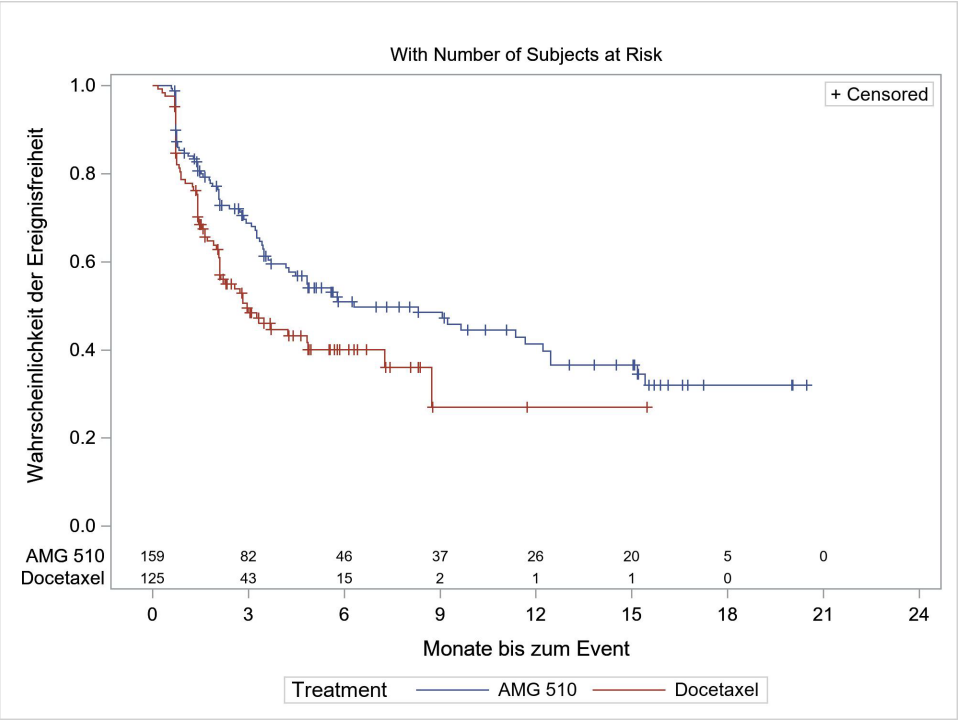

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von Schmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

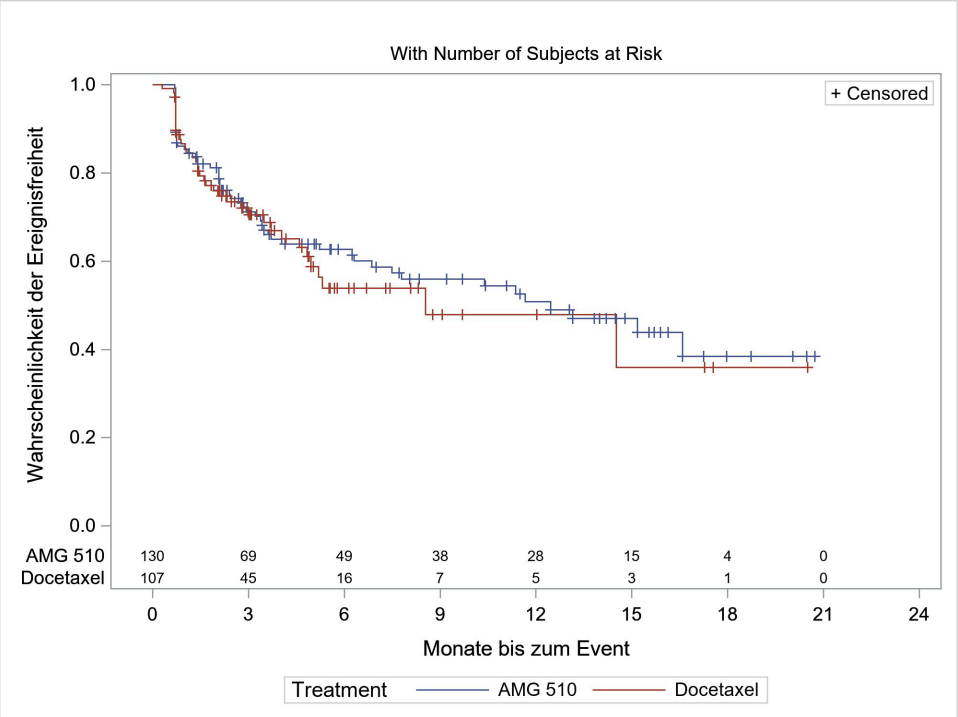

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von Muskelschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

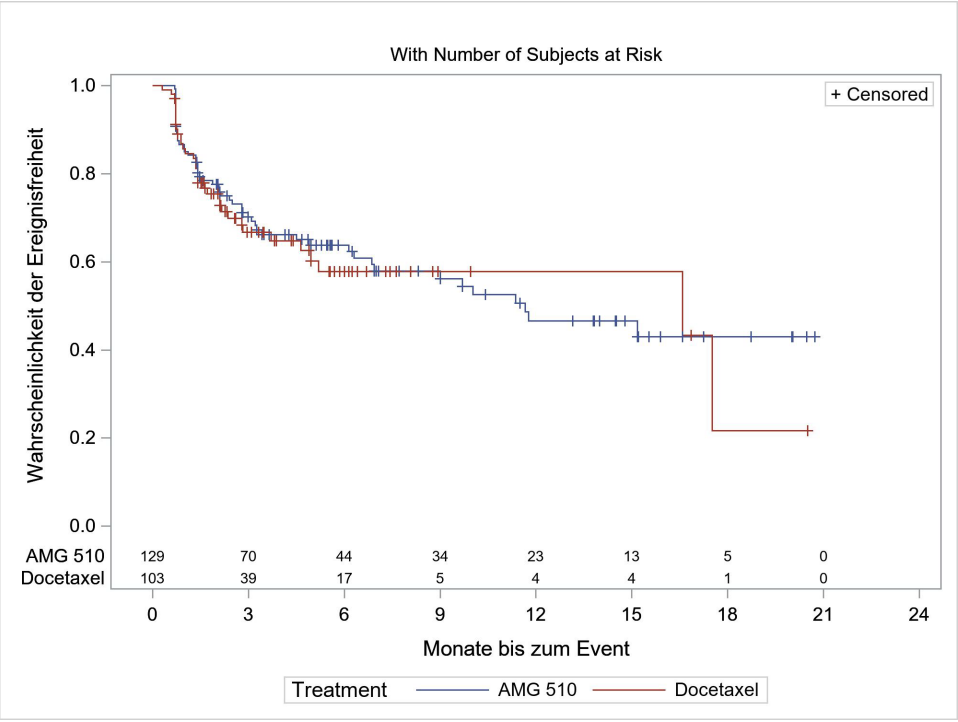

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schweregrad von Gelenkschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

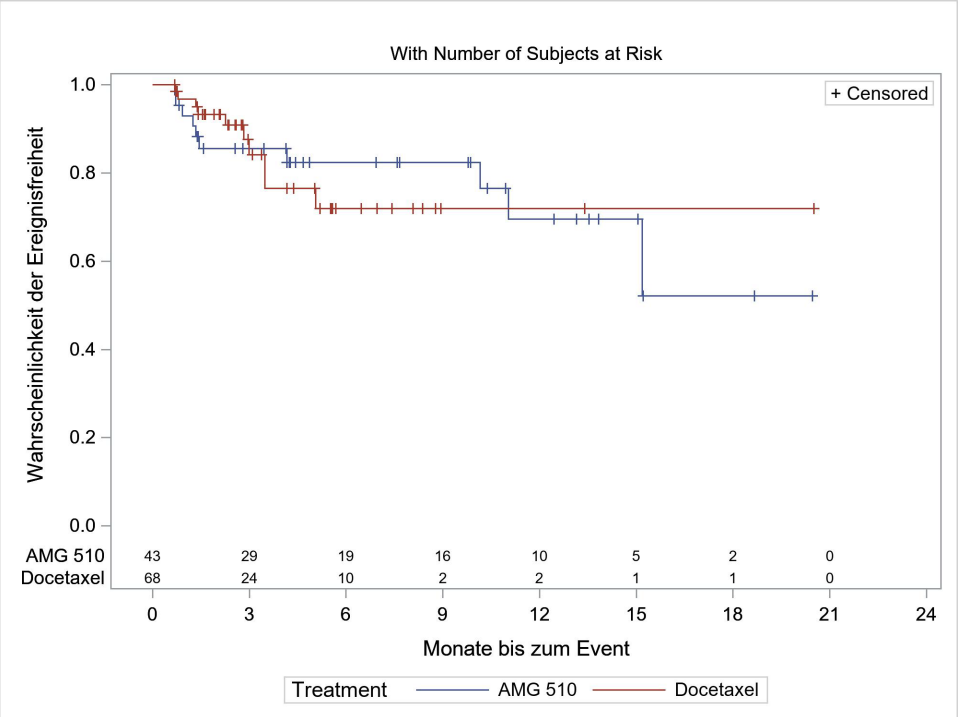

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

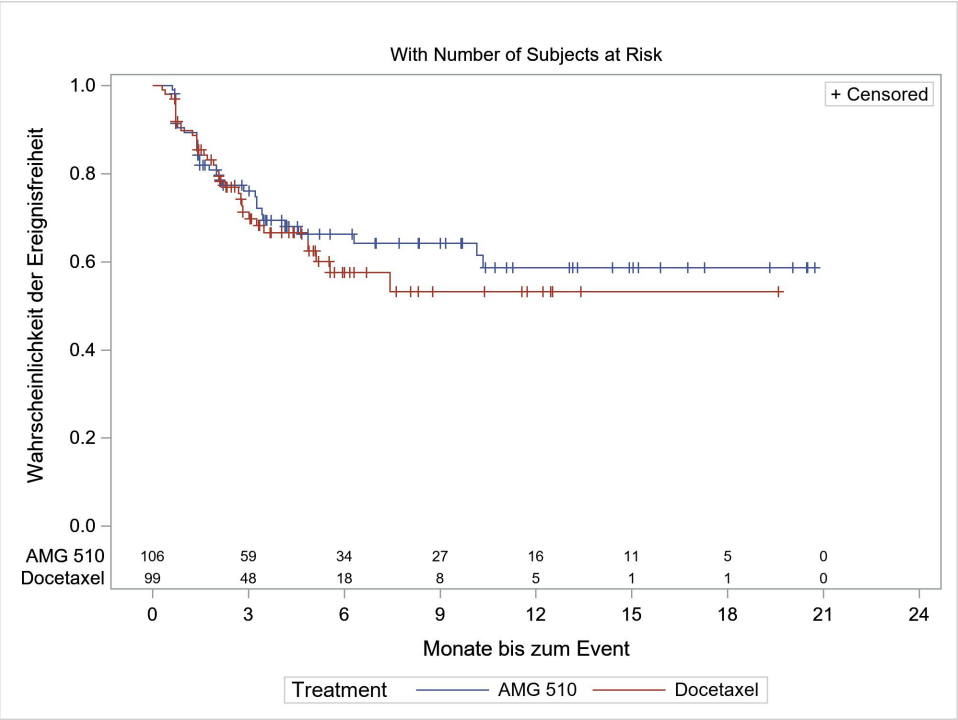

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

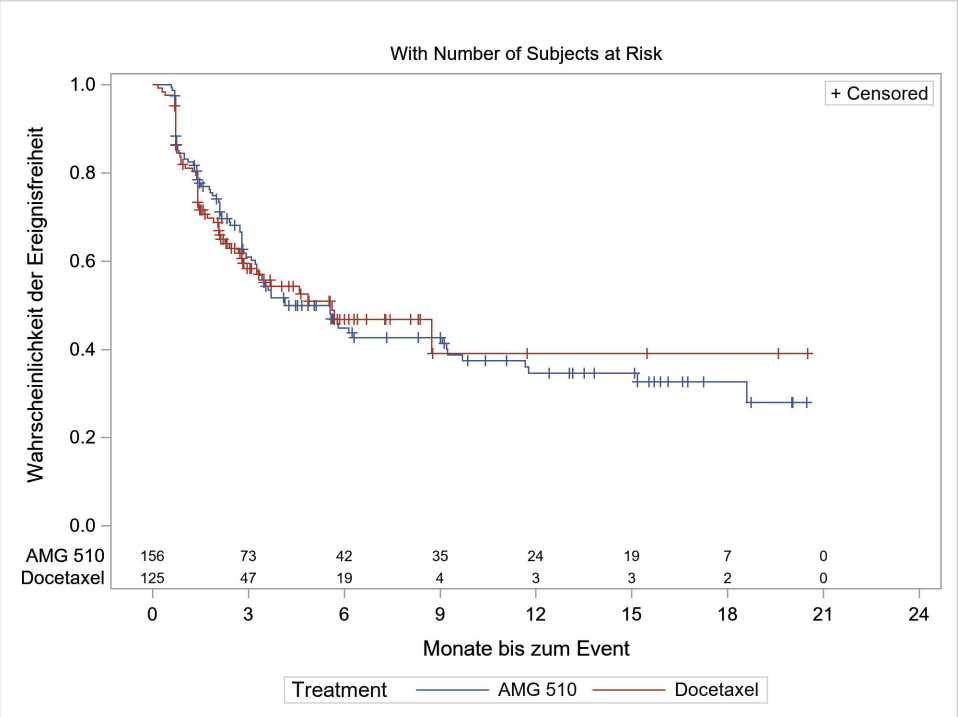

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Beeinträchtigung durch Schmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

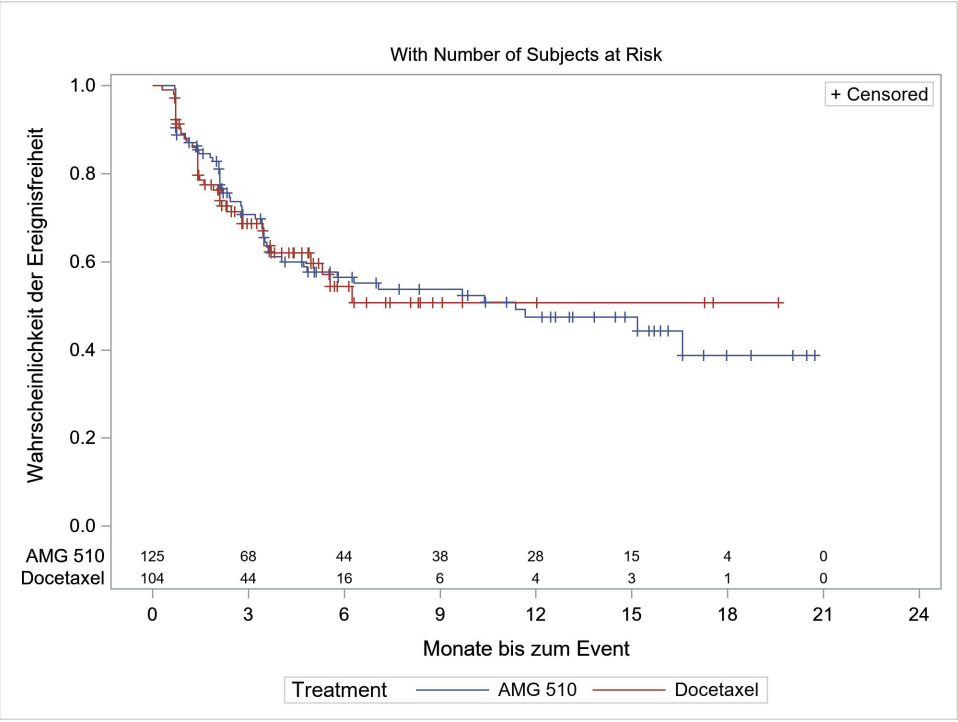

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Beeinträchtigung durch Muskelschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

