

**Dossier zur Nutzenbewertung
gemäß § 35a SGB V**

Quizartinib (VANFLYTA)

Daiichi Sankyo Europe GmbH

Modul 4 A – Anhang 4-G

*Erwachsene Patienten mit neu diagnostizierter akuter
myeloischer Leukämie (AML) mit FLT3-ITD-Mutation*

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

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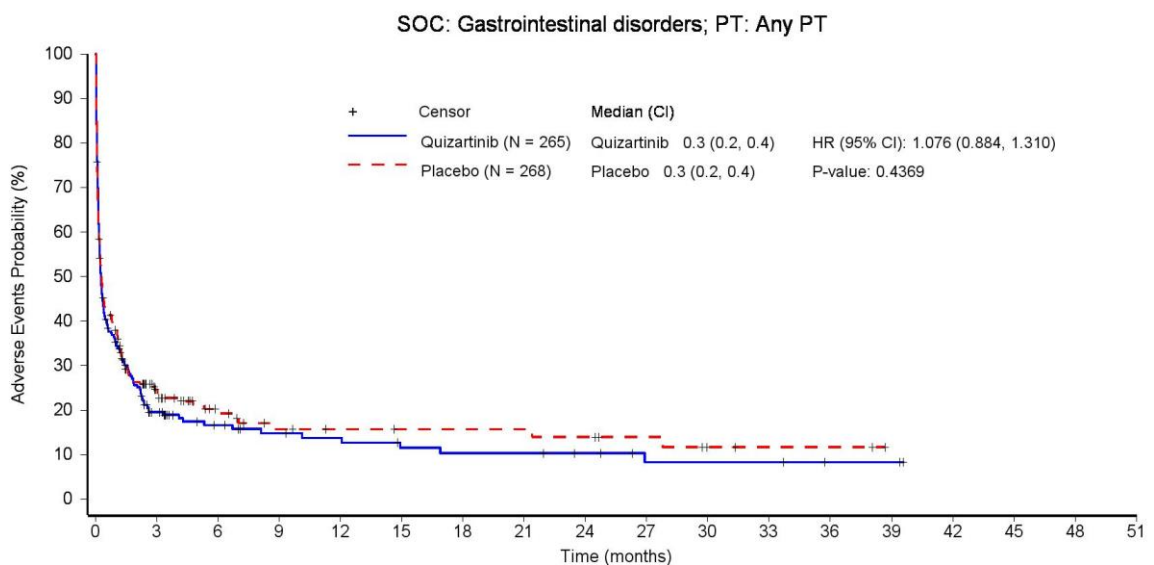
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Anhang 4-G: Darstellung der Kaplan-Meier-Kurven für UE nach SOC und PT und für nicht statistisch signifikante Ergebnisse für UE von besonderem Interesse Studie QuANTUM-First

Anhang 4-G1: UE nach SOC und PT (alle Schweregrade)

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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39				
Quizartinib (N = 265)	265	34	20	15	13	10	9	9	7	4	4	4	2	2	0	0	0	0
Placebo (N = 268)	268	39	19	12	10	9	9	9	8	6	3	2	2	0	0	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

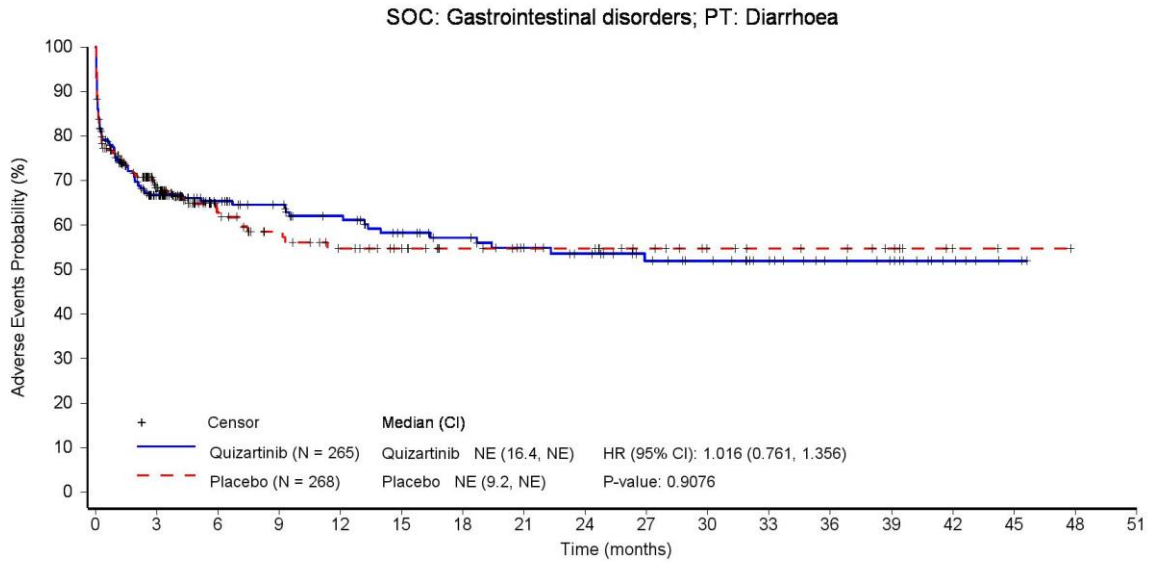
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Patients still at risk:

Quizartinib (N = 265)	265	120	88	78	68	58	52	44	39	32	28	22	16	13	6	2	0	0
Placebo (N = 268)	268	112	62	48	39	32	26	24	24	19	14	12	11	8	2	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

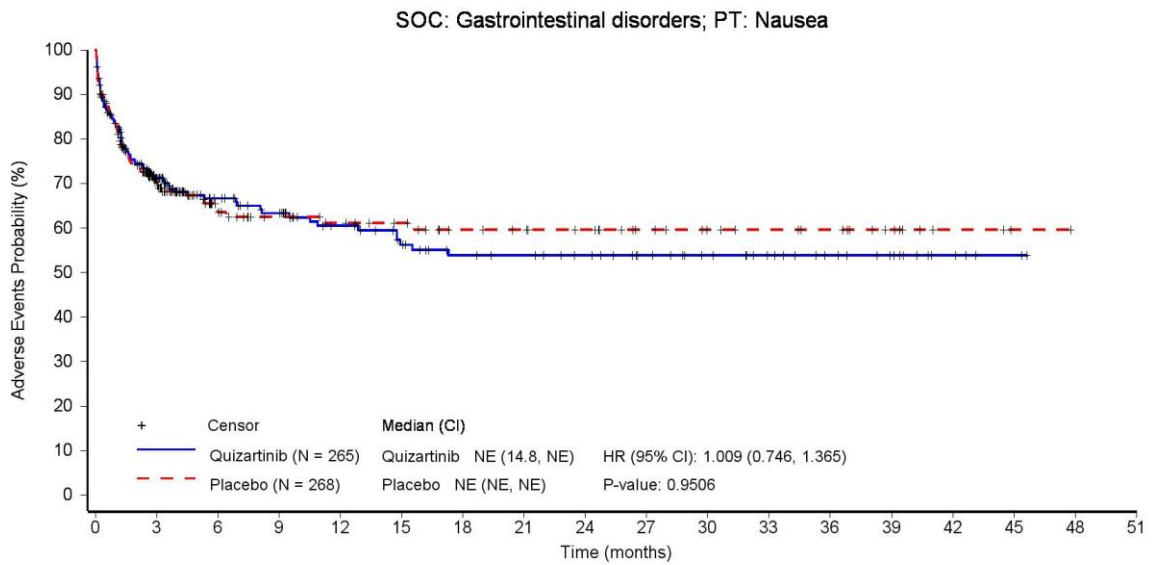
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Quizartinib (N = 265)	265	122	86	74	62	51	43	41	37	31	26	21	16	12	6	2	0	0
Placebo (N = 268)	268	108	63	52	45	41	33	31	28	22	18	16	14	9	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

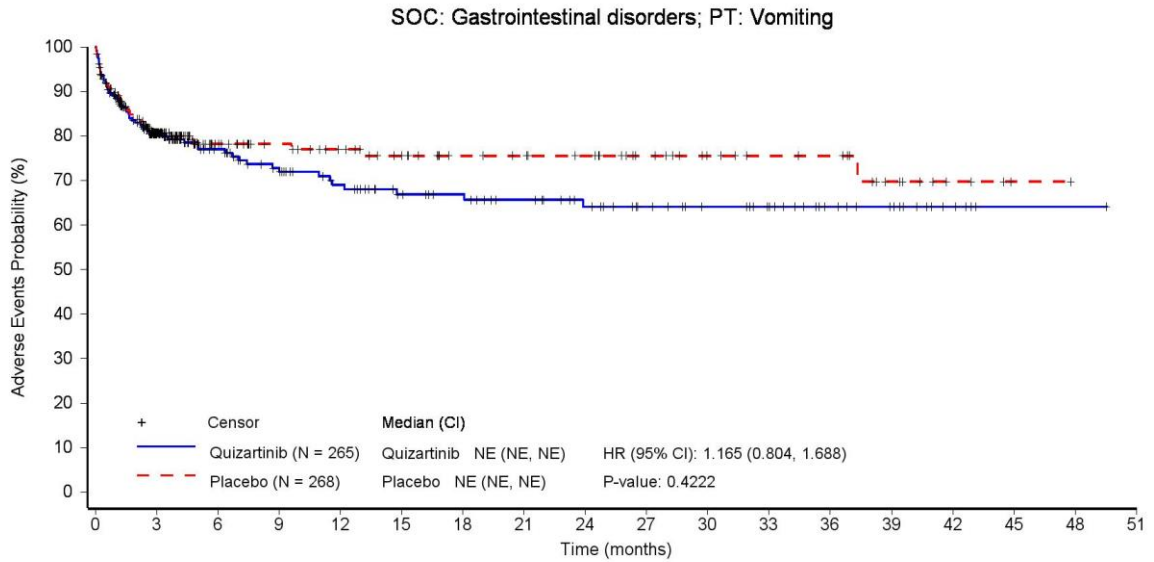
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	137	97	82	70	58	54	48	41	34	29	25	17	13	6	1	1	0
Placebo (N = 268)	268	129	77	64	55	47	39	37	34	26	20	17	16	9	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

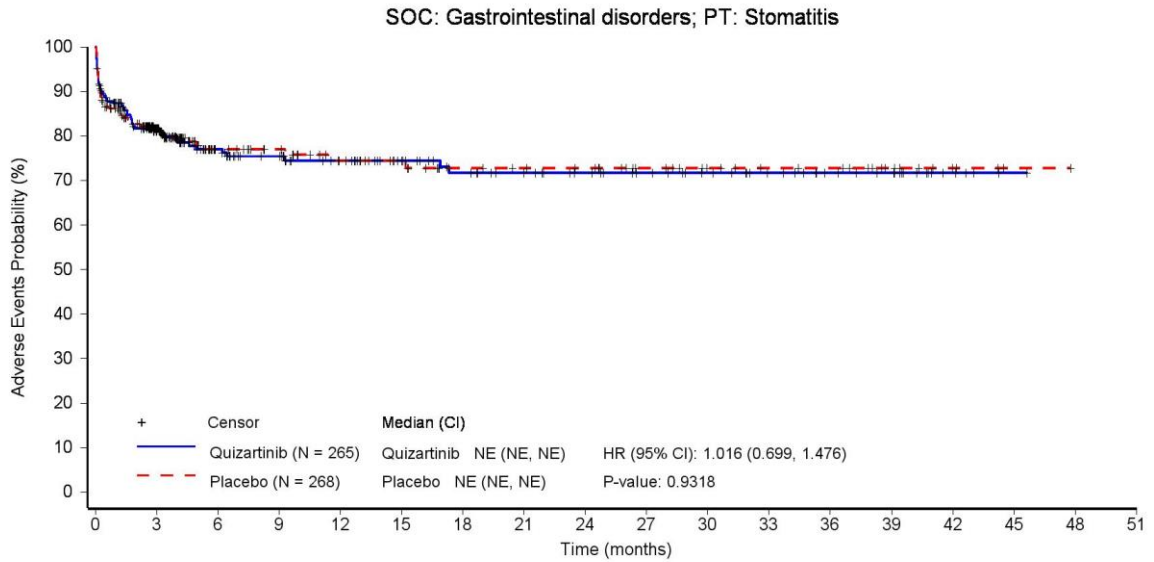
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Patients still at risk:

Quizartinib (N = 265)	265	137	96	83	71	61	52	46	41	36	31	25	19	16	6	1	0	0
Placebo (N = 268)	268	130	74	65	53	45	37	35	33	25	20	17	16	10	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