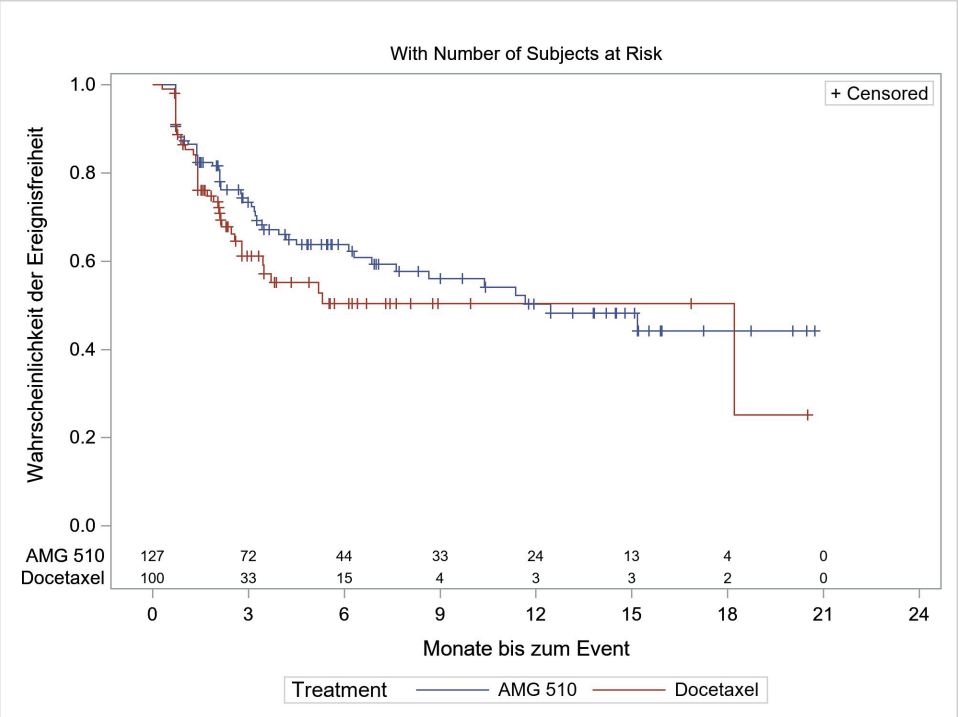

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Beeinträchtigung durch Gelenkschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

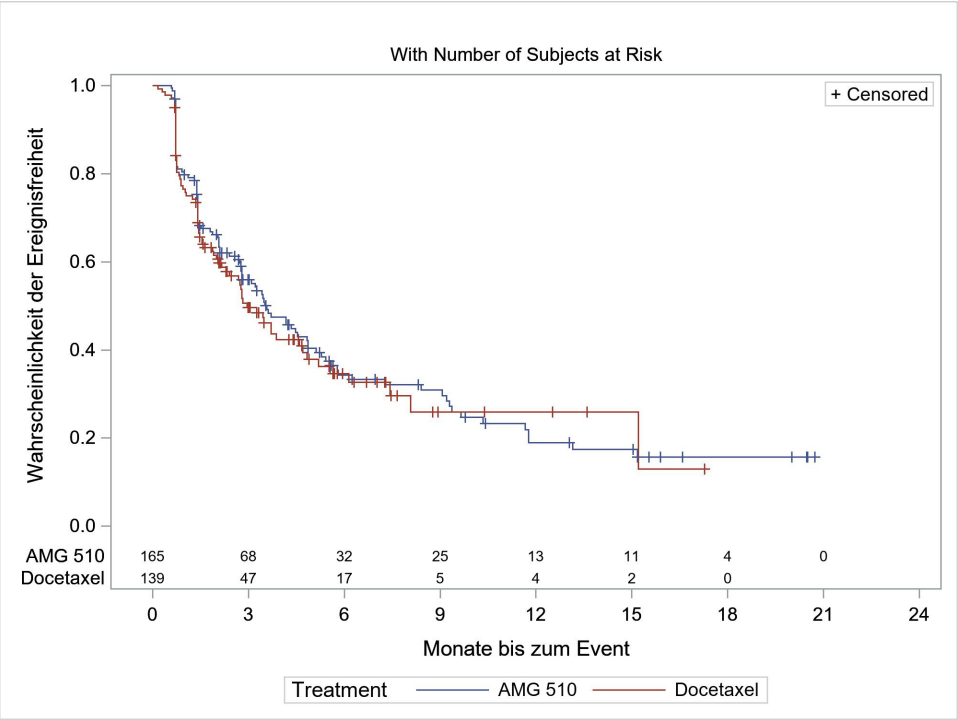

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Schmerzfrequenz, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

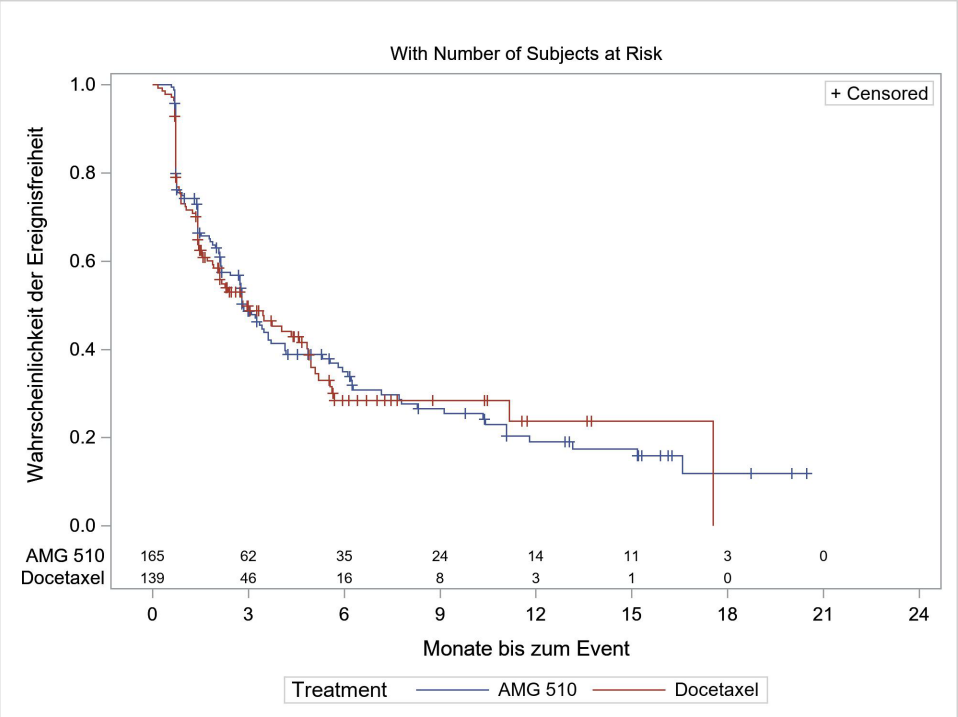

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Frequenz von Muskelschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

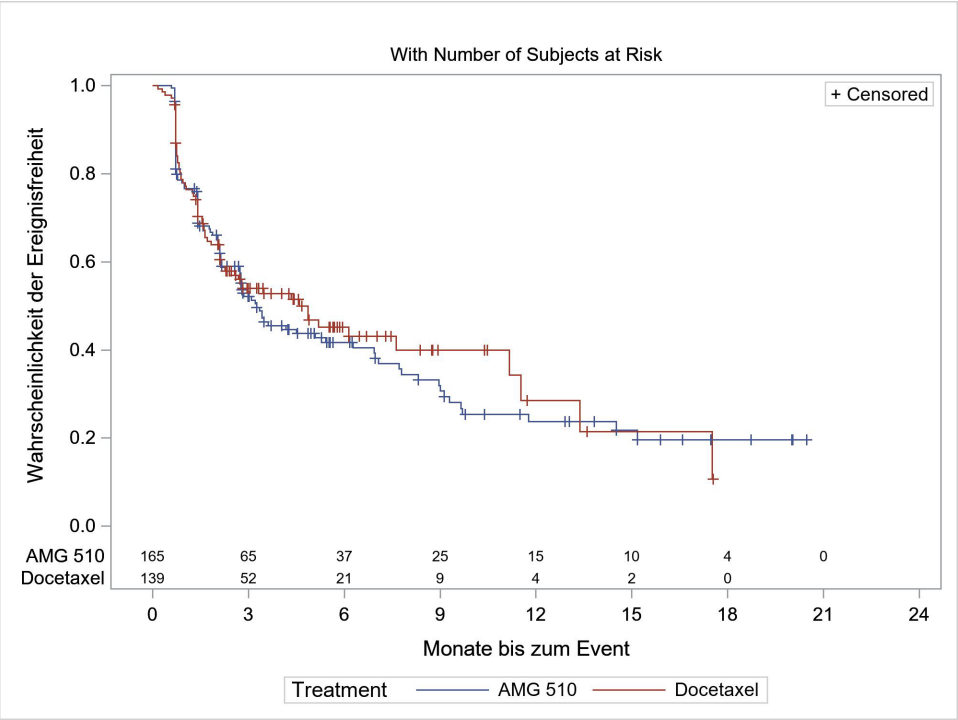

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "PRO-CTCAE Frequenz von Gelenkschmerzen, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