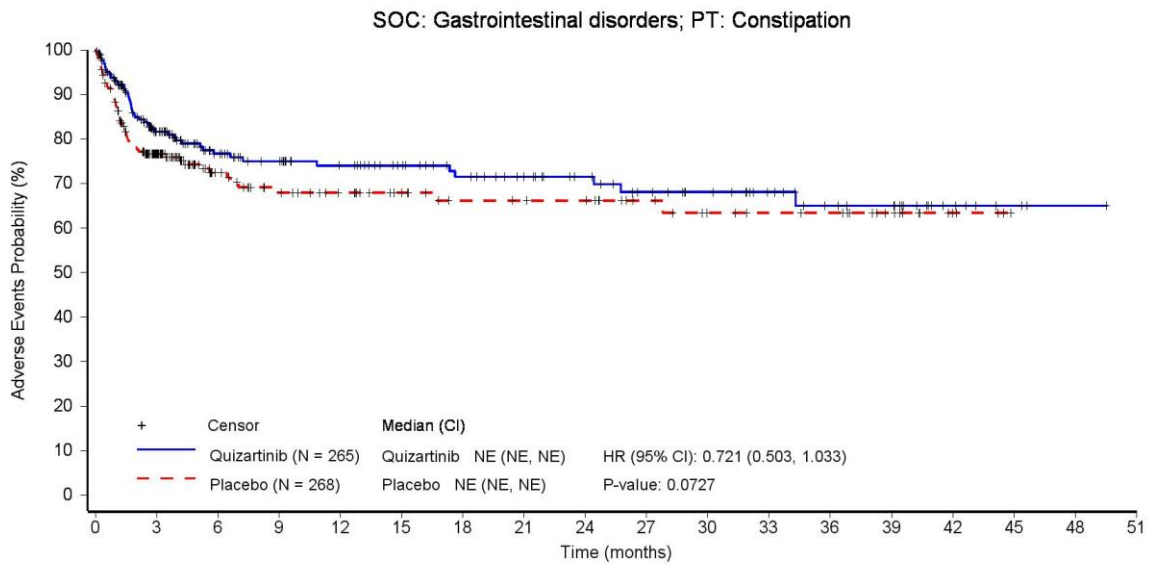
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	137	97	85	75	65	57	50	44	37	32	25	19	17	7	3	1	0
Placebo (N = 268)	268	120	70	56	49	41	35	34	33	25	20	18	17	11	4	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

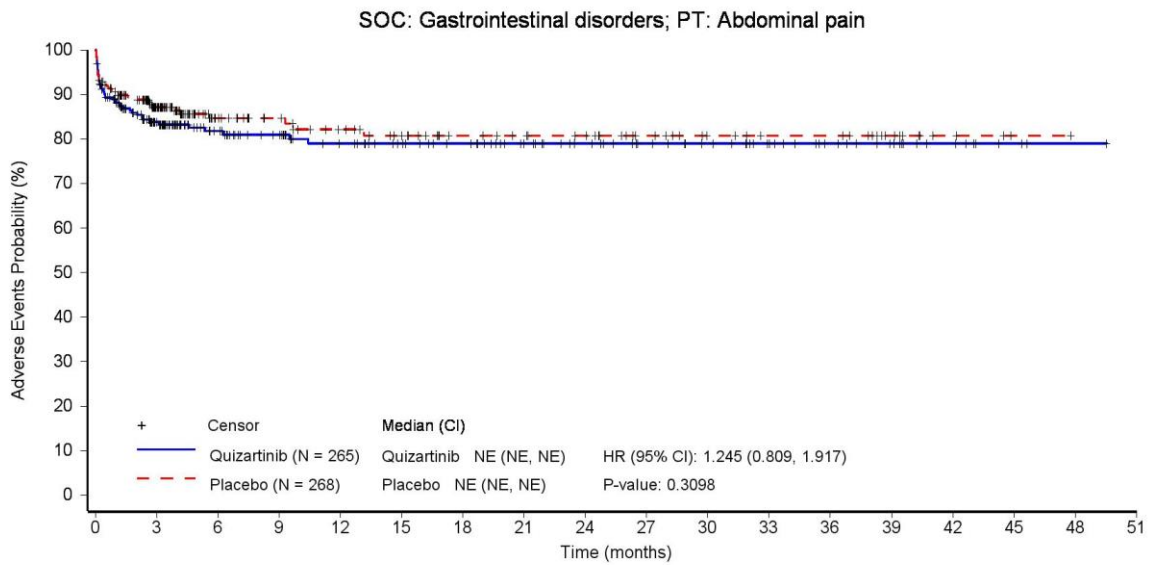
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	144	104	90	77	69	63	53	46	38	33	26	19	14	8	3	1	0
Placebo (N = 268)	268	136	82	70	59	51	42	39	36	27	21	18	18	11	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

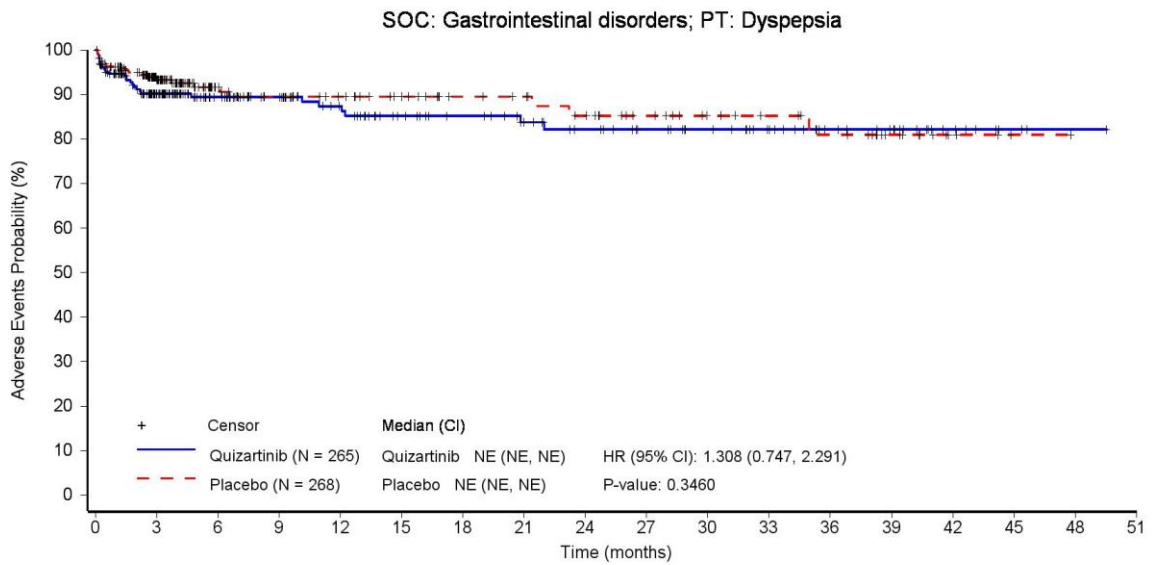
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	149	108	96	82	68	62	55	49	42	37	30	21	17	8	3	1	0
Placebo (N = 268)	268	145	88	72	63	55	46	44	39	31	25	22	19	12	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

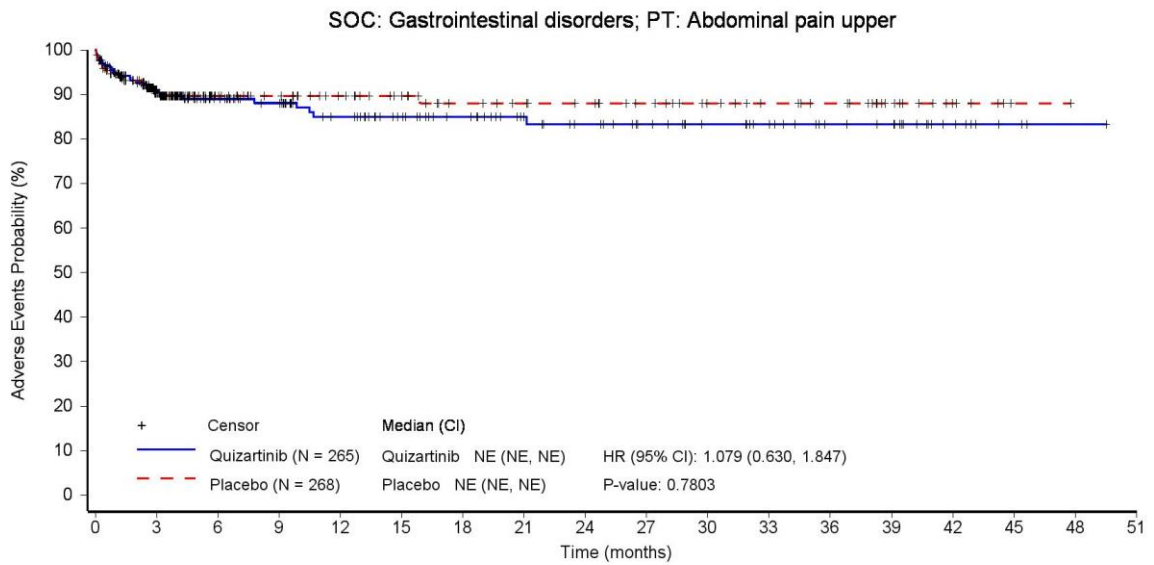
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	147	107	95	80	68	60	50	45	38	32	28	21	19	9	3	1	0
Placebo (N = 268)	268	138	87	75	64	56	46	43	40	35	29	25	22	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

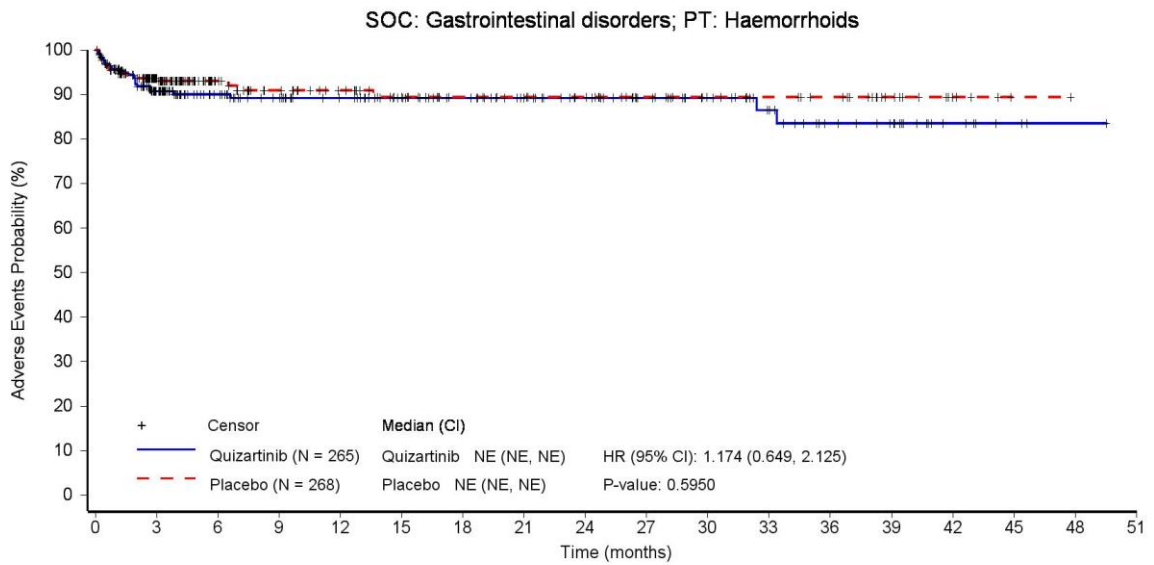
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Patients still at risk:

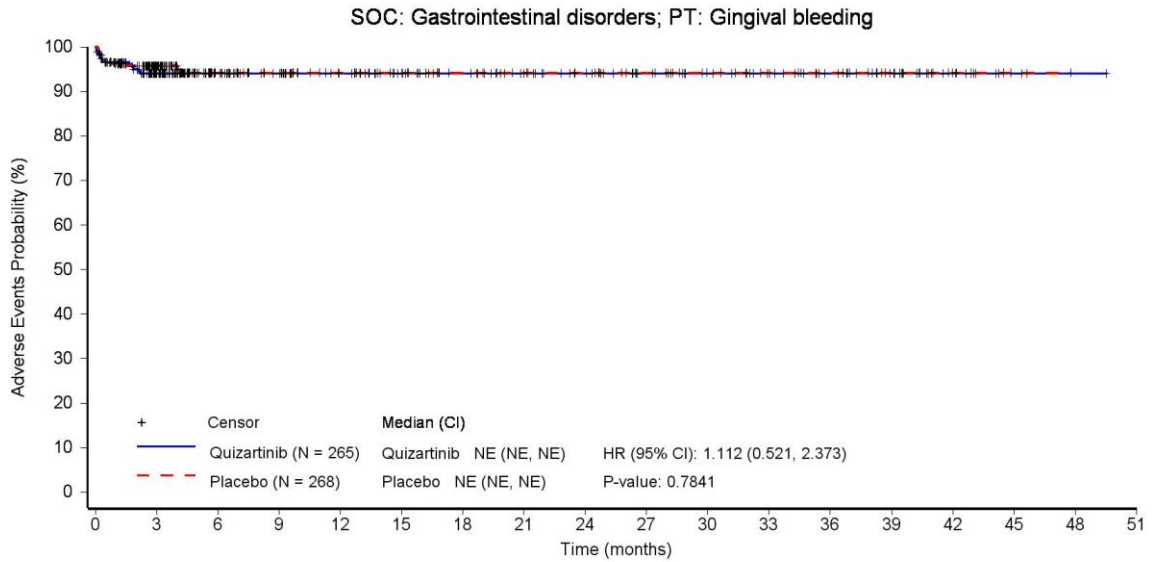
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	149	113	99	89	78	71	61	54	46	39	31	22	18	8	3	1	0
Placebo (N = 268)	268	147	92	76	66	55	47	45	42	33	28	25	22	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	115	102	91	80	73	63	56	48	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	149	92	80	69	60	50	47	44	35	29	25	23	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