4.12.5 Subgruppenanalysen für den Endpunkt PRO-CTCAE (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Alter bei Studienbeginn							
<65 Jahre	37/87 (42,5)	9,4 [4,9; n.b.]	42/80 (52,5)	2,8 [1,4; 8,4]	0,4 [0,3; 0,7]	0,0009	0,0388
≥65 Jahre	23/78 (29,5)	15,2 [9,3; n.b.]	35/59 (59,3)	1,7 [1,4; 4,4]	0,2 [0,1; 0,4]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Geschlecht							
Weiblich	23/60 (38,3)	13,8 [6,7; n.b.]	35/58 (60,3)	1,9 [1,4; 5,8]	0,3 [0,2; 0,6]	0,0003	0,8651
Männlich	37/105 (35,2)	15,2 [6,3; n.b.]	42/81 (51,9)	2,8 [1,5; n.b.]	0,3 [0,2; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Region 2							
Nordamerika und Europa	46/140 (32,9)	15,2 [11,4; n.b.]	58/118 (49,2)	4,2 [1,9; n.b.]	0,4 [0,3; 0,6]	<,0001	0,8680
Rest der Welt	14/25 (56,0)	4,1 [1,8; 9,3]	19/21 (90,5)	1,1 [0,8; 1,5]	0,3 [0,1; 0,8]	0,0153	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Region 1							
Nordamerika	4/19 (21,1)	n.b. [6,1; n.b.]	5/16 (31,3)	n.b. [1,6; n.b.]	1,0 [0,2; 4,9]	0,9694	0,7786
Europa	42/121 (34,7)	15,2 [9,4; n.b.]	53/102 (52,0)	2,8 [1,6; 8,4]	0,4 [0,2; 0,5]	<,0001	
Rest der Welt	14/25 (56,0)	4,1 [1,8; 9,3]	19/21 (90,5)	1,1 [0,8; 1,5]	0,3 [0,1; 0,8]	0,0153	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; ECOG Performance-Status							
0	22/58 (37,9)	13,8 [6,3; n.b.]	23/52 (44,2)	8,4 [2,4; n.b.]	0,6 [0,3; 1,1]	0,0974	0,0198
1	38/107 (35,5)	13,8 [6,9; n.b.]	54/87 (62,1)	1,6 [1,4; 2,8]	0,3 [0,2; 0,4]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Lebermetastasen bei Studienbeginn							
Nein	45/135 (33,3)	15,2 [9,9; n.b.]	61/115 (53,0)	2,8 [1,5; 8,4]	0,4 [0,2; 0,5]	<,0001	0,9606
Ja	15/30 (50,0)	6,1 [2,9; n.b.]	16/24 (66,7)	1,6 [1,0; 8,1]	0,3 [0,1; 0,8]	0,0108	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Knochenmetastasen bei Studienbeginn							
Nein	35/86 (40,7)	11,7 [6,3; n.b.]	46/84 (54,8)	1,9 [1,4; n.b.]	0,4 [0,3; 0,7]	0,0006	0,6100
Ja	25/79 (31,6)	n.b. [6,7; n.b.]	31/55 (56,4)	3,7 [1,6; 8,1]	0,4 [0,2; 0,6]	0,0004	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; PD-L1-Proteinexpression							
<1%	23/54 (42,6)	13,8 [5,8; n.b.]	23/44 (52,3)	3,7 [1,4; n.b.]	0,5 [0,2; 0,9]	0,0190	0,7151
≥1% und <50%	16/45 (35,6)	9,3 [6,3; n.b.]	32/55 (58,2)	2,4 [1,4; 4,4]	0,3 [0,1; 0,6]	0,0002	
≥50%	17/59 (28,8)	n.b. [6,7; n.b.]	16/31 (51,6)	2,8 [1,4; n.b.]	0,4 [0,2; 0,9]	0,0170	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Ethnie-2							
Asiatisch	11/21 (52,4)	6,9 [1,8; 9,3]	15/18 (83,3)	1,1 [0,7; 1,5]	0,4 [0,2; 1,0]	0,0333	0,8334
Nicht asiatisch	49/143 (34,3)	15,2 [9,4; n.b.]	61/120 (50,8)	3,4 [1,7; n.b.]	0,4 [0,3; 0,6]	<,0001	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Vorgeschichte einer Beteiligung des ZNS							
Nein	37/109 (33,9)	13,8 [6,3; n.b.]	49/92 (53,3)	2,8 [1,5; 8,4]	0,4 [0,2; 0,6]	<,0001	0,7735
Ja	23/56 (41,1)	11,4 [6,7; n.b.]	28/47 (59,6)	1,4 [0,8; 8,1]	0,4 [0,2; 0,7]	0,0013	
PRO-CTCAE, Schweregrad von Wunden oder offenen Stellen in Mund oder Hals; Anzahl an vorherigen Therapielinien							
1	27/72 (37,5)	9,4 [4,3; n.b.]	40/62 (64,5)	1,5 [1,4; 2,8]	0,3 [0,2; 0,6]	<,0001	0,3155
2	22/64 (34,4)	n.b. [9,9; n.b.]	29/56 (51,8)	4,2 [1,3; n.b.]	0,4 [0,2; 0,7]	0,0027	
>2	11/29 (37,9)	7,0 [6,3; 15,2]	8/21 (38,1)	n.b. [1,6; n.b.]	0,5 [0,2; 1,4]	0,1582	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Alter bei Studienbeginn							
<65 Jahre	32/87 (36,8)	13,8 [5,8; n.b.]	38/80 (47,5)	4,6 [2,1; n.b.]	0,5 [0,3; 0,9]	0,0143	0,1346
≥65 Jahre	26/78 (33,3)	15,2 [6,7; n.b.]	26/59 (44,1)	5,0 [2,5; n.b.]	0,2 [0,1; 0,5]	<,0001	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Geschlecht							
Weiblich	21/60 (35,0)	13,8 [6,7; n.b.]	27/58 (46,6)	4,6 [1,9; n.b.]	0,4 [0,2; 0,7]	0,0020	0,7676
Männlich	37/105 (35,2)	15,2 [6,3; n.b.]	37/81 (45,7)	5,0 [2,8; n.b.]	0,4 [0,2; 0,6]	0,0002	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Region 2							
Nordamerika und Europa	45/140 (32,1)	n.b. [8,7; n.b.]	51/118 (43,2)	5,1 [3,7; n.b.]	0,5 [0,3; 0,7]	0,0002	0,7457
Rest der Welt	13/25 (52,0)	6,7 [2,9; n.b.]	13/21 (61,9)	1,5 [0,8; n.b.]	0,4 [0,1; 1,0]	0,0389	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Region 1							
Nordamerika	4/19 (21,1)	n.b. [6,1; n.b.]	3/16 (18,8)	n.b. [5,1; n.b.]	0,5 [0,0; 6,3]	0,6054	0,6623
Europa	41/121 (33,9)	15,2 [7,6; n.b.]	48/102 (47,1)	4,8 [2,8; n.b.]	0,4 [0,3; 0,7]	0,0002	
Rest der Welt	13/25 (52,0)	6,7 [2,9; n.b.]	13/21 (61,9)	1,5 [0,8; n.b.]	0,4 [0,1; 1,0]	0,0389	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; ECOG Performance-Status							
0	18/58 (31,0)	n.b. [8,7; n.b.]	21/52 (40,4)	11,2 [4,6; n.b.]	0,5 [0,2; 0,9]	0,0206	0,4585
1	40/107 (37,4)	9,2 [6,2; n.b.]	43/87 (49,4)	2,8 [1,7; n.b.]	0,3 [0,2; 0,6]	<,0001	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Lebermetastasen bei Studienbeginn							
Nein	45/135 (33,3)	15,2 [8,3; n.b.]	51/115 (44,3)	5,1 [3,7; n.b.]	0,4 [0,3; 0,7]	0,0001	0,7476
Ja	13/30 (43,3)	6,1 [2,9; n.b.]	13/24 (54,2)	1,9 [1,0; n.b.]	0,3 [0,1; 1,0]	0,0341	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Knochenmetastasen bei Studienbeginn							
Nein	29/86 (33,7)	n.b. [9,1; n.b.]	38/84 (45,2)	5,8 [2,6; n.b.]	0,4 [0,2; 0,7]	0,0009	0,5420
Ja	29/79 (36,7)	7,6 [5,8; n.b.]	26/55 (47,3)	3,7 [2,0; n.b.]	0,4 [0,2; 0,8]	0,0044	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; PD-L1-Proteinexpression							
<1%	21/54 (38,9)	15,2 [6,1; n.b.]	21/44 (47,7)	5,0 [1,0; n.b.]	0,4 [0,2; 0,8]	0,0054	0,5711
≥1% und <50%	20/45 (44,4)	8,3 [6,2; n.b.]	25/55 (45,5)	2,8 [2,0; n.b.]	0,5 [0,3; 1,0]	0,0322	
≥50%	14/59 (23,7)	n.b. [6,9; n.b.]	13/31 (41,9)	5,8 [4,2; n.b.]	0,4 [0,1; 0,8]	0,0157	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Ethnie-2							
Asiatisch	10/21 (47,6)	6,9 [2,6; n.b.]	10/18 (55,6)	1,5 [0,7; n.b.]	0,4 [0,1; 1,1]	0,0549	0,9080
Nicht asiatisch	48/143 (33,6)	15,2 [8,3; n.b.]	53/120 (44,2)	5,0 [3,5; n.b.]	0,5 [0,3; 0,7]	0,0003	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Vorgeschichte einer Beteiligung des ZNS							
Nein	38/109 (34,9)	13,8 [6,3; n.b.]	43/92 (46,7)	5,0 [2,7; n.b.]	0,4 [0,3; 0,7]	0,0002	0,7065
Ja	20/56 (35,7)	15,2 [6,7; n.b.]	21/47 (44,7)	4,8 [0,9; n.b.]	0,4 [0,2; 0,8]	0,0045	
PRO-CTCAE, Schweregrad von rissigen Mundwinkeln; Anzahl an vorherigen Therapielinien							
1	25/72 (34,7)	9,3 [6,1; n.b.]	27/62 (43,5)	11,2 [2,0; n.b.]	0,5 [0,3; 0,9]	0,0206	0,9679
2	22/64 (34,4)	n.b. [6,3; n.b.]	27/56 (48,2)	5,0 [2,6; n.b.]	0,4 [0,2; 0,7]	0,0012	
>2	11/29 (37,9)	7,6 [4,8; 15,2]	10/21 (47,6)	5,0 [1,4; n.b.]	0,4 [0,2; 1,1]	0,0680	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von juckender Haut; Alter bei Studienbeginn							
<65 Jahre	49/87 (56,3)	3,5 [2,1; 9,2]	42/80 (52,5)	2,8 [1,4; 5,6]	0,9 [0,6; 1,4]	0,6649	0,4310
≥65 Jahre	49/78 (62,8)	3,4 [2,1; 6,3]	32/59 (54,2)	2,8 [1,5; n.b.]	1,2 [0,8; 2,0]	0,4050	
PRO-CTCAE, Schweregrad von juckender Haut; Geschlecht							
Weiblich	35/60 (58,3)	3,5 [2,1; 7,6]	34/58 (58,6)	2,1 [1,4; 5,6]	0,7 [0,4; 1,2]	0,2210	0,4495
Männlich	63/105 (60,0)	3,4 [2,1; 6,3]	40/81 (49,4)	3,1 [2,1; n.b.]	1,0 [0,6; 1,5]	0,8812	
PRO-CTCAE, Schweregrad von juckender Haut; Region 2							
Nordamerika und Europa	81/140 (57,9)	3,5 [2,4; 6,3]	58/118 (49,2)	3,7 [2,1; n.b.]	1,0 [0,7; 1,5]	0,8497	0,2403
Rest der Welt	17/25 (68,0)	2,8 [0,8; 7,5]	16/21 (76,2)	1,4 [1,0; 3,5]	0,5 [0,2; 1,1]	0,0930	
PRO-CTCAE, Schweregrad von juckender Haut; Region 1							
Nordamerika	10/19 (52,6)	4,4 [0,7; n.b.]	7/16 (43,8)	n.b. [1,4; n.b.]	1,1 [0,3; 3,7]	0,9002	0,3928
Europa	71/121 (58,7)	3,5 [2,7; 6,3]	51/102 (50,0)	3,1 [2,1; 8,9]	1,0 [0,7; 1,4]	0,8102	
Rest der Welt	17/25 (68,0)	2,8 [0,8; 7,5]	16/21 (76,2)	1,4 [1,0; 3,5]	0,5 [0,2; 1,1]	0,0930	
PRO-CTCAE, Schweregrad von juckender Haut; ECOG Performance-Status							
0	31/58 (53,4)	6,3 [2,8; 9,7]	20/52 (38,5)	8,9 [4,2; n.b.]	1,3 [0,7; 2,3]	0,4639	0,0900
1	67/107 (62,6)	2,9 [1,8; 4,2]	54/87 (62,1)	1,9 [1,4; 2,8]	0,8 [0,6; 1,2]	0,2665	
PRO-CTCAE, Schweregrad von juckender Haut; Lebermetastasen bei Studienbeginn							
Nein	77/135 (57,0)	3,5 [2,7; 7,5]	55/115 (47,8)	4,2 [2,7; n.b.]	1,0 [0,7; 1,5]	0,8812	0,2406
Ja	21/30 (70,0)	2,9 [0,8; 5,8]	19/24 (79,2)	1,4 [1,2; 1,9]	0,5 [0,2; 1,2]	0,1207	
PRO-CTCAE, Schweregrad von juckender Haut; Knochenmetastasen bei Studienbeginn							
Nein	54/86 (62,8)	3,5 [1,8; 7,5]	42/84 (50,0)	4,2 [2,1; n.b.]	1,1 [0,7; 1,7]	0,5950	0,2277
Ja	44/79 (55,7)	3,4 [2,1; 6,9]	32/55 (58,2)	2,5 [1,4; 3,7]	0,7 [0,4; 1,1]	0,1404	
PRO-CTCAE, Schweregrad von juckender Haut; PD-L1-Proteinexpression							
<1%	33/54 (61,1)	3,2 [1,6; 7,6]	23/44 (52,3)	3,5 [1,4; n.b.]	1,1 [0,6; 2,0]	0,7281	0,4977
≥1% und <50%	30/45 (66,7)	3,5 [1,4; 6,3]	27/55 (49,1)	3,0 [1,9; 5,6]	1,3 [0,7; 2,2]	0,4309	
≥50%	30/59 (50,8)	5,8 [2,1; 8,7]	17/31 (54,8)	2,8 [1,4; n.b.]	0,7 [0,4; 1,5]	0,3860	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von juckender Haut; Ethnie-2							
Asiatisch	15/21 (71,4)	2,9 [1,3; 7,5]	13/18 (72,2)	1,5 [1,4; 3,5]	0,7 [0,3; 1,7]	0,4822	0,7096
Nicht asiatisch	83/143 (58,0)	3,5 [2,4; 6,3]	60/120 (50,0)	3,1 [2,1; n.b.]	1,0 [0,7; 1,5]	0,8120	
PRO-CTCAE, Schweregrad von juckender Haut; Vorgeschichte einer Beteiligung des ZNS							
Nein	62/109 (56,9)	3,5 [2,4; 6,3]	47/92 (51,1)	4,2 [1,9; 8,9]	1,1 [0,7; 1,6]	0,7537	0,2560
Ja	36/56 (64,3)	2,8 [1,8; 6,9]	27/47 (57,4)	2,2 [1,4; 3,5]	0,9 [0,5; 1,4]	0,5442	
PRO-CTCAE, Schweregrad von juckender Haut; Anzahl an vorherigen Therapielinien							
1	36/72 (50,0)	4,1 [2,9; 11,3]	37/62 (59,7)	1,9 [1,4; 2,8]	0,7 [0,4; 1,1]	0,1036	0,0583
2	40/64 (62,5)	4,2 [2,0; 7,5]	27/56 (48,2)	4,9 [2,5; n.b.]	1,2 [0,7; 2,0]	0,4398	
>2	22/29 (75,9)	2,1 [0,7; 3,5]	10/21 (47,6)	8,9 [1,4; 8,9]	1,5 [0,7; 3,4]	0,2979	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Alter bei Studienbeginn							
<65 Jahre	50/87 (57,5)	2,9 [2,1; 6,3]	49/80 (61,3)	2,1 [1,4; 3,5]	0,8 [0,5; 1,2]	0,2946	0,4235
≥65 Jahre	42/78 (53,8)	6,1 [3,3; 9,0]	36/59 (61,0)	2,8 [2,1; 4,3]	0,5 [0,3; 0,9]	0,0133	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Geschlecht							
Weiblich	31/60 (51,7)	3,3 [2,1; n.b.]	41/58 (70,7)	2,1 [1,4; 3,5]	0,6 [0,4; 1,0]	0,0334	0,3192
Männlich	61/105 (58,1)	5,7 [3,0; 6,9]	44/81 (54,3)	2,8 [2,1; 4,3]	0,7 [0,5; 1,1]	0,1188	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Region 2							
Nordamerika und Europa	76/140 (54,3)	5,6 [3,0; 7,6]	71/118 (60,2)	2,8 [2,1; 3,7]	0,7 [0,5; 1,0]	0,0645	0,3263
Rest der Welt	16/25 (64,0)	4,3 [1,4; 7,5]	14/21 (66,7)	1,5 [1,3; 2,8]	0,5 [0,2; 1,2]	0,0991	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Region 1							
Nordamerika	11/19 (57,9)	4,2 [0,7; n.b.]	11/16 (68,8)	3,4 [2,1; 8,5]	0,8 [0,3; 2,2]	0,6799	0,6118
Europa	65/121 (53,7)	5,6 [3,0; 7,7]	60/102 (58,8)	2,5 [1,6; 4,3]	0,7 [0,5; 1,0]	0,0584	
Rest der Welt	16/25 (64,0)	4,3 [1,4; 7,5]	14/21 (66,7)	1,5 [1,3; 2,8]	0,5 [0,2; 1,2]	0,0991	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; ECOG Performance-Status							
0	33/58 (56,9)	6,3 [3,1; 9,0]	29/52 (55,8)	3,5 [2,1; 9,9]	0,8 [0,5; 1,3]	0,3305	0,1246
1	59/107 (55,1)	3,4 [2,8; 6,1]	56/87 (64,4)	2,0 [1,4; 3,4]	0,6 [0,4; 0,9]	0,0107	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Lebermetastasen bei Studienbeginn							
Nein	74/135 (54,8)	5,6 [2,9; 7,7]	67/115 (58,3)	3,1 [2,1; 4,2]	0,7 [0,5; 1,0]	0,0492	0,2093
Ja	18/30 (60,0)	3,4 [1,4; 6,3]	18/24 (75,0)	1,4 [1,2; 2,1]	0,7 [0,3; 1,5]	0,3397	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Knochenmetastasen bei Studienbeginn							
Nein	56/86 (65,1)	3,3 [2,1; 6,3]	53/84 (63,1)	2,8 [2,1; 3,5]	0,8 [0,6; 1,3]	0,4048	0,1243
Ja	36/79 (45,6)	5,8 [3,0; n.b.]	32/55 (58,2)	2,1 [1,4; 4,9]	0,6 [0,3; 0,9]	0,0215	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; PD-L1-Proteinexpression							
<1%	31/54 (57,4)	5,7 [3,2; 13,4]	31/44 (70,5)	2,8 [1,4; 3,5]	0,5 [0,3; 0,9]	0,0150	0,0962
≥1% und <50%	30/45 (66,7)	2,7 [1,4; 6,3]	27/55 (49,1)	4,2 [1,9; 8,5]	1,2 [0,7; 2,0]	0,5887	
≥50%	26/59 (44,1)	6,9 [2,9; n.b.]	18/31 (58,1)	2,8 [1,4; n.b.]	0,6 [0,3; 1,1]	0,1142	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Ethnie-2							