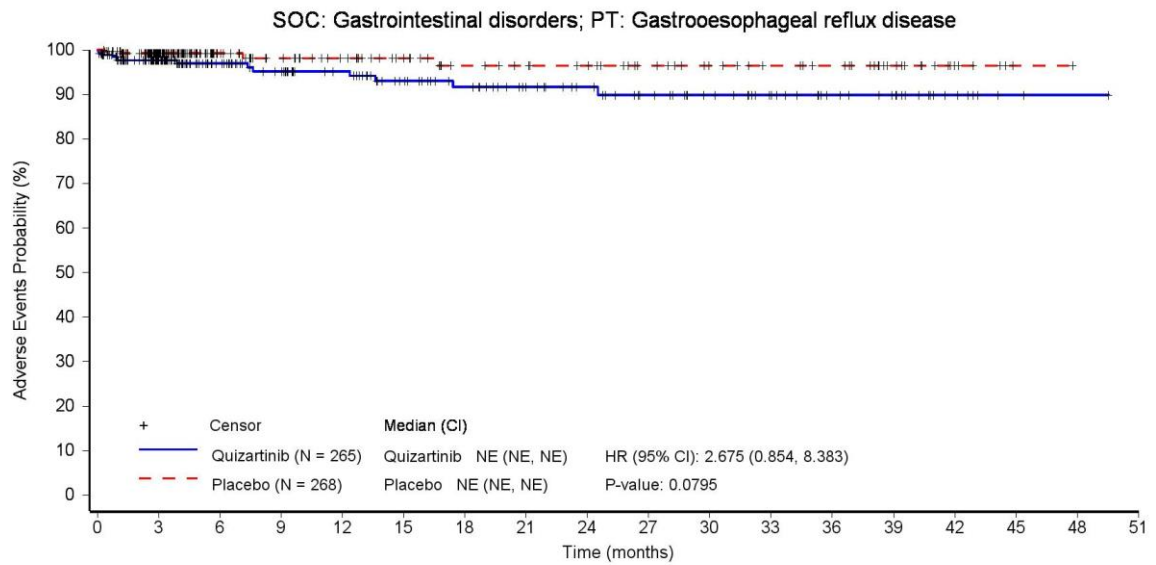
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	120	104	92	77	68	58	52	43	36	29	21	17	8	2	1	0
Placebo (N = 268)	268	157	98	83	72	62	51	48	45	37	31	27	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

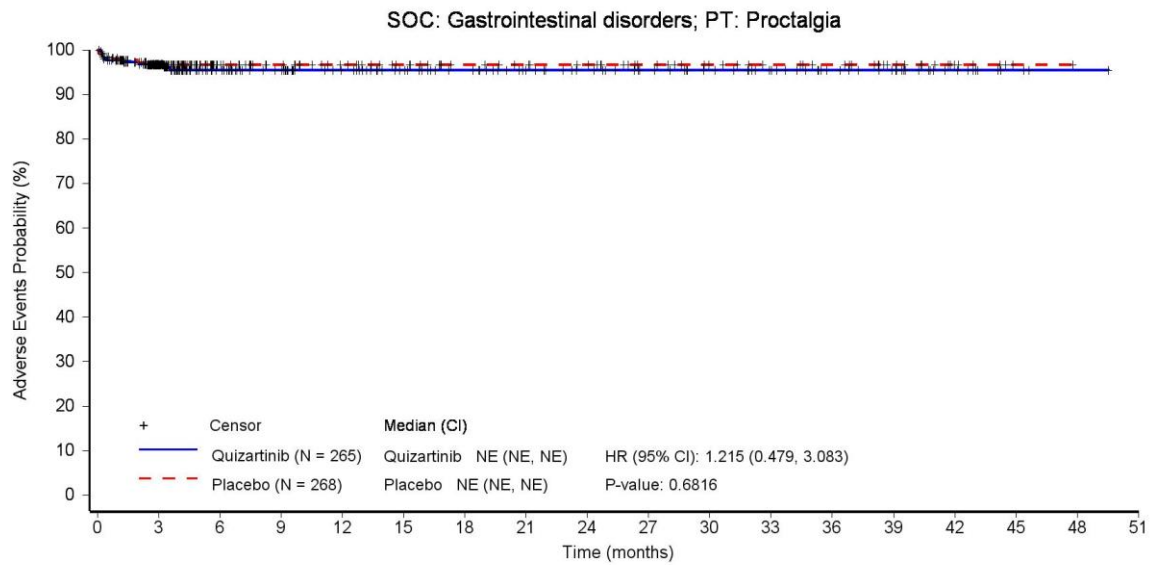
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	118	104	91	79	71	61	55	47	41	34	25	20	10	3	1	0
Placebo (N = 268)	268	151	92	79	68	60	50	47	44	35	29	25	22	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

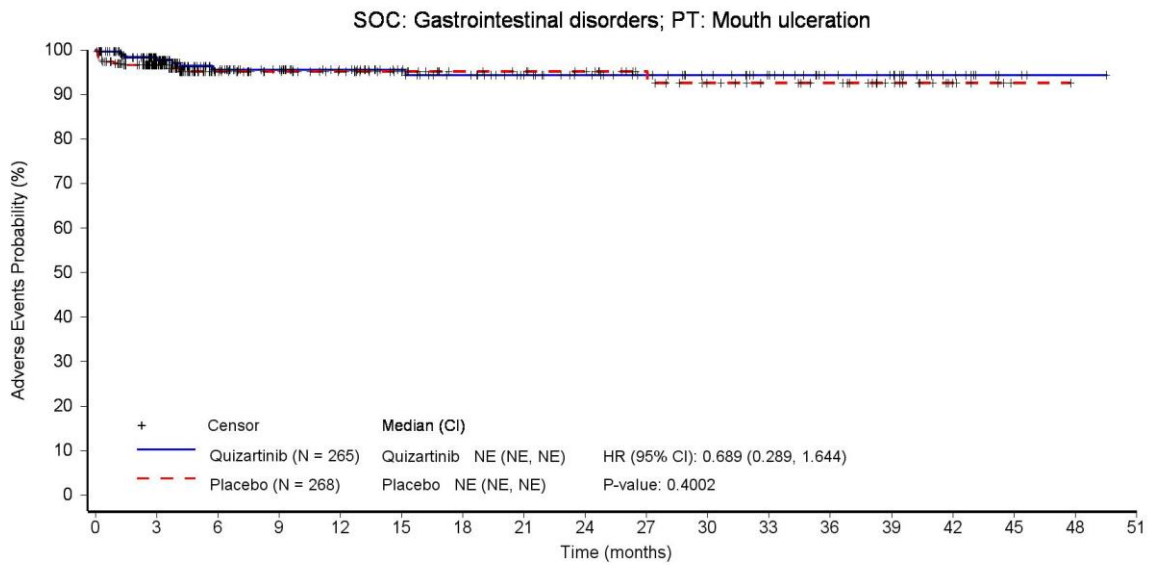
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	116	103	91	78	70	60	53	47	41	34	25	21	11	3	1	0
Placebo (N = 268)	268	153	95	81	71	61	51	49	46	37	31	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

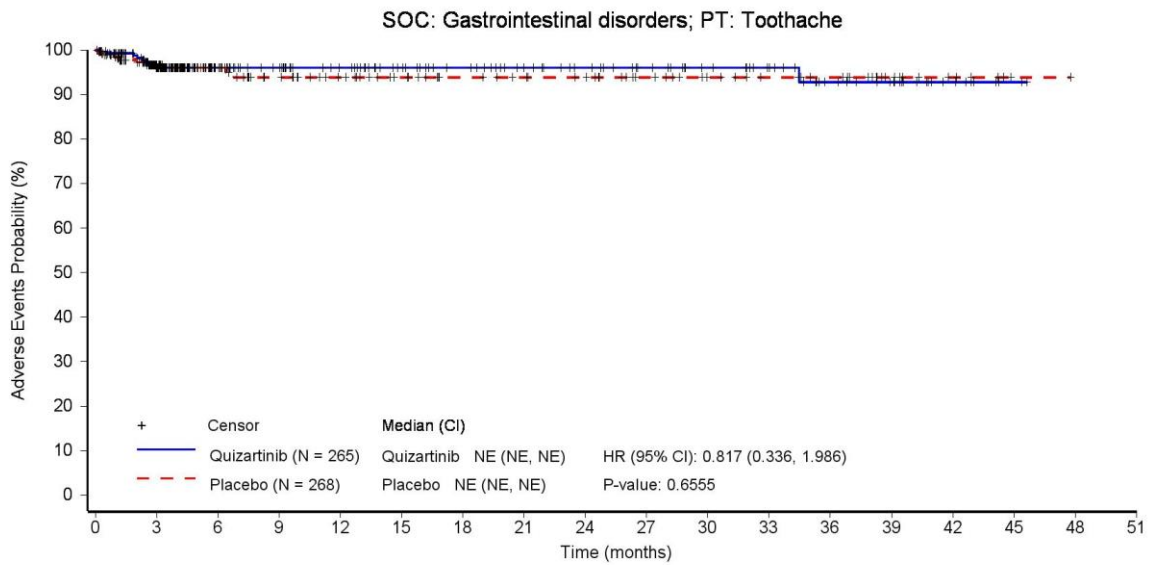
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	116	102	90	77	69	60	54	47	40	34	24	19	9	2	0	0
Placebo (N = 268)	268	149	92	77	66	58	49	46	43	34	28	24	21	12	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

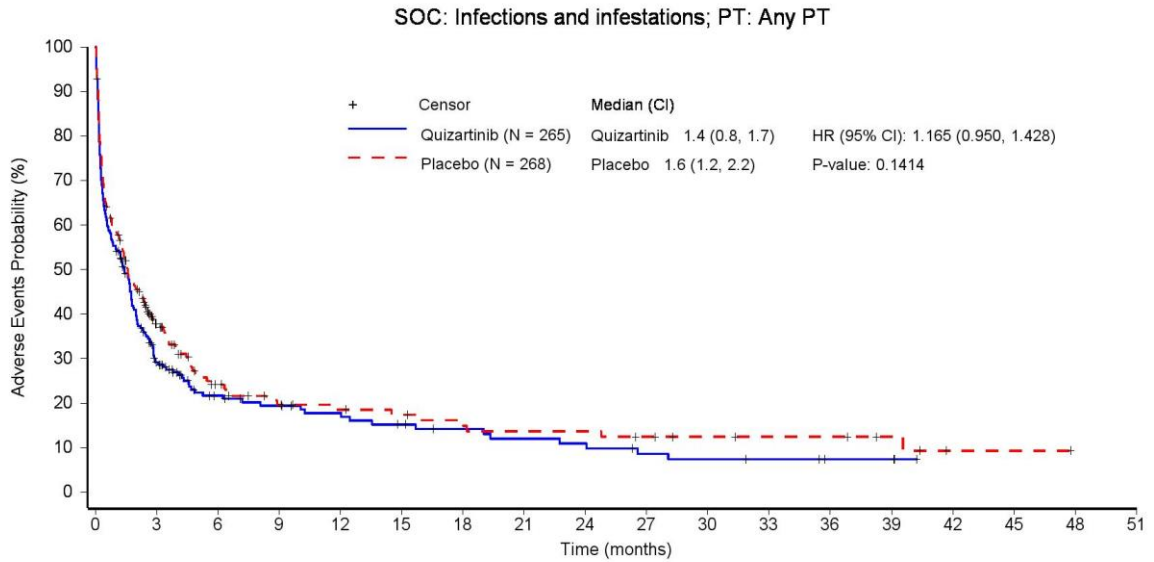
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	57	30	25	21	16	13	11	10	7	6	5	3	3	0	0	0	0
Placebo (N = 268)	268	60	29	20	17	15	13	11	11	9	7	6	6	4	1	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