Asiatisch	12/21 (57,1)	4,3 [2,2; 9,3]	11/18 (61,1)	1,6 [1,3; n.b.]	0,4 [0,2; 1,2]	0,0899	0,8203
Nicht asiatisch	80/143 (55,9)	5,3 [2,9; 6,3]	73/120 (60,8)	2,8 [2,0; 3,5]	0,7 [0,5; 1,0]	0,0426	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Vorgeschichte einer Beteiligung des ZNS							
Nein	63/109 (57,8)	3,4 [2,9; 5,8]	59/92 (64,1)	2,3 [1,6; 3,4]	0,7 [0,5; 1,0]	0,0319	0,6754
Ja	29/56 (51,8)	7,6 [2,2; n.b.]	26/47 (55,3)	3,5 [1,4; 4,9]	0,6 [0,3; 1,0]	0,0690	
PRO-CTCAE, Schweregrad von Taubheitsgefühl in Händen oder Füßen; Anzahl an vorherigen Therapielinien							
1	41/72 (56,9)	4,2 [2,8; 8,5]	37/62 (59,7)	2,8 [1,9; 3,4]	0,7 [0,4; 1,0]	0,0715	0,4109
2	33/64 (51,6)	6,3 [3,3; n.b.]	36/56 (64,3)	2,5 [1,4; 4,3]	0,6 [0,4; 0,9]	0,0262	
>2	18/29 (62,1)	2,8 [1,4; 15,2]	12/21 (57,1)	3,5 [0,8; n.b.]	1,1 [0,5; 2,3]	0,8718	
PRO-CTCAE, Schweregrad von Schmerzen; Alter bei Studienbeginn							
<65 Jahre	46/86 (53,5)	5,6 [3,4; 9,7]	42/72 (58,3)	2,6 [1,4; 4,9]	0,6 [0,4; 0,9]	0,0245	0,6937
≥65 Jahre	32/73 (43,8)	12,5 [4,2; n.b.]	24/53 (45,3)	3,5 [2,1; n.b.]	0,8 [0,4; 1,4]	0,4368	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Schmerzen; Geschlecht							
Weiblich	29/57 (50,9)	4,5 [3,1; n.b.]	35/51 (68,6)	1,7 [0,9; 3,0]	0,5 [0,3; 0,8]	0,0060	0,1384
Männlich	49/102 (48,0)	9,1 [4,8; 12,5]	31/74 (41,9)	4,8 [2,8; n.b.]	0,7 [0,4; 1,2]	0,1979	
PRO-CTCAE, Schweregrad von Schmerzen; Region 2							
Nordamerika und Europa	66/136 (48,5)	6,3 [3,6; 11,7]	59/107 (55,1)	3,0 [2,1; 4,9]	0,7 [0,5; 1,0]	0,0267	0,6965
Rest der Welt	12/23 (52,2)	4,8 [2,9; 15,4]	7/18 (38,9)	n.b. [1,3; n.b.]	0,7 [0,2; 2,3]	0,5343	
PRO-CTCAE, Schweregrad von Schmerzen; Region 1							
Nordamerika	7/18 (38,9)	12,2 [2,1; n.b.]	8/14 (57,1)	3,0 [1,5; n.b.]	0,7 [0,2; 2,6]	0,5772	0,8471
Europa	59/118 (50,0)	6,3 [3,5; 11,4]	51/93 (54,8)	3,0 [2,1; 7,3]	0,7 [0,4; 1,0]	0,0380	
Rest der Welt	12/23 (52,2)	4,8 [2,9; 15,4]	7/18 (38,9)	n.b. [1,3; n.b.]	0,7 [0,2; 2,3]	0,5343	
PRO-CTCAE, Schweregrad von Schmerzen; ECOG Performance-Status							
0	27/56 (48,2)	9,7 [3,7; n.b.]	19/45 (42,2)	7,3 [3,3; n.b.]	1,0 [0,5; 2,0]	0,9761	0,0591
1	51/103 (49,5)	5,6 [3,3; 12,5]	47/80 (58,8)	2,1 [1,4; 2,8]	0,5 [0,3; 0,8]	0,0016	
PRO-CTCAE, Schweregrad von Schmerzen; Lebermetastasen bei Studienbeginn							
Nein	58/130 (44,6)	11,4 [4,9; 15,4]	52/101 (51,5)	3,3 [2,1; 8,7]	0,6 [0,4; 0,9]	0,0066	0,2504
Ja	20/29 (69,0)	3,3 [1,4; 5,8]	14/24 (58,3)	2,3 [1,4; n.b.]	0,8 [0,4; 2,0]	0,7105	
PRO-CTCAE, Schweregrad von Schmerzen; Knochenmetastasen bei Studienbeginn							
Nein	37/83 (44,6)	11,7 [5,6; 15,4]	38/72 (52,8)	2,8 [2,1; n.b.]	0,6 [0,3; 1,0]	0,0306	0,6710
Ja	41/76 (53,9)	4,3 [3,2; 9,2]	28/53 (52,8)	3,0 [1,6; 8,7]	0,6 [0,4; 1,1]	0,0936	
PRO-CTCAE, Schweregrad von Schmerzen; PD-L1-Proteinexpression							
<1%	29/51 (56,9)	5,8 [3,4; 15,2]	17/42 (40,5)	n.b. [2,3; n.b.]	0,9 [0,5; 1,8]	0,8563	0,2140
≥1% und <50%	21/44 (47,7)	6,3 [2,1; n.b.]	27/49 (55,1)	2,6 [1,7; 4,9]	0,7 [0,4; 1,3]	0,2264	
≥50%	24/57 (42,1)	5,8 [3,4; n.b.]	16/26 (61,5)	1,9 [1,4; 7,3]	0,5 [0,2; 0,9]	0,0321	
PRO-CTCAE, Schweregrad von Schmerzen; Ethnie-2							
Asiatisch	9/19 (47,4)	12,5 [2,1; n.b.]	6/16 (37,5)	n.b. [0,8; n.b.]	0,7 [0,2; 2,2]	0,5287	0,8279
Nicht asiatisch	69/139 (49,6)	6,3 [3,7; 11,7]	59/108 (54,6)	3,0 [2,1; 4,9]	0,6 [0,5; 0,9]	0,0193	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Schmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	51/104 (49,0)	5,8 [3,4; 12,5]	45/83 (54,2)	3,3 [2,1; 7,3]	0,7 [0,5; 1,1]	0,1506	0,3437
Ja	27/55 (49,1)	9,1 [4,5; 15,2]	21/42 (50,0)	3,0 [1,4; n.b.]	0,4 [0,2; 0,8]	0,0093	
PRO-CTCAE, Schweregrad von Schmerzen; Anzahl an vorherigen Therapielinien							
1	37/70 (52,9)	4,3 [2,9; 9,2]	30/57 (52,6)	2,3 [2,0; 4,9]	0,7 [0,4; 1,2]	0,2286	0,4265
2	25/62 (40,3)	12,2 [5,8; n.b.]	26/47 (55,3)	3,5 [1,4; n.b.]	0,5 [0,3; 0,9]	0,0162	
>2	16/27 (59,3)	4,8 [2,1; 15,2]	10/21 (47,6)	3,3 [1,6; 8,7]	0,8 [0,3; 1,9]	0,5719	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	32/68 (47,1)	11,4 [3,2; n.b.]	23/61 (37,7)	14,5 [4,0; n.b.]	1,1 [0,6; 2,0]	0,6930	0,2453
≥65 Jahre	23/62 (37,1)	12,5 [7,5; n.b.]	15/46 (32,6)	8,5 [3,7; n.b.]	0,7 [0,3; 1,4]	0,3038	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Geschlecht							
Weiblich	21/48 (43,8)	10,4 [3,6; n.b.]	15/46 (32,6)	14,5 [5,3; n.b.]	0,9 [0,4; 1,9]	0,8198	0,7177
Männlich	34/82 (41,5)	13,1 [6,9; n.b.]	23/61 (37,7)	5,0 [3,5; n.b.]	0,8 [0,5; 1,4]	0,4545	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Region 2							
Nordamerika und Europa	48/109 (44,0)	13,1 [5,2; n.b.]	33/92 (35,9)	8,5 [4,8; n.b.]	0,9 [0,6; 1,5]	0,7957	0,9615
Rest der Welt	7/21 (33,3)	12,5 [3,5; n.b.]	5/15 (33,3)	n.b. [0,9; n.b.]	0,8 [0,2; 3,1]	0,6986	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Region 1							
Nordamerika	10/15 (66,7)	2,9 [0,7; 10,4]	1/12 (8,3)	n.b. [8,5; n.b.]	227160000,0 [0,0; n.b.]	0,0101	0,0293
Europa	38/94 (40,4)	15,2 [6,3; n.b.]	32/80 (40,0)	5,2 [3,7; n.b.]	0,7 [0,4; 1,1]	0,1226	
Rest der Welt	7/21 (33,3)	12,5 [3,5; n.b.]	5/15 (33,3)	n.b. [0,9; n.b.]	0,8 [0,2; 3,1]	0,6986	
PRO-CTCAE, Schweregrad von Muskelschmerzen; ECOG Performance-Status							
0	16/47 (34,0)	16,6 [11,4; n.b.]	12/41 (29,3)	n.b. [4,8; n.b.]	0,6 [0,3; 1,5]	0,3094	0,9415
1	39/83 (47,0)	7,8 [3,2; n.b.]	26/66 (39,4)	5,2 [3,7; n.b.]	1,0 [0,6; 1,7]	0,9549	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	48/114 (42,1)	13,1 [6,9; n.b.]	29/87 (33,3)	8,5 [5,0; n.b.]	0,9 [0,5; 1,4]	0,5579	0,6858
Ja	7/16 (43,8)	3,4 [2,1; n.b.]	9/20 (45,0)	3,0 [1,5; n.b.]	0,6 [0,2; 1,8]	0,3184	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	27/72 (37,5)	15,2 [7,8; n.b.]	20/61 (32,8)	8,5 [5,0; n.b.]	0,7 [0,4; 1,4]	0,3421	0,6915
Ja	28/58 (48,3)	6,9 [3,4; n.b.]	18/46 (39,1)	14,5 [3,0; n.b.]	0,9 [0,5; 1,6]	0,6590	
PRO-CTCAE, Schweregrad von Muskelschmerzen; PD-L1-Proteinexpression							
<1%	21/42 (50,0)	7,8 [2,9; n.b.]	13/35 (37,1)	14,5 [3,5; n.b.]	0,9 [0,4; 1,9]	0,8128	0,9024
≥1% und <50%	13/34 (38,2)	n.b. [2,8; n.b.]	13/39 (33,3)	n.b. [2,8; n.b.]	1,1 [0,5; 2,4]	0,8925	
≥50%	18/47 (38,3)	16,6 [4,0; n.b.]	8/24 (33,3)	8,5 [5,2; n.b.]	0,9 [0,3; 2,3]	0,7607	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Ethnie-2							
Asiatisch	6/17 (35,3)	10,4 [3,4; n.b.]	3/12 (25,0)	n.b. [1,3; n.b.]	1,3 [0,3; 5,5]	0,7339	0,8627
Nicht asiatisch	49/112 (43,8)	12,5 [5,2; n.b.]	34/94 (36,2)	8,5 [4,8; n.b.]	0,9 [0,6; 1,5]	0,7371	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	32/82 (39,0)	n.b. [4,0; n.b.]	28/71 (39,4)	8,5 [4,0; n.b.]	0,8 [0,5; 1,3]	0,3782	0,2276
Ja	23/48 (47,9)	11,4 [6,2; 16,6]	10/36 (27,8)	n.b. [3,0; n.b.]	1,3 [0,6; 2,8]	0,5146	
PRO-CTCAE, Schweregrad von Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	22/57 (38,6)	13,1 [3,2; n.b.]	12/47 (25,5)	14,5 [5,2; n.b.]	1,4 [0,7; 2,8]	0,4096	0,1953
2	19/49 (38,8)	16,6 [7,8; n.b.]	20/44 (45,5)	5,0 [3,0; n.b.]	0,5 [0,3; 1,1]	0,0765	
>2	14/24 (58,3)	5,2 [2,1; n.b.]	6/16 (37,5)	n.b. [0,8; n.b.]	1,3 [0,5; 3,3]	0,6525	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	33/65 (50,8)	9,0 [2,8; n.b.]	23/56 (41,1)	16,6 [2,1; 17,5]	0,9 [0,5; 1,7]	0,8601	0,7053
≥65 Jahre	20/64 (31,3)	n.b. [6,9; n.b.]	12/47 (25,5)	n.b. [5,0; n.b.]	0,8 [0,3; 1,8]	0,5457	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Geschlecht							
Weiblich	23/48 (47,9)	11,8 [2,1; n.b.]	15/42 (35,7)	16,6 [2,8; n.b.]	1,4 [0,6; 2,9]	0,4219	0,1670
Männlich	30/81 (37,0)	11,7 [6,9; n.b.]	20/61 (32,8)	n.b. [3,7; n.b.]	0,6 [0,3; 1,2]	0,1874	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Region 2							
Nordamerika und Europa	43/109 (39,4)	15,2 [6,9; n.b.]	31/85 (36,5)	16,6 [4,6; n.b.]	0,9 [0,5; 1,4]	0,5350	0,4991
Rest der Welt	10/20 (50,0)	6,9 [1,4; n.b.]	4/18 (22,2)	n.b. [1,3; n.b.]	1,0 [0,2; 4,4]	0,9817	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Region 1							
Nordamerika	6/13 (46,2)	11,8 [1,9; n.b.]	1/10 (10,0)	16,6 [n.b.; n.b.]	281190000,0 [0,0; n.b.]	0,1032	0,5900
Europa	37/96 (38,5)	15,2 [6,9; n.b.]	30/75 (40,0)	5,2 [2,8; n.b.]	0,7 [0,4; 1,1]	0,1350	
Rest der Welt	10/20 (50,0)	6,9 [1,4; n.b.]	4/18 (22,2)	n.b. [1,3; n.b.]	1,0 [0,2; 4,4]	0,9817	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; ECOG Performance-Status							
0	16/46 (34,8)	n.b. [9,0; n.b.]	9/39 (23,1)	n.b. [n.b.; n.b.]	0,8 [0,3; 1,9]	0,5910	0,4999
1	37/83 (44,6)	9,7 [3,4; n.b.]	26/64 (40,6)	5,2 [2,4; 17,5]	0,8 [0,5; 1,4]	0,5170	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	46/109 (42,2)	11,7 [6,9; n.b.]	29/84 (34,5)	17,5 [4,6; n.b.]	0,9 [0,5; 1,5]	0,6205	0,9760
Ja	7/20 (35,0)	n.b. [3,3; n.b.]	6/19 (31,6)	16,6 [0,9; 16,6]	0,2 [0,0; 1,3]	0,0724	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	31/69 (44,9)	11,4 [6,3; n.b.]	20/56 (35,7)	n.b. [2,8; n.b.]	0,8 [0,4; 1,4]	0,3826	0,9097
Ja	22/60 (36,7)	n.b. [4,5; n.b.]	15/47 (31,9)	16,6 [3,7; 17,5]	0,9 [0,4; 1,9]	0,7731	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	22/44 (50,0)	10,0 [3,2; n.b.]	7/32 (21,9)	17,5 [5,0; n.b.]	1,7 [0,7; 4,4]	0,2753	0,1507
≥1% und <50%	9/32 (28,1)	n.b. [6,3; n.b.]	13/40 (32,5)	16,6 [2,4; n.b.]	0,6 [0,2; 1,5]	0,2616	
≥50%	17/46 (37,0)	n.b. [3,3; n.b.]	10/23 (43,5)	5,2 [1,4; n.b.]	0,7 [0,3; 1,6]	0,3431	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Ethnie-2							
Asiatisch	8/17 (47,1)	9,7 [1,5; n.b.]	3/16 (18,8)	n.b. [1,3; n.b.]	1,5 [0,4; 6,2]	0,5523	0,4328
Nicht asiatisch	45/111 (40,5)	11,8 [6,3; n.b.]	31/86 (36,0)	16,6 [4,6; n.b.]	0,9 [0,6; 1,5]	0,6681	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	27/80 (33,8)	n.b. [6,1; n.b.]	20/66 (30,3)	17,5 [4,6; n.b.]	0,9 [0,5; 1,6]	0,6937	0,7183
Ja	26/49 (53,1)	9,7 [2,8; 15,2]	15/37 (40,5)	16,6 [1,4; 16,6]	1,0 [0,5; 1,9]	0,9306	
PRO-CTCAE, Schweregrad von Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	20/57 (35,1)	n.b. [3,2; n.b.]	11/46 (23,9)	17,5 [5,2; n.b.]	1,2 [0,6; 2,7]	0,5859	0,0672
2	18/48 (37,5)	n.b. [6,9; n.b.]	20/42 (47,6)	4,6 [2,1; n.b.]	0,5 [0,3; 1,0]	0,0637	
>2	15/24 (62,5)	6,3 [1,4; 10,0]	4/15 (26,7)	16,6 [0,8; 16,6]	2,6 [0,7; 9,3]	0,1252	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Alter bei Studienbeginn							
<65 Jahre	3/24 (12,5)	n.b. [10,2; n.b.]	6/36 (16,7)	n.b. [3,5; n.b.]	0,4 [0,1; 2,0]	0,2480	0,4967
≥65 Jahre	7/19 (36,8)	15,2 [4,2; n.b.]	4/32 (12,5)	n.b. [n.b.; n.b.]	1,9 [0,3; 11,3]	0,4551	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Geschlecht							
Weiblich	7/19 (36,8)	11,0 [4,2; n.b.]	5/29 (17,2)	n.b. [3,5; n.b.]	1,2 [0,2; 6,8]	0,8110	0,5834
Männlich	3/24 (12,5)	15,2 [15,2; n.b.]	5/39 (12,8)	n.b. [n.b.; n.b.]	0,6 [0,1; 4,3]	0,6416	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Region 2							
Nordamerika und Europa	8/31 (25,8)	n.b. [11,0; n.b.]	8/51 (15,7)	n.b. [5,1; n.b.]	0,6 [0,2; 2,2]	0,4637	0,5143
Rest der Welt	2/12 (16,7)	n.b. [0,7; n.b.]	2/17 (11,8)	n.b. [n.b.; n.b.]	0,6 [0,0; 6,9]	0,6490	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Region 1							
Nordamerika	2/4 (50,0)		1/6 (16,7)			n. b.	n. b.
Europa	6/27 (22,2)	15,2 [11,0; n.b.]	7/45 (15,6)	n.b. [3,5; n.b.]	0,5 [0,1; 2,1]	0,3417	
Rest der Welt	2/12 (16,7)	n.b. [0,7; n.b.]	2/17 (11,8)	n.b. [n.b.; n.b.]	0,6 [0,0; 6,9]	0,6490	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; ECOG Performance-Status							
0	2/19 (10,5)	n.b. [10,2; n.b.]	4/28 (14,3)	n.b. [5,1; n.b.]	0,3 [0,0; 2,9]	0,2802	0,5055
1	8/24 (33,3)	15,2 [4,2; n.b.]	6/40 (15,0)	n.b. [3,5; n.b.]	1,3 [0,4; 4,9]	0,6586	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Lebermetastasen bei Studienbeginn							
Nein	7/35 (20,0)	n.b. [11,0; n.b.]	8/58 (13,8)	n.b. [n.b.; n.b.]	0,4 [0,1; 1,5]	0,1586	n. b.
Ja	3/8 (37,5)	-	2/10 (20,0)	-	-	n. b.	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Knochenmetastasen bei Studienbeginn							
Nein	5/28 (17,9)	n.b. [15,2; n.b.]	4/42 (9,5)	n.b. [n.b.; n.b.]	0,5 [0,1; 3,5]	0,4932	0,9540
Ja	5/15 (33,3)	n.b. [1,3; n.b.]	6/26 (23,1)	n.b. [3,0; n.b.]	0,9 [0,2; 3,8]	0,8597	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; PD-L1-Proteinexpression							
<1%	3/13 (23,1)		3/22 (13,6)				n. a.
≥1% und <50%	2/10 (20,0)		5/24 (20,8)				
≥50%	4/17 (23,5)		1/16 (6,3)				