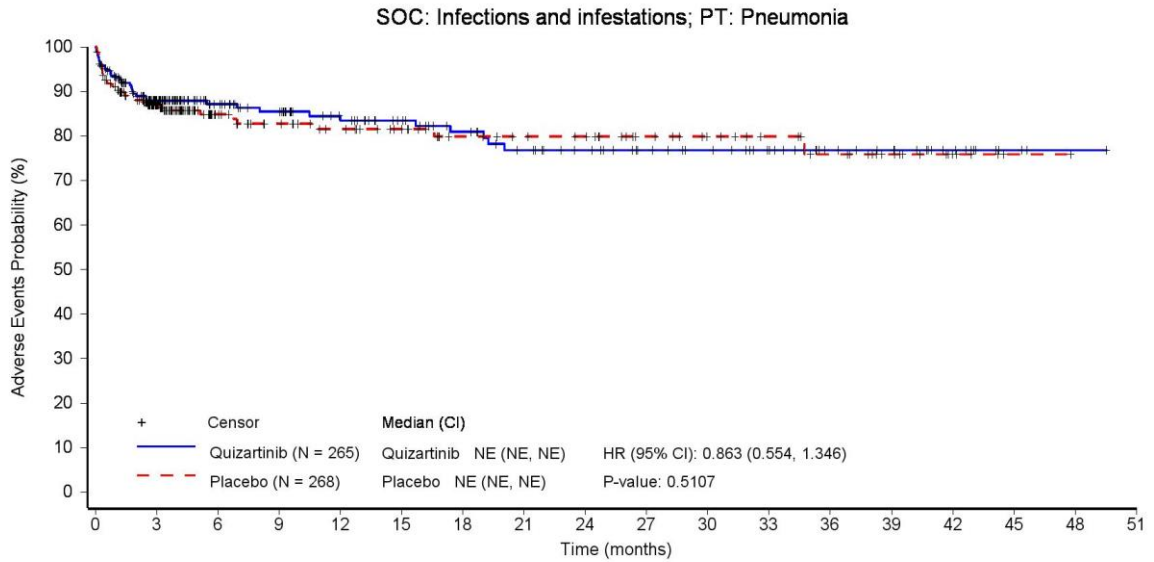
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	150	109	97	82	71	62	54	48	40	36	30	21	18	11	3	1	0
Placebo (N = 268)	268	141	86	72	62	54	45	42	40	31	26	22	18	12	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

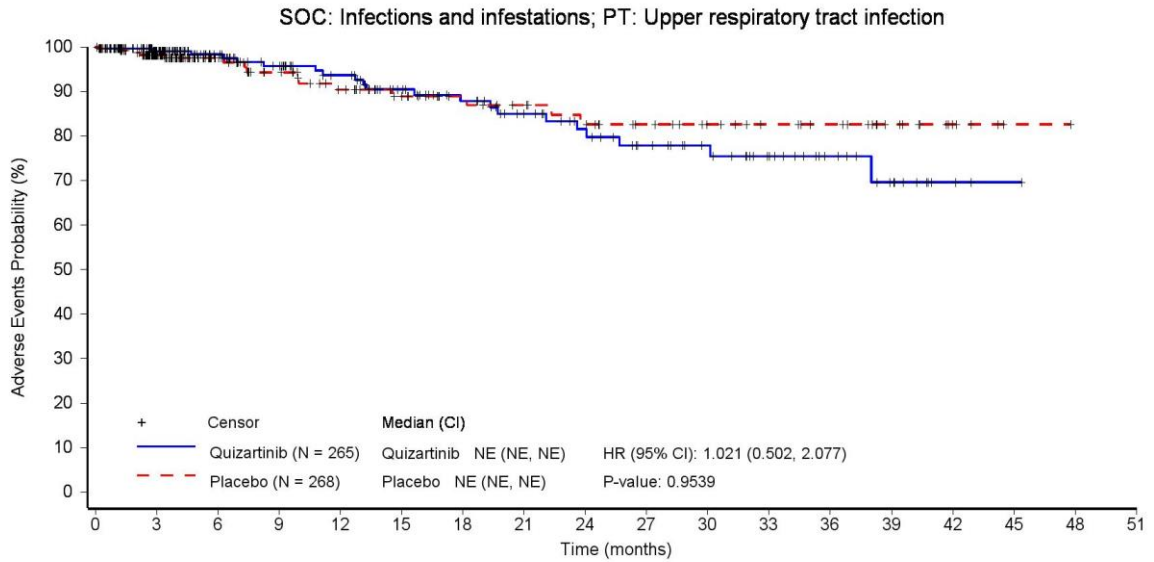
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	165	121	104	91	75	65	54	46	38	32	24	16	10	3	1	0	0
Placebo (N = 268)	268	155	97	80	66	55	46	42	38	31	26	22	19	12	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

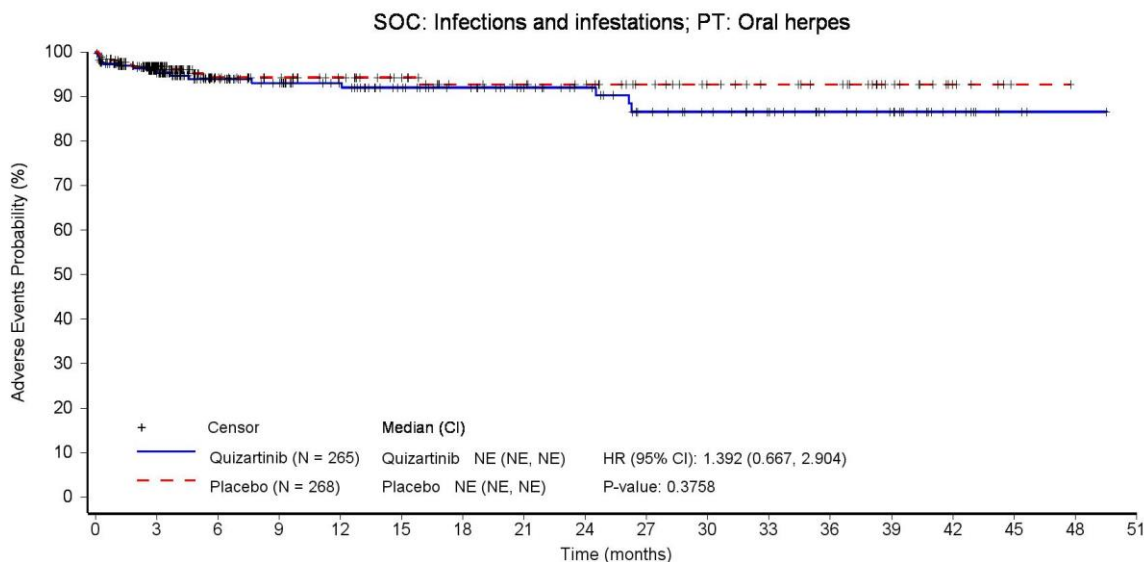
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	158	118	104	92	78	70	60	54	44	39	33	25	21	11	3	1	0
Placebo (N = 268)	268	153	93	81	71	62	51	49	46	37	31	27	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