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Ethnie-2							
Asiatisch	2/11 (18,2)	n.b. [1,3; n.b.]	2/15 (13,3)	n.b. [n.b.; n.b.]	1,4 [0,2; 10,5]	0,7586	0,7082
Nicht asiatisch	8/32 (25,0)	n.b. [11,0; n.b.]	8/53 (15,1)	n.b. [5,1; n.b.]	0,7 [0,2; 2,3]	0,5828	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Vorgeschichte einer Beteiligung des ZNS							
Nein	6/28 (21,4)	n.b. [11,0; n.b.]	7/44 (15,9)	n.b. [5,1; n.b.]	0,8 [0,2; 2,6]	0,6918	0,9785
Ja	4/15 (26,7)	15,2 [10,2; n.b.]	3/24 (12,5)	n.b. [3,0; n.b.]	1,0 [0,1; 6,2]	0,9640	
PRO-CTCAE, Beeinträchtigung durch Wunden oder offene Stellen in Mund oder Hals; Anzahl an vorherigen Therapielinien							
1	3/19 (15,8)		5/35 (14,3)				n. a.
2	3/15 (20,0)		5/27 (18,5)				
>2	4/9 (44,4)		0/6				
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Alter bei Studienbeginn							
<65 Jahre	18/54 (33,3)	n.b. [3,4; n.b.]	19/56 (33,9)	n.b. [4,9; n.b.]	0,9 [0,5; 1,9]	0,8598	0,7534
≥65 Jahre	15/52 (28,8)	n.b. [10,3; n.b.]	14/43 (32,6)	n.b. [3,3; n.b.]	1,0 [0,4; 2,2]	0,9348	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Geschlecht							
Weiblich	14/38 (36,8)	10,2 [3,3; n.b.]	15/42 (35,7)	n.b. [2,8; n.b.]	0,8 [0,4; 1,8]	0,6331	0,7578
Männlich	19/68 (27,9)	n.b. [10,3; n.b.]	18/57 (31,6)	n.b. [4,9; n.b.]	0,8 [0,4; 1,6]	0,5124	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Region 2							
Nordamerika und Europa	29/88 (33,0)	n.b. [10,2; n.b.]	30/86 (34,9)	n.b. [4,9; n.b.]	0,9 [0,5; 1,5]	0,5682	0,8100
Rest der Welt	4/18 (22,2)	n.b. [4,1; n.b.]	3/13 (23,1)	n.b. [0,9; n.b.]	2,2 [0,2; 22,9]	0,5155	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Region 1							
Nordamerika	6/14 (42,9)	n.b. [0,7; n.b.]	2/12 (16,7)	n.b. [2,0; n.b.]	2,0 [0,3; 13,1]	0,4587	0,1110
Europa	23/74 (31,1)	n.b. [10,2; n.b.]	28/74 (37,8)	7,4 [4,9; n.b.]	0,6 [0,4; 1,2]	0,1362	
Rest der Welt	4/18 (22,2)	n.b. [4,1; n.b.]	3/13 (23,1)	n.b. [0,9; n.b.]	2,2 [0,2; 22,9]	0,5155	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; ECOG Performance-Status							
0	11/39 (28,2)	n.b. [10,2; n.b.]	11/34 (32,4)	n.b. [4,9; n.b.]	0,6 [0,2; 1,6]	0,2994	0,8093
1	22/67 (32,8)	n.b. [3,4; n.b.]	22/65 (33,8)	n.b. [2,8; n.b.]	0,9 [0,5; 1,6]	0,7063	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Lebermetastasen bei Studienbeginn							
Nein	23/89 (25,8)	n.b. [10,3; n.b.]	22/79 (27,8)	n.b. [5,6; n.b.]	0,8 [0,4; 1,5]	0,5335	0,9718
Ja	10/17 (58,8)	3,3 [1,5; n.b.]	11/20 (55,0)	2,3 [1,2; n.b.]	0,6 [0,2; 1,8]	0,3612	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Knochenmetastasen bei Studienbeginn							
Nein	16/63 (25,4)	n.b. [n.b.; n.b.]	18/60 (30,0)	n.b. [5,1; n.b.]	0,8 [0,4; 1,7]	0,6142	0,9626
Ja	17/43 (39,5)	10,3 [3,2; n.b.]	15/39 (38,5)	5,6 [2,8; n.b.]	0,8 [0,4; 1,7]	0,5562	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; PD-L1-Proteinexpression							
<1%	11/32 (34,4)	n.b. [3,2; n.b.]	8/33 (24,2)	n.b. [7,4; n.b.]	1,5 [0,6; 3,9]	0,4059	0,4170
≥1% und <50%	10/30 (33,3)	n.b. [3,4; n.b.]	16/35 (45,7)	4,9 [2,0; n.b.]	0,6 [0,3; 1,4]	0,2730	
≥50%	11/38 (28,9)	n.b. [4,1; n.b.]	7/23 (30,4)	n.b. [2,8; n.b.]	0,9 [0,3; 2,7]	0,8781	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Ethnie-2							
Asiatisch	3/14 (21,4)	-	1/9 (11,1)	-	-	n. b.	n. b.
Nicht asiatisch	30/92 (32,6)	n.b. [10,2; n.b.]	32/90 (35,6)	7,4 [4,9; n.b.]	0,8 [0,5; 1,4]	0,4978	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Vorgeschichte einer Beteiligung des ZNS							
Nein	17/71 (23,9)	n.b. [n.b.; n.b.]	21/66 (31,8)	n.b. [4,9; n.b.]	0,8 [0,4; 1,5]	0,4799	0,5379
Ja	16/35 (45,7)	10,2 [2,1; n.b.]	12/33 (36,4)	n.b. [2,1; n.b.]	1,0 [0,5; 2,2]	0,9674	
PRO-CTCAE, Beeinträchtigung durch Taubheitsgefühl in Händen oder Füßen; Anzahl an vorherigen Therapielinien							
1	13/42 (31,0)	n.b. [10,2; n.b.]	14/41 (34,1)	7,4 [3,0; n.b.]	0,8 [0,4; 1,8]	0,6628	0,8622
2	11/41 (26,8)	n.b. [10,3; n.b.]	14/42 (33,3)	n.b. [4,9; n.b.]	0,7 [0,3; 1,7]	0,4852	
>2	9/23 (39,1)	6,3 [3,4; n.b.]	5/16 (31,3)	n.b. [1,6; n.b.]	1,2 [0,4; 3,6]	0,7709	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Alter bei Studienbeginn							
<65 Jahre	48/84 (57,1)	3,6 [2,8; 6,3]	37/72 (51,4)	3,3 [1,4; n.b.]	0,9 [0,5; 1,4]	0,5389	0,5035
≥65 Jahre	36/72 (50,0)	6,1 [3,5; 15,2]	18/53 (34,0)	n.b. [3,5; n.b.]	1,2 [0,6; 2,3]	0,5665	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Geschlecht							
Weiblich	31/55 (56,4)	3,3 [2,0; n.b.]	29/51 (56,9)	2,7 [1,4; 5,6]	0,8 [0,5; 1,4]	0,3907	0,2685
Männlich	53/101 (52,5)	5,6 [3,4; 9,7]	26/74 (35,1)	8,7 [3,5; n.b.]	1,1 [0,6; 1,8]	0,8182	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Region 2							
Nordamerika und Europa	71/133 (53,4)	5,6 [3,2; 9,2]	52/107 (48,6)	4,6 [2,4; n.b.]	0,9 [0,6; 1,3]	0,6199	0,1487
Rest der Welt	13/23 (56,5)	3,5 [2,4; 11,8]	3/18 (16,7)	n.b. [2,8; n.b.]	2,0 [0,4; 10,0]	0,3720	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Region 1							
Nordamerika	9/17 (52,9)	5,6 [0,7; n.b.]	5/14 (35,7)	5,6 [2,1; n.b.]	2,5 [0,6; 10,9]	0,2230	0,2028
Europa	62/116 (53,4)	5,6 [3,1; 9,7]	47/93 (50,5)	3,7 [2,1; n.b.]	0,8 [0,6; 1,2]	0,3821	
Rest der Welt	13/23 (56,5)	3,5 [2,4; 11,8]	3/18 (16,7)	n.b. [2,8; n.b.]	2,0 [0,4; 10,0]	0,3720	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; ECOG Performance-Status							
0	24/55 (43,6)	9,7 [5,6; n.b.]	16/45 (35,6)	8,7 [4,6; n.b.]	1,1 [0,5; 2,1]	0,8156	0,3687
1	60/101 (59,4)	3,4 [2,8; 5,8]	39/80 (48,8)	2,8 [1,9; n.b.]	0,8 [0,6; 1,3]	0,4354	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Lebermetastasen bei Studienbeginn							
Nein	63/128 (49,2)	5,6 [3,5; 15,2]	41/101 (40,6)	8,7 [3,5; n.b.]	0,9 [0,6; 1,4]	0,7958	0,9505
Ja	21/28 (75,0)	3,3 [1,4; 5,8]	14/24 (58,3)	2,3 [1,4; n.b.]	0,8 [0,4; 1,9]	0,6253	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Knochenmetastasen bei Studienbeginn							
Nein	43/80 (53,8)	5,6 [3,1; 15,2]	28/72 (38,9)	n.b. [2,7; n.b.]	1,1 [0,6; 1,8]	0,7677	0,4394
Ja	41/76 (53,9)	3,5 [2,4; 9,1]	27/53 (50,9)	3,7 [2,4; 8,7]	0,8 [0,5; 1,4]	0,4448	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; PD-L1-Proteinexpression							
<1%	30/51 (58,8)	5,6 [3,1; 15,2]	14/42 (33,3)	n.b. [3,7; n.b.]	1,4 [0,7; 2,6]	0,3650	0,2788
≥1% und <50%	22/44 (50,0)	6,3 [2,1; n.b.]	24/49 (49,0)	3,0 [1,7; 5,7]	0,8 [0,4; 1,6]	0,5832	
≥50%	27/54 (50,0)	3,6 [2,8; n.b.]	13/26 (50,0)	2,8 [1,4; n.b.]	0,8 [0,4; 1,6]	0,4964	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Ethnie-2							
Asiatisch	10/19 (52,6)	3,5 [2,1; n.b.]	3/16 (18,8)	n.b. [2,8; n.b.]	1,6 [0,4; 6,2]	0,4850	0,2456
Nicht asiatisch	73/136 (53,7)	5,6 [3,3; 9,2]	51/108 (47,2)	4,9 [2,7; n.b.]	0,9 [0,6; 1,4]	0,7342	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	52/101 (51,5)	3,7 [2,9; 9,7]	35/83 (42,2)	5,6 [3,3; n.b.]	1,1 [0,7; 1,7]	0,5937	0,2308
Ja	32/55 (58,2)	5,6 [3,3; 11,7]	20/42 (47,6)	3,0 [1,4; n.b.]	0,7 [0,4; 1,3]	0,2334	
PRO-CTCAE, Beeinträchtigung durch Schmerzen; Anzahl an vorherigen Therapielinien							
1	39/69 (56,5)	3,4 [2,4; 9,2]	23/57 (40,4)	4,6 [2,3; n.b.]	1,2 [0,7; 2,0]	0,4812	0,6509
2	29/60 (48,3)	5,8 [3,3; n.b.]	21/47 (44,7)	n.b. [1,6; n.b.]	0,9 [0,5; 1,6]	0,6748	
>2	16/27 (59,3)	4,1 [2,8; 15,2]	11/21 (52,4)	4,9 [1,4; 8,7]	0,7 [0,3; 1,7]	0,4477	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	33/65 (50,8)	6,3 [3,2; n.b.]	23/59 (39,0)	n.b. [2,8; n.b.]	1,0 [0,6; 1,7]	0,9474	0,5380
≥65 Jahre	22/60 (36,7)	15,2 [4,8; n.b.]	14/45 (31,1)	6,2 [5,0; n.b.]	0,8 [0,4; 1,7]	0,5433	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Geschlecht							
Weiblich	20/46 (43,5)	10,4 [3,5; n.b.]	16/44 (36,4)	n.b. [2,2; n.b.]	0,9 [0,4; 1,9]	0,7984	0,8852
Männlich	35/79 (44,3)	11,4 [3,6; n.b.]	21/60 (35,0)	6,2 [3,5; n.b.]	0,9 [0,5; 1,6]	0,7794	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Region 2							
Nordamerika und Europa	49/105 (46,7)	10,4 [3,7; n.b.]	32/89 (36,0)	6,2 [3,7; n.b.]	1,0 [0,6; 1,6]	0,9688	0,6038
Rest der Welt	6/20 (30,0)	n.b. [3,5; n.b.]	5/15 (33,3)	n.b. [0,9; n.b.]	0,8 [0,2; 3,3]	0,7458	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Region 1							
Nordamerika	8/14 (57,1)	4,8 [1,4; n.b.]	2/12 (16,7)	n.b. [6,2; n.b.]	2,5 [0,5; 13,7]	0,2636	0,1590
Europa	41/91 (45,1)	11,7 [3,6; n.b.]	30/77 (39,0)	5,6 [3,5; n.b.]	0,8 [0,5; 1,3]	0,4185	
Rest der Welt	6/20 (30,0)	n.b. [3,5; n.b.]	5/15 (33,3)	n.b. [0,9; n.b.]	0,8 [0,2; 3,3]	0,7458	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; ECOG Performance-Status							
0	17/45 (37,8)	16,6 [7,1; n.b.]	13/39 (33,3)	n.b. [3,5; n.b.]	0,7 [0,3; 1,6]	0,4179	0,9300
1	38/80 (47,5)	4,8 [3,4; n.b.]	24/65 (36,9)	6,2 [2,8; n.b.]	1,0 [0,6; 1,8]	0,9244	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	48/110 (43,6)	11,7 [4,7; n.b.]	28/84 (33,3)	n.b. [5,0; n.b.]	1,0 [0,6; 1,6]	0,8914	0,6566
Ja	7/15 (46,7)	4,8 [1,4; n.b.]	9/20 (45,0)	2,5 [1,4; n.b.]	0,2 [0,0; 0,8]	0,0117	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	27/69 (39,1)	15,2 [5,8; n.b.]	20/58 (34,5)	6,2 [5,0; n.b.]	0,8 [0,4; 1,6]	0,5589	0,8119
Ja	28/56 (50,0)	4,8 [3,2; n.b.]	17/46 (37,0)	n.b. [2,8; n.b.]	0,9 [0,5; 1,8]	0,8713	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; PD-L1-Proteinexpression							
<1%	19/41 (46,3)	11,7 [3,6; n.b.]	12/35 (34,3)	n.b. [3,7; n.b.]	0,8 [0,4; 1,8]	0,6710	0,7906
≥1% und <50%	14/32 (43,8)	n.b. [2,8; n.b.]	11/37 (29,7)	n.b. [2,8; n.b.]	1,0 [0,4; 2,4]	0,9472	
≥50%	19/45 (42,2)	10,4 [3,5; n.b.]	9/23 (39,1)	5,3 [2,1; n.b.]	0,7 [0,3; 1,8]	0,5128	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Ethnie-2							
Asiatisch	6/16 (37,5)	10,4 [2,4; n.b.]	3/12 (25,0)	n.b. [1,3; n.b.]	1,4 [0,3; 5,9]	0,6820	0,9203
Nicht asiatisch	49/108 (45,4)	11,4 [3,7; n.b.]	33/91 (36,3)	6,2 [5,0; n.b.]	1,0 [0,6; 1,5]	0,9240	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	31/78 (39,7)	n.b. [3,6; n.b.]	27/70 (38,6)	6,2 [3,7; n.b.]	0,9 [0,5; 1,4]	0,5482	0,2907
Ja	24/47 (51,1)	9,7 [3,5; 16,6]	10/34 (29,4)	n.b. [2,8; n.b.]	1,2 [0,6; 2,7]	0,5927	
PRO-CTCAE, Beeinträchtigung durch Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	22/54 (40,7)	9,7 [3,6; n.b.]	14/44 (31,8)	6,2 [3,7; n.b.]	1,1 [0,5; 2,1]	0,8673	0,7274
2	19/47 (40,4)	16,6 [4,7; n.b.]	17/44 (38,6)	5,3 [3,4; n.b.]	0,7 [0,4; 1,5]	0,4050	
>2	14/24 (58,3)	3,5 [2,1; n.b.]	6/16 (37,5)	n.b. [0,8; n.b.]	1,1 [0,4; 3,1]	0,7814	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	28/64 (43,8)	11,4 [3,2; n.b.]	26/55 (47,3)	2,8 [2,1; 18,2]	0,7 [0,4; 1,2]	0,1819	0,5664
≥65 Jahre	23/63 (36,5)	15,2 [6,9; n.b.]	12/45 (26,7)	n.b. [3,7; n.b.]	1,0 [0,4; 2,1]	0,9126	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Geschlecht							
Weiblich	21/47 (44,7)	6,3 [3,1; n.b.]	18/40 (45,0)	18,2 [2,1; n.b.]	0,8 [0,4; 1,6]	0,4853	0,8311
Männlich	30/80 (37,5)	15,2 [7,6; n.b.]	20/60 (33,3)	5,2 [2,8; n.b.]	0,7 [0,4; 1,3]	0,2144	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Region 2							
Nordamerika und Europa	43/107 (40,2)	15,2 [6,3; n.b.]	32/82 (39,0)	18,2 [2,8; n.b.]	0,7 [0,5; 1,2]	0,2408	0,5157
Rest der Welt	8/20 (40,0)	8,6 [3,0; n.b.]	6/18 (33,3)	2,6 [1,3; n.b.]	0,6 [0,2; 2,3]	0,4988	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Region 1							
Nordamerika	8/13 (61,5)	-	1/9 (11,1)	-	-	n. b.	n. b.
Europa	35/94 (37,2)	n.b. [7,6; n.b.]	31/73 (42,5)	5,2 [2,8; n.b.]	0,6 [0,4; 1,0]	0,0488	
Rest der Welt	8/20 (40,0)	8,6 [3,0; n.b.]	6/18 (33,3)	2,6 [1,3; n.b.]	0,6 [0,2; 2,3]	0,4988	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; ECOG Performance-Status							
0	14/44 (31,8)	n.b. [8,6; n.b.]	13/38 (34,2)	n.b. [3,4; n.b.]	0,5 [0,2; 1,1]	0,0771	0,9986
1	37/83 (44,6)	10,4 [3,4; n.b.]	25/62 (40,3)	5,2 [2,1; 18,2]	0,8 [0,4; 1,3]	0,3346	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	43/107 (40,2)	12,5 [6,9; n.b.]	30/81 (37,0)	18,2 [3,4; n.b.]	0,8 [0,5; 1,3]	0,2870	0,3270
Ja	8/20 (40,0)	n.b. [3,0; n.b.]	8/19 (42,1)	2,5 [1,0; n.b.]	0,3 [0,1; 1,1]	0,0533	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	28/69 (40,6)	12,5 [6,3; n.b.]	20/53 (37,7)	n.b. [2,6; n.b.]	0,7 [0,4; 1,4]	0,3004	0,7081
Ja	23/58 (39,7)	10,4 [3,5; n.b.]	18/47 (38,3)	3,7 [2,5; 18,2]	0,7 [0,4; 1,3]	0,2688	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	21/43 (48,8)	8,6 [3,4; n.b.]	13/31 (41,9)	18,2 [2,2; n.b.]	0,7 [0,3; 1,6]	0,4399	0,8484
≥1% und <50%	10/32 (31,3)	n.b. [3,0; n.b.]	12/38 (31,6)	n.b. [2,5; n.b.]	0,6 [0,2; 1,5]	0,2495	
≥50%	17/45 (37,8)	10,4 [3,5; n.b.]	9/23 (39,1)	5,3 [1,9; n.b.]	0,6 [0,3; 1,6]	0,3432	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Ethnie-2							
Asiatisch	8/17 (47,1)	8,6 [3,0; n.b.]	3/16 (18,8)	n.b. [1,3; n.b.]	1,2 [0,3; 5,1]	0,8226	0,4065
Nicht asiatisch	43/109 (39,4)	15,2 [6,1; n.b.]	34/83 (41,0)	5,3 [2,8; n.b.]	0,7 [0,4; 1,1]	0,1592	
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	29/78 (37,2)	n.b. [4,5; n.b.]	25/64 (39,1)	5,3 [2,8; n.b.]	0,7 [0,4; 1,3]	0,2752	0,9573
Ja	22/49 (44,9)	11,4 [6,3; n.b.]	13/36 (36,1)	n.b. [2,1; n.b.]	0,7 [0,3; 1,4]	0,2857	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Beeinträchtigung durch Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	20/56 (35,7)	n.b. [3,2; n.b.]	16/44 (36,4)	18,2 [2,6; n.b.]	0,8 [0,4; 1,6]	0,4671	0,3882
2	18/48 (37,5)	n.b. [6,9; n.b.]	18/41 (43,9)	3,5 [2,2; n.b.]	0,6 [0,3; 1,1]	0,0896	
>2	13/23 (56,5)	6,3 [3,2; 15,2]	4/15 (26,7)	n.b. [0,8; n.b.]	1,3 [0,4; 4,2]	0,6953	
PRO-CTCAE, Schmerzfrequenz; Alter bei Studienbeginn							
<65 Jahre	57/87 (65,5)	3,4 [2,7; 4,9]	48/80 (60,0)	2,7 [1,4; 4,7]	0,9 [0,6; 1,3]	0,4732	0,4453
≥65 Jahre	49/78 (62,8)	4,2 [2,1; 5,4]	30/59 (50,8)	3,7 [2,2; 6,1]	1,1 [0,6; 1,8]	0,8026	
PRO-CTCAE, Schmerzfrequenz; Geschlecht							
Weiblich	39/60 (65,0)	2,8 [1,5; 4,5]	35/58 (60,3)	2,7 [1,4; 7,4]	0,9 [0,6; 1,5]	0,6945	0,7350
Männlich	67/105 (63,8)	4,2 [3,2; 5,6]	43/81 (53,1)	3,5 [2,3; 4,8]	0,8 [0,5; 1,2]	0,2762	
PRO-CTCAE, Schmerzfrequenz; Region 2							
Nordamerika und Europa	90/140 (64,3)	3,5 [2,7; 4,8]	66/118 (55,9)	3,3 [2,2; 4,7]	1,0 [0,7; 1,4]	0,8770	0,7257
Rest der Welt	16/25 (64,0)	4,2 [2,1; 7,3]	12/21 (57,1)	2,8 [1,3; 8,1]	0,7 [0,3; 1,7]	0,3889	
PRO-CTCAE, Schmerzfrequenz; Region 1							
Nordamerika	12/19 (63,2)	3,7 [2,1; 11,8]	11/16 (68,8)	2,8 [1,4; n.b.]	1,2 [0,5; 3,2]	0,6691	0,9115
Europa	78/121 (64,5)	3,4 [2,7; 4,9]	55/102 (53,9)	3,7 [2,2; 5,2]	0,9 [0,6; 1,3]	0,5686	
Rest der Welt	16/25 (64,0)	4,2 [2,1; 7,3]	12/21 (57,1)	2,8 [1,3; 8,1]	0,7 [0,3; 1,7]	0,3889	
PRO-CTCAE, Schmerzfrequenz; ECOG Performance-Status							
0	41/58 (70,7)	3,1 [2,1; 5,6]	29/52 (55,8)	4,6 [1,4; 7,4]	1,0 [0,6; 1,7]	0,9773	0,5261
1	65/107 (60,7)	3,6 [2,8; 5,1]	49/87 (56,3)	2,8 [2,0; 3,7]	0,8 [0,5; 1,2]	0,2882	
PRO-CTCAE, Schmerzfrequenz; Lebermetastasen bei Studienbeginn							
Nein	86/135 (63,7)	3,7 [2,8; 5,1]	64/115 (55,7)	3,4 [2,2; 4,8]	0,9 [0,7; 1,3]	0,6388	0,9511
Ja	20/30 (66,7)	2,1 [1,4; 5,8]	14/24 (58,3)	2,7 [1,4; 8,1]	0,7 [0,3; 1,6]	0,3509	
PRO-CTCAE, Schmerzfrequenz; Knochenmetastasen bei Studienbeginn							
Nein	61/86 (70,9)	3,3 [2,1; 4,3]	52/84 (61,9)	2,8 [1,5; 4,6]	0,9 [0,6; 1,3]	0,4741	0,5766
Ja	45/79 (57,0)	4,5 [2,8; 7,3]	26/55 (47,3)	3,7 [1,9; n.b.]	0,9 [0,6; 1,6]	0,7984	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Schmerzfrequenz; PD-L1-Proteinexpression							
<1%	35/54 (64,8)	3,7 [2,8; 9,1]	25/44 (56,8)	3,7 [2,1; 8,1]	0,9 [0,5; 1,5]	0,5827	0,9033
≥1% und <50%	28/45 (62,2)	2,1 [1,4; 9,2]	28/55 (50,9)	2,7 [1,4; 4,6]	0,9 [0,5; 1,5]	0,6041	
≥50%	36/59 (61,0)	3,5 [2,1; 5,4]	18/31 (58,1)	3,3 [1,4; 6,1]	1,0 [0,5; 1,9]	0,9559	
PRO-CTCAE, Schmerzfrequenz; Ethnie-2							
Asiatisch	12/21 (57,1)	4,2 [2,1; 9,3]	11/18 (61,1)	2,8 [1,3; 8,1]	0,7 [0,3; 1,7]	0,4027	0,6263
Nicht asiatisch	93/143 (65,0)	3,4 [2,7; 4,8]	66/120 (55,0)	3,3 [2,1; 4,8]	1,0 [0,7; 1,3]	0,8741	
PRO-CTCAE, Schmerzfrequenz; Vorgeschichte einer Beteiligung des ZNS							
Nein	64/109 (58,7)	3,7 [2,7; 5,8]	51/92 (55,4)	3,4 [1,9; 5,2]	0,9 [0,6; 1,2]	0,3997	0,5163
Ja	42/56 (75,0)	3,5 [2,1; 4,5]	27/47 (57,4)	2,8 [1,4; 7,4]	1,0 [0,6; 1,7]	0,9378	
PRO-CTCAE, Schmerzfrequenz; Anzahl an vorherigen Therapielinien							
1	42/72 (58,3)	3,1 [2,4; 9,1]	38/62 (61,3)	2,8 [1,5; 3,7]	0,8 [0,5; 1,2]	0,2281	0,3339
2	45/64 (70,3)	3,7 [1,5; 5,4]	28/56 (50,0)	4,7 [1,5; n.b.]	1,2 [0,7; 1,9]	0,5006	
>2	19/29 (65,5)	3,4 [1,4; 7,3]	12/21 (57,1)	3,3 [1,4; n.b.]	0,9 [0,4; 2,0]	0,8741	
PRO-CTCAE, Frequenz von Muskelschmerzen; Alter bei Studienbeginn							
<65 Jahre	61/87 (70,1)	2,8 [1,8; 3,4]	51/80 (63,8)	1,9 [1,4; 4,6]	0,9 [0,6; 1,4]	0,7544	0,8253
≥65 Jahre	51/78 (65,4)	4,1 [2,7; 5,9]	32/59 (54,2)	4,3 [2,3; 5,2]	0,9 [0,5; 1,4]	0,5327	
PRO-CTCAE, Frequenz von Muskelschmerzen; Geschlecht							
Weiblich	39/60 (65,0)	3,1 [2,1; 7,2]	40/58 (69,0)	1,9 [1,1; 4,0]	0,7 [0,4; 1,1]	0,1351	0,1679
Männlich	73/105 (69,5)	2,8 [2,1; 4,1]	43/81 (53,1)	3,7 [2,2; 5,2]	1,1 [0,7; 1,6]	0,7128	
PRO-CTCAE, Frequenz von Muskelschmerzen; Region 2							
Nordamerika und Europa	92/140 (65,7)	3,3 [2,7; 5,6]	70/118 (59,3)	3,4 [2,1; 5,0]	0,9 [0,7; 1,3]	0,6740	0,5881
Rest der Welt	20/25 (80,0)	2,1 [1,4; 2,9]	13/21 (61,9)	1,5 [0,9; n.b.]	1,2 [0,5; 3,0]	0,6200	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Frequenz von Muskelschmerzen; Region 1							
Nordamerika	11/19 (57,9)	2,8 [0,7; n.b.]	8/16 (50,0)	5,6 [1,4; n.b.]	1,5 [0,5; 4,5]	0,4290	0,5607
Europa	81/121 (66,9)	3,4 [2,7; 5,8]	62/102 (60,8)	3,1 [2,1; 4,8]	0,9 [0,6; 1,2]	0,3706	
Rest der Welt	20/25 (80,0)	2,1 [1,4; 2,9]	13/21 (61,9)	1,5 [0,9; n.b.]	1,2 [0,5; 3,0]	0,6200	
PRO-CTCAE, Frequenz von Muskelschmerzen; ECOG Performance-Status							
0	42/58 (72,4)	3,5 [2,4; 6,2]	31/52 (59,6)	4,6 [2,1; 5,7]	1,0 [0,6; 1,7]	0,8689	0,4152
1	70/107 (65,4)	2,7 [2,1; 3,6]	52/87 (59,8)	2,2 [1,4; 4,0]	0,8 [0,6; 1,2]	0,3480	
PRO-CTCAE, Frequenz von Muskelschmerzen; Lebermetastasen bei Studienbeginn							
Nein	95/135 (70,4)	2,8 [2,1; 3,7]	67/115 (58,3)	3,5 [2,1; 5,0]	1,0 [0,8; 1,4]	0,7898	0,1035
Ja	17/30 (56,7)	3,4 [2,1; 7,7]	16/24 (66,7)	1,4 [0,9; 4,9]	0,5 [0,2; 1,2]	0,1310	
PRO-CTCAE, Frequenz von Muskelschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	61/86 (70,9)	3,5 [2,1; 5,9]	49/84 (58,3)	4,0 [1,9; 5,1]	1,1 [0,7; 1,6]	0,6997	0,3074
Ja	51/79 (64,6)	2,8 [1,9; 3,4]	34/55 (61,8)	2,2 [1,4; 3,5]	0,7 [0,4; 1,2]	0,1727	
PRO-CTCAE, Frequenz von Muskelschmerzen; PD-L1-Proteinexpression							
<1%	37/54 (68,5)	3,4 [2,4; 7,8]	28/44 (63,6)	2,3 [0,9; 5,1]	0,7 [0,4; 1,1]	0,1406	0,1519
≥1% und <50%	35/45 (77,8)	2,2 [0,7; 4,1]	30/55 (54,5)	4,0 [2,1; 5,0]	1,4 [0,8; 2,4]	0,2063	
≥50%	33/59 (55,9)	3,3 [2,1; 6,1]	18/31 (58,1)	2,8 [1,4; n.b.]	0,8 [0,4; 1,6]	0,5445	
PRO-CTCAE, Frequenz von Muskelschmerzen; Ethnie-2							
Asiatisch	16/21 (76,2)	2,7 [1,4; 4,1]	12/18 (66,7)	1,4 [0,7; n.b.]	0,8 [0,4; 1,7]	0,5269	0,5695
Nicht asiatisch	95/143 (66,4)	3,1 [2,2; 4,2]	70/120 (58,3)	3,4 [2,1; 5,0]	1,0 [0,7; 1,3]	0,8722	
PRO-CTCAE, Frequenz von Muskelschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	69/109 (63,3)	3,3 [2,7; 5,9]	55/92 (59,8)	3,5 [2,1; 5,0]	0,9 [0,6; 1,3]	0,4605	0,7247
Ja	43/56 (76,8)	2,4 [1,4; 3,6]	28/47 (59,6)	2,1 [0,9; 5,7]	1,0 [0,6; 1,6]	0,9263	
PRO-CTCAE, Frequenz von Muskelschmerzen; Anzahl an vorherigen Therapielinien							
1	46/72 (63,9)	2,8 [1,9; 4,1]	39/62 (62,9)	2,3 [1,4; 4,9]	0,9 [0,6; 1,3]	0,5070	0,7056
2	46/64 (71,9)	3,5 [1,4; 6,1]	33/56 (58,9)	4,0 [1,4; 5,1]	1,0 [0,6; 1,6]	0,9606	
>2	20/29 (69,0)	2,8 [2,1; 4,2]	11/21 (52,4)	2,1 [0,7; n.b.]	1,0 [0,5; 2,2]	0,9363	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Frequenz von Gelenkschmerzen; Alter bei Studienbeginn							
<65 Jahre	58/87 (66,7)	2,2 [1,9; 3,4]	38/80 (47,5)	7,6 [2,1; 17,5]	1,4 [0,9; 2,1]	0,1267	0,0290
≥65 Jahre	43/78 (55,1)	6,9 [3,1; 9,0]	33/59 (55,9)	4,3 [1,7; 6,1]	0,7 [0,4; 1,1]	0,1469	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Geschlecht							
Weiblich	38/60 (63,3)	2,8 [1,4; 6,9]	33/58 (56,9)	4,6 [1,7; 13,4]	1,1 [0,7; 1,8]	0,7637	0,6796
Männlich	63/105 (60,0)	3,5 [2,8; 7,1]	38/81 (46,9)	4,9 [2,1; 11,2]	1,0 [0,6; 1,5]	0,8984	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Region 2							
Nordamerika und Europa	87/140 (62,1)	3,3 [2,2; 6,9]	56/118 (47,5)	5,2 [2,8; 11,5]	1,2 [0,9; 1,7]	0,2500	0,0322
Rest der Welt	14/25 (56,0)	4,2 [1,4; 9,3]	15/21 (71,4)	1,5 [0,9; 2,6]	0,4 [0,2; 1,1]	0,0624	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Region 1							
Nordamerika	9/19 (47,4)	n.b. [0,8; n.b.]	7/16 (43,8)	7,6 [2,1; n.b.]	1,1 [0,3; 3,7]	0,8884	0,1030
Europa	78/121 (64,5)	3,2 [2,2; 6,3]	49/102 (48,0)	4,9 [2,7; 13,4]	1,2 [0,9; 1,8]	0,2521	
Rest der Welt	14/25 (56,0)	4,2 [1,4; 9,3]	15/21 (71,4)	1,5 [0,9; 2,6]	0,4 [0,2; 1,1]	0,0624	
PRO-CTCAE, Frequenz von Gelenkschmerzen; ECOG Performance-Status							
0	40/58 (69,0)	2,8 [2,1; 6,3]	26/52 (50,0)	6,1 [2,3; 13,4]	1,3 [0,8; 2,2]	0,3576	0,1625
1	61/107 (57,0)	3,4 [2,7; 7,7]	45/87 (51,7)	2,8 [1,6; 17,5]	0,9 [0,6; 1,3]	0,4757	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Lebermetastasen bei Studienbeginn							
Nein	83/135 (61,5)	3,2 [2,1; 6,9]	55/115 (47,8)	5,2 [2,8; 13,4]	1,2 [0,8; 1,7]	0,4056	0,1316
Ja	18/30 (60,0)	3,4 [2,1; 14,5]	16/24 (66,7)	2,1 [1,4; 4,9]	0,4 [0,2; 1,0]	0,0480	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Knochenmetastasen bei Studienbeginn							
Nein	55/86 (64,0)	3,1 [2,1; 6,9]	45/84 (53,6)	4,6 [2,1; 6,1]	1,1 [0,7; 1,6]	0,7751	0,9260
Ja	46/79 (58,2)	3,4 [2,1; 7,1]	26/55 (47,3)	7,6 [1,6; 17,5]	1,0 [0,6; 1,7]	0,9515	
PRO-CTCAE, Frequenz von Gelenkschmerzen; PD-L1-Proteinexpression							
<1%	36/54 (66,7)	3,2 [2,0; 5,1]	20/44 (45,5)	13,4 [1,6; 17,5]	1,5 [0,8; 2,7]	0,1834	0,1041
≥1% und <50%	28/45 (62,2)	3,5 [2,1; 9,0]	25/55 (45,5)	4,6 [2,1; 11,5]	1,1 [0,6; 2,0]	0,7065	
≥50%	31/59 (52,5)	3,4 [1,8; 9,0]	20/31 (64,5)	2,1 [1,4; 6,1]	0,5 [0,3; 1,0]	0,0599	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
PRO-CTCAE, Frequenz von Gelenkschmerzen; Ethnie-2							
Asiatisch	12/21 (57,1)	4,2 [1,4; 9,3]	13/18 (72,2)	1,5 [0,8; 3,5]	0,4 [0,2; 1,1]	0,0617	0,0672
Nicht asiatisch	88/143 (61,5)	3,3 [2,2; 6,9]	57/120 (47,5)	5,2 [2,8; 11,5]	1,2 [0,8; 1,6]	0,3590	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Vorgeschichte einer Beteiligung des ZNS							
Nein	59/109 (54,1)	5,1 [2,9; 8,3]	46/92 (50,0)	4,9 [2,7; 11,2]	1,0 [0,6; 1,4]	0,8621	0,7071
Ja	42/56 (75,0)	2,1 [1,4; 3,3]	25/47 (53,2)	2,1 [1,3; n.b.]	1,1 [0,6; 1,8]	0,7967	
PRO-CTCAE, Frequenz von Gelenkschmerzen; Anzahl an vorherigen Therapielinien							
1	42/72 (58,3)	3,2 [2,0; 9,0]	35/62 (56,5)	3,5 [1,7; 5,2]	0,9 [0,6; 1,4]	0,6652	0,7221
2	39/64 (60,9)	3,4 [2,1; 7,8]	26/56 (46,4)	7,6 [1,6; n.b.]	1,1 [0,7; 1,9]	0,6195	
>2	20/29 (69,0)	2,8 [0,8; 6,9]	10/21 (47,6)	6,1 [1,6; 11,5]	1,2 [0,6; 2,7]	0,6249	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; PRO-CTCAE = Patient-Reported Outcome Version der Common Technology Criteria for Adverse Events; ZNS = Zentrales Nervensystem

4.13 FACT-G GP5

4.13.1 Verlaufskurve für den Endpunkt FACT-G GP5

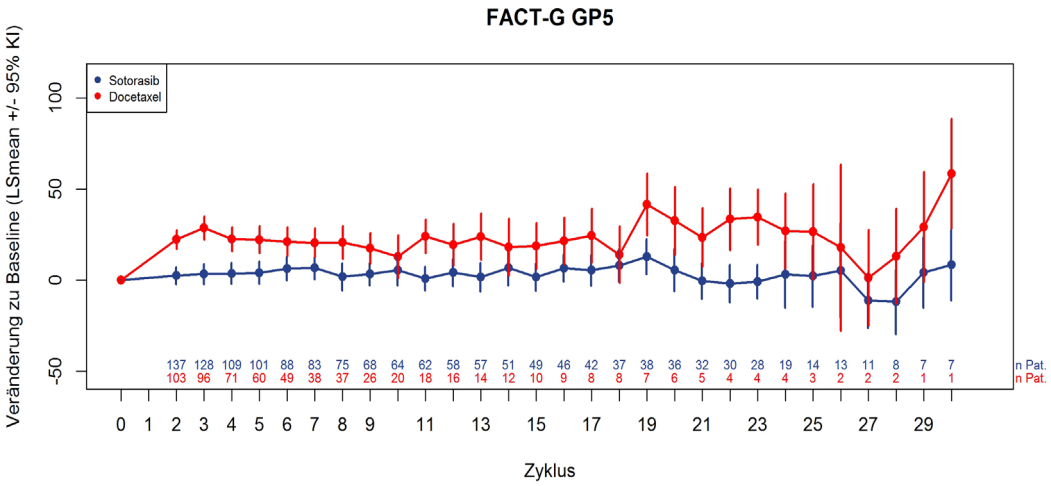

Abbildung 31: Verlaufskurve für den Endpunkt FACT-G GP5, aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

4.13.2 Subgruppenanalysen für den Endpunkt FACT-G GP5 (Zeit bis zur Verschlechterung um ≥ 15 Punkte)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
FACT-G GP5; Alter bei Studienbeginn							
<65 Jahre	48/85 (56,5)	2,3 [1,5; 6,4]	49/69 (71,0)	1,4 [0,8; 2,1]	0,6 [0,4; 0,9]	0,0087	0,4194
≥65 Jahre	44/78 (56,4)	3,3 [2,3; 4,9]	47/59 (79,7)	0,8 [0,7; 1,4]	0,4 [0,3; 0,7]	0,0004	
FACT-G GP5; Geschlecht							
Weiblich	33/60 (55,0)	2,3 [2,0; 5,7]	40/51 (78,4)	1,4 [0,7; 1,4]	0,5 [0,3; 0,8]	0,0036	0,5830
Männlich	59/103 (57,3)	3,0 [2,2; 6,2]	56/77 (72,7)	1,4 [0,8; 2,0]	0,6 [0,4; 0,8]	0,0038	
FACT-G GP5; Region 2							
Nordamerika und Europa	78/138 (56,5)	2,8 [2,1; 4,9]	84/109 (77,1)	1,4 [0,8; 1,5]	0,5 [0,4; 0,7]	0,0001	0,8404
Rest der Welt	14/25 (56,0)	3,5 [2,2; 12,5]	12/19 (63,2)	0,8 [0,8; n.b.]	0,5 [0,2; 1,3]	0,1433	
FACT-G GP5; Region 1							
Nordamerika	8/19 (42,1)	9,9 [1,4; n.b.]	14/16 (87,5)	0,8 [0,7; 2,0]	0,2 [0,0; 0,6]	0,0030	0,1865
Europa	70/119 (58,8)	2,7 [2,0; 3,4]	70/93 (75,3)	1,4 [0,8; 1,5]	0,6 [0,4; 0,8]	0,0016	
Rest der Welt	14/25 (56,0)	3,5 [2,2; 12,5]	12/19 (63,2)	0,8 [0,8; n.b.]	0,5 [0,2; 1,3]	0,1433	
FACT-G GP5; ECOG Performance-Status							
0	33/57 (57,9)	3,0 [2,2; 6,4]	40/52 (76,9)	1,3 [0,8; 2,1]	0,5 [0,3; 0,9]	0,0115	0,8673
1	59/106 (55,7)	2,8 [2,1; 3,6]	56/76 (73,7)	1,4 [0,8; 1,5]	0,5 [0,3; 0,7]	0,0003	
FACT-G GP5; Lebermetastasen bei Studienbeginn							
Nein	75/135 (55,6)	2,9 [2,1; 6,2]	79/107 (73,8)	1,4 [0,8; 2,0]	0,5 [0,4; 0,8]	0,0002	0,3608
Ja	17/28 (60,7)	2,8 [1,4; 3,6]	17/21 (81,0)	0,8 [0,7; 1,4]	0,4 [0,1; 0,9]	0,0285	
FACT-G GP5; Knochenmetastasen bei Studienbeginn							
Nein	51/86 (59,3)	2,8 [2,2; 4,9]	59/77 (76,6)	1,4 [0,8; 2,0]	0,4 [0,3; 0,7]	0,0002	0,9846
Ja	41/77 (53,2)	2,8 [1,4; n.b.]	37/51 (72,5)	1,3 [0,7; 1,4]	0,6 [0,3; 0,9]	0,0190	
FACT-G GP5; PD-L1-Proteinexpression							
<1%	26/54 (48,1)	3,0 [2,1; 17,3]	31/41 (75,6)	0,8 [0,7; 1,5]	0,4 [0,2; 0,7]	0,0008	0,2997
≥1% und <50%	27/44 (61,4)	2,1 [1,4; 3,0]	35/49 (71,4)	1,4 [0,8; 2,1]	0,6 [0,4; 1,1]	0,1042	
≥50%	35/58 (60,3)	3,3 [2,2; 4,9]	23/30 (76,7)	1,4 [0,7; 3,1]	0,6 [0,3; 1,0]	0,0644	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
FACT-G GP5; Ethnie-2							
Asiatisch	14/21 (66,7)	3,0 [1,4; 4,1]	13/18 (72,2)	0,8 [0,7; 2,0]	0,5 [0,2; 1,3]	0,1694	0,7908
Nicht asiatisch	78/141 (55,3)	2,8 [2,1; 5,7]	82/109 (75,2)	1,4 [0,8; 1,5]	0,5 [0,4; 0,7]	<,0001	
FACT-G GP5; Vorgeschichte einer Beteiligung des ZNS							
Nein	59/108 (54,6)	2,8 [2,1; 4,9]	70/88 (79,5)	1,3 [0,8; 1,4]	0,5 [0,3; 0,7]	<,0001	0,4494
Ja	33/55 (60,0)	2,8 [2,1; 6,4]	26/40 (65,0)	1,4 [0,8; 2,1]	0,6 [0,4; 1,1]	0,1029	
FACT-G GP5; Anzahl an vorherigen Therapielinien							
1	36/71 (50,7)	3,0 [2,2; 7,0]	45/58 (77,6)	1,4 [0,8; 1,5]	0,4 [0,3; 0,7]	0,0002	0,3042
2	39/63 (61,9)	2,2 [1,4; 3,3]	36/51 (70,6)	1,4 [0,7; 2,3]	0,7 [0,4; 1,1]	0,1465	
>2	17/29 (58,6)	3,5 [2,1; n.b.]	15/19 (78,9)	0,8 [0,7; 2,1]	0,4 [0,2; 0,9]	0,0234	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).
2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.
FACT-G = Functional Assessment of Cancer Therapy Toll General Form; KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; ZNS = Zentrales Nervensystem

4.13.3 Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt FACT-G GP5 (präspezifizierte Analyse inkl. Tod als Ereignis)

Sotorasib			Docetaxel			Sotorasib vs. Docetaxel		
N	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**N**	**Patienten mit Ereignis n (%)**	**Median (Monate) [95% KI]**	**Hazard Ratio [95% KI]**	**p(Cox)1**	**p(logrank)2**
FACT-G GP5, Zeit bis zur Verschlechterung um ≥15%								
165	111 (67,3)	2,8 [2,1; 3,2]	139	108 (77,7)	1,1 [0,8; 1,4]	0,53 [0,40; 0,71]	<,0001	<,0001
1) p-Wert des Cox-Modells 2) p-Wert des Logrank-Tests Die Auswertung erfolgte auf Grundlage der ITT-Population.								
FACT-G = Functional Assessment of Cancer Therapy Toll General Form; KI = Konfidenzintervall; n.b. = nicht berechenbar								

4.13.4 Kaplan-Meier Kurven für die Zeit bis zur Verschlechterung um ≥ 15 Punkte für den Endpunkt FACT-G GP5 (präspezifizierte Analyse inkl. Tod als Ereignis)

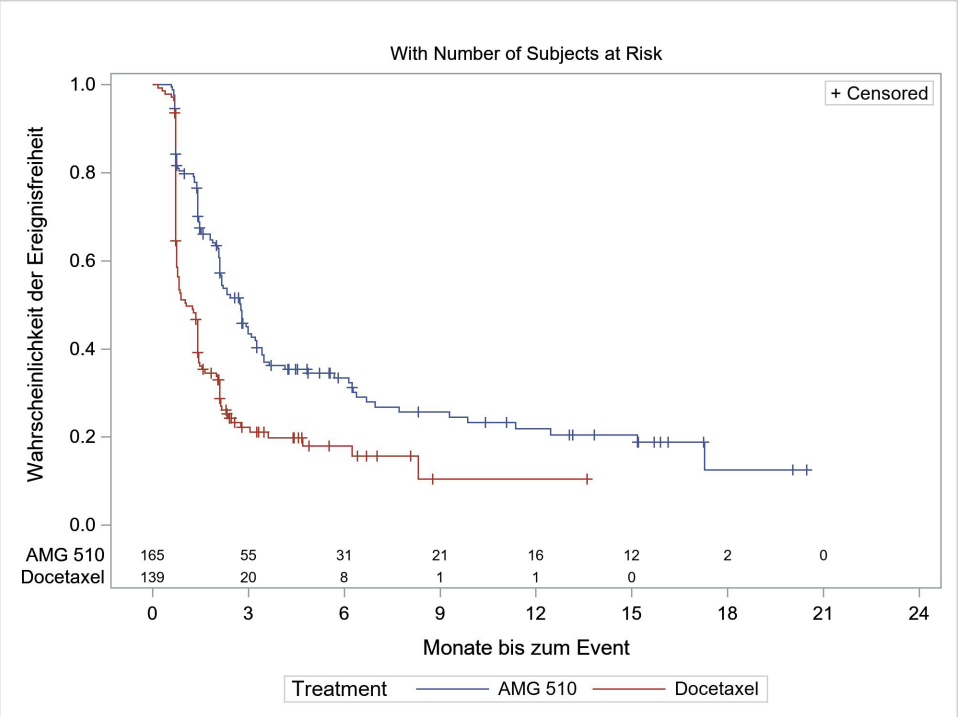

Abbildung x.xx: Kaplan-Meier Kurve für den Endpunkt "FACT-G, Zeit bis zur Verschlechterung um ≥15%" aus Studie 20190009 mit dem zu bewertenden Arzneimittel.

4.13.5 Subgruppenanalysen für den Endpunkt FACT-G GP5 (Zeit bis zur Verschlechterung um ≥ 15 Punkte; präspezifizierte Analyse inkl. Tod als Ereignis)

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
FACT-G GP5; Alter bei Studienbeginn							
<65 Jahre	59/87 (67,8)	2,1 [1,5; 2,9]	61/80 (76,3)	1,2 [0,8; 1,4]	0,6 [0,4; 0,8]	0,0046	0,5365
≥65 Jahre	52/78 (66,7)	3,1 [2,4; 4,1]	47/59 (79,7)	0,8 [0,7; 1,4]	0,5 [0,3; 0,7]	0,0008	
FACT-G GP5; Geschlecht							
Weiblich	39/60 (65,0)	2,2 [2,0; 3,3]	48/58 (82,8)	0,9 [0,8; 1,4]	0,4 [0,3; 0,7]	0,0006	0,3238
Männlich	72/105 (68,6)	2,8 [2,1; 3,5]	60/81 (74,1)	1,3 [0,8; 1,5]	0,6 [0,4; 0,9]	0,0058	
FACT-G GP5; Region 2							
Nordamerika und Europa	95/140 (67,9)	2,3 [2,1; 3,1]	93/118 (78,8)	1,3 [0,8; 1,4]	0,6 [0,4; 0,8]	0,0002	0,6989
Rest der Welt	16/25 (64,0)	3,5 [2,2; 6,7]	15/21 (71,4)	0,9 [0,8; 2,0]	0,4 [0,1; 1,0]	0,0435	
FACT-G GP5; Region 1							
Nordamerika	10/19 (52,6)	6,1 [1,4; n.b.]	14/16 (87,5)	0,8 [0,7; 2,0]	0,2 [0,1; 0,7]	0,0054	0,2225
Europa	85/121 (70,2)	2,2 [1,8; 2,8]	79/102 (77,5)	1,4 [0,8; 1,4]	0,6 [0,4; 0,8]	0,0014	
Rest der Welt	16/25 (64,0)	3,5 [2,2; 6,7]	15/21 (71,4)	0,9 [0,8; 2,0]	0,4 [0,1; 1,0]	0,0435	
FACT-G GP5; ECOG Performance-Status							
0	38/58 (65,5)	3,0 [2,2; 6,2]	40/52 (76,9)	1,3 [0,8; 2,1]	0,6 [0,3; 0,9]	0,0250	0,5816
1	73/107 (68,2)	2,3 [2,1; 3,2]	68/87 (78,2)	1,0 [0,8; 1,4]	0,5 [0,3; 0,7]	<,0001	
FACT-G GP5; Lebermetastasen bei Studienbeginn							
Nein	88/135 (65,2)	2,8 [2,1; 3,5]	88/115 (76,5)	1,3 [0,8; 1,4]	0,5 [0,4; 0,8]	0,0001	0,5486
Ja	23/30 (76,7)	2,2 [1,4; 3,3]	20/24 (83,3)	0,9 [0,7; 1,4]	0,4 [0,2; 0,9]	0,0247	
FACT-G GP5; Knochenmetastasen bei Studienbeginn							
Nein	61/86 (70,9)	2,8 [2,1; 3,5]	66/84 (78,6)	1,2 [0,8; 1,5]	0,5 [0,3; 0,7]	0,0002	0,9240
Ja	50/79 (63,3)	2,2 [1,4; 3,4]	42/55 (76,4)	0,9 [0,7; 1,4]	0,6 [0,3; 0,9]	0,0095	

	Sotorasib		Docetaxel		Sotorasib vs. Docetaxel		
Kategorie	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Patienten mit Ereignis n/N (%)**	**Median [95% KI]**	**Hazard Ratio [95% KI]**	**p(lr)[1]**	**p(int)[2]**
FACT-G GP5; PD-L1-Proteinexpression							
<1%	34/54 (63,0)	2,9 [2,1; 6,4]	35/44 (79,5)	0,8 [0,7; 1,4]	0,4 [0,2; 0,7]	0,0008	0,4031
≥1% und <50%	34/45 (75,6)	1,9 [1,4; 2,8]	41/55 (74,5)	1,4 [0,8; 1,6]	0,6 [0,4; 1,1]	0,0768	
≥50%	38/59 (64,4)	3,3 [2,1; 4,1]	24/31 (77,4)	1,4 [0,7; 2,6]	0,6 [0,3; 1,0]	0,0449	
FACT-G GP5; Ethnie-2							
Asiatisch	15/21 (71,4)	3,0 [1,4; 4,1]	14/18 (77,8)	0,8 [0,7; 1,3]	0,5 [0,2; 1,1]	0,0823	0,6143
Nicht asiatisch	96/143 (67,1)	2,7 [2,1; 3,1]	93/120 (77,5)	1,3 [0,8; 1,4]	0,6 [0,4; 0,7]	<,0001	
FACT-G GP5; Vorgeschichte einer Beteiligung des ZNS							
Nein	71/109 (65,1)	2,8 [2,1; 3,3]	75/92 (81,5)	1,1 [0,8; 1,4]	0,5 [0,3; 0,7]	<,0001	0,6767
Ja	40/56 (71,4)	2,4 [1,9; 4,1]	33/47 (70,2)	1,3 [0,8; 1,5]	0,6 [0,4; 1,0]	0,0343	
FACT-G GP5; Anzahl an vorherigen Therapielinien							
1	46/72 (63,9)	2,8 [2,1; 3,6]	50/62 (80,6)	1,3 [0,8; 1,4]	0,5 [0,3; 0,7]	0,0002	0,3919
2	45/64 (70,3)	2,2 [1,4; 2,8]	41/56 (73,2)	1,3 [0,7; 2,1]	0,7 [0,4; 1,1]	0,1001	
>2	20/29 (69,0)	3,4 [2,1; 6,7]	17/21 (81,0)	0,8 [0,7; 1,6]	0,4 [0,2; 0,9]	0,0174	

1) p-Wert des log-rank Tests aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

2) Interaktions-p-Wert aus dem Cox-Modell mit den Strata Anzahl vorangegangener Therapielinien in fortgeschrittener Krankheit (1 vs. 2 vs. >2), Ethnische Herkunft (Asiatisch vs. Nicht-asiatisch) und Vorgeschichte der Einbeziehung des ZNS (ja vs. nein).

Die Auswertung erfolgte auf Grundlage der ITT-Population.

FACT-G = Functional Assessment of Cancer Therapy Toll General Form; KI = Konfidenzintervall; n.b. = nicht berechenbar; p(lr) = p-Wert des log-rank Tests; p(int) = p-Wert des Interaktionstests; ZNS = Zentrales Nervensystem