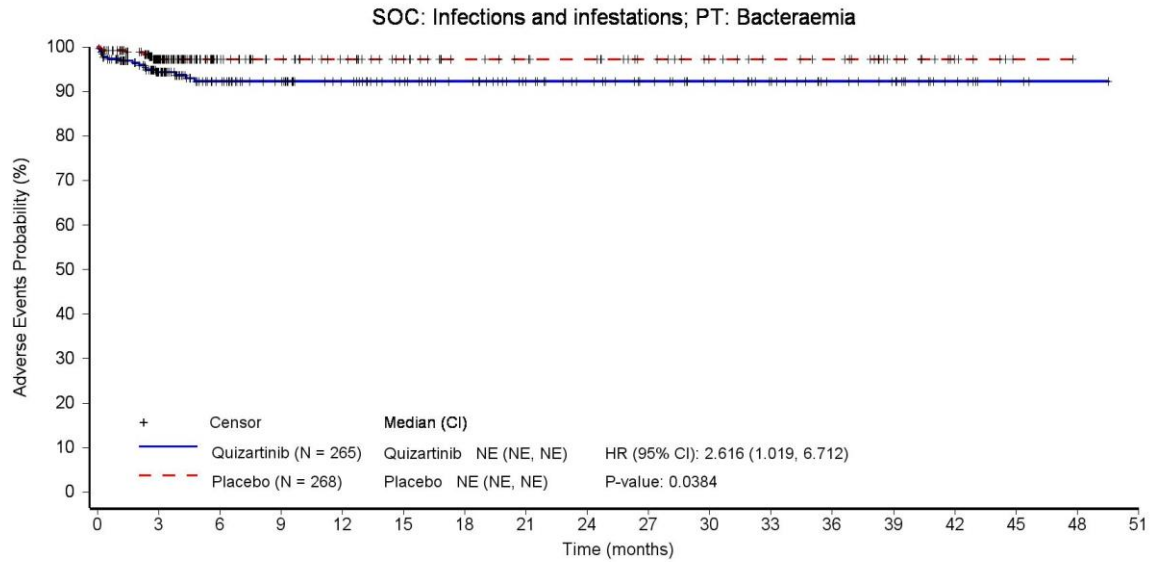
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	120	106	93	81	73	62	55	47	40	33	24	20	10	3	1	0
Placebo (N = 268)	268	152	93	79	68	58	48	45	43	35	29	25	23	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

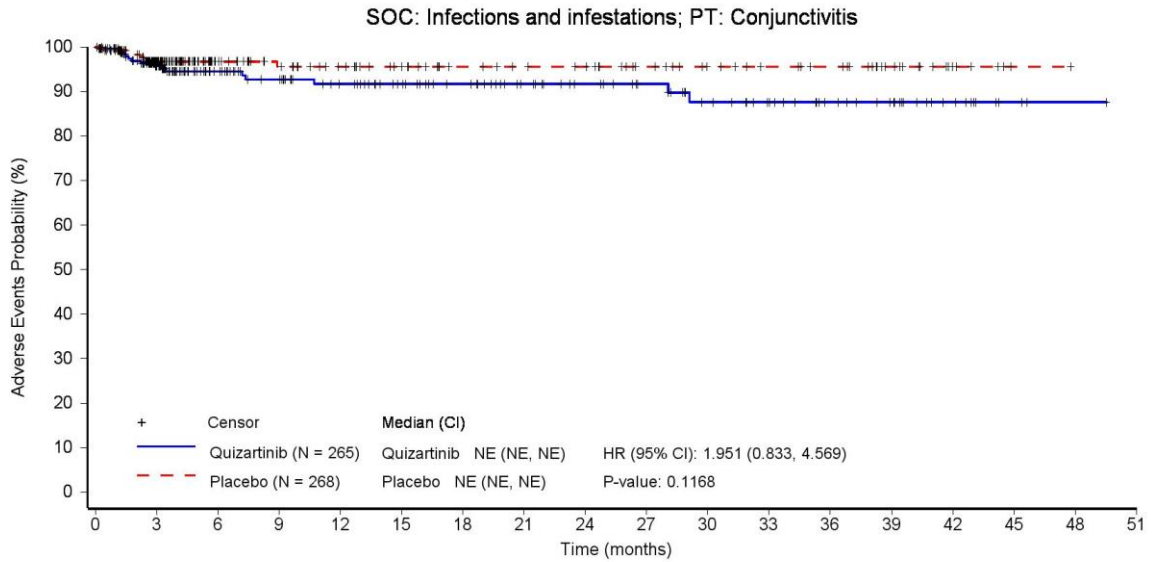
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	158	116	102	90	79	71	61	54	47	39	33	25	20	11	3	1	0
Placebo (N = 268)	268	152	95	80	70	61	52	49	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

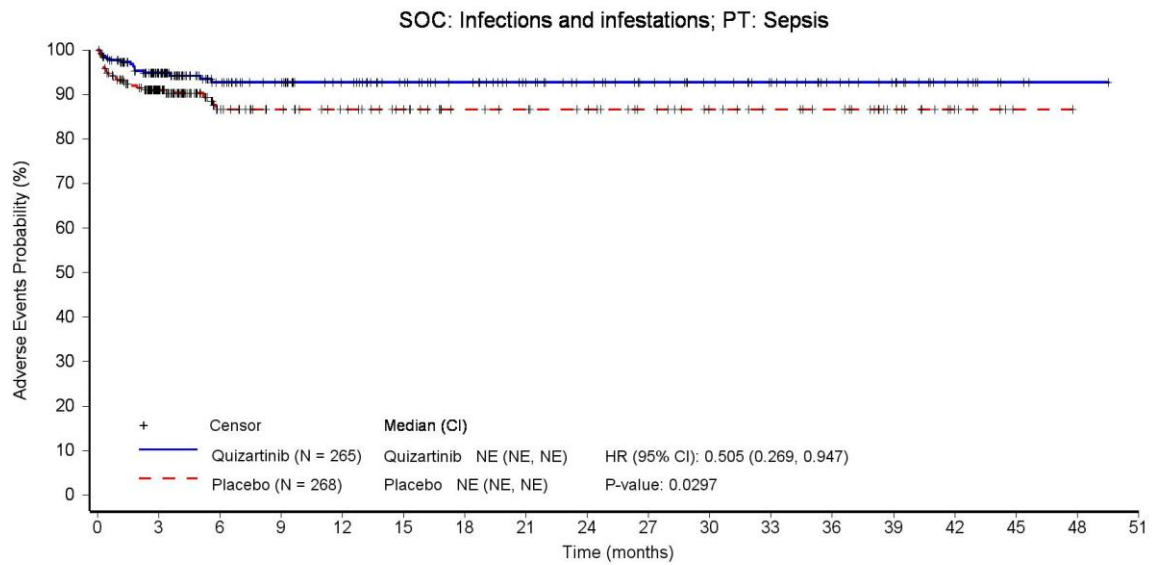
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	118	105	92	80	72	61	54	46	40	34	25	20	11	3	1	0
Placebo (N = 268)	268	146	89	76	68	60	50	48	45	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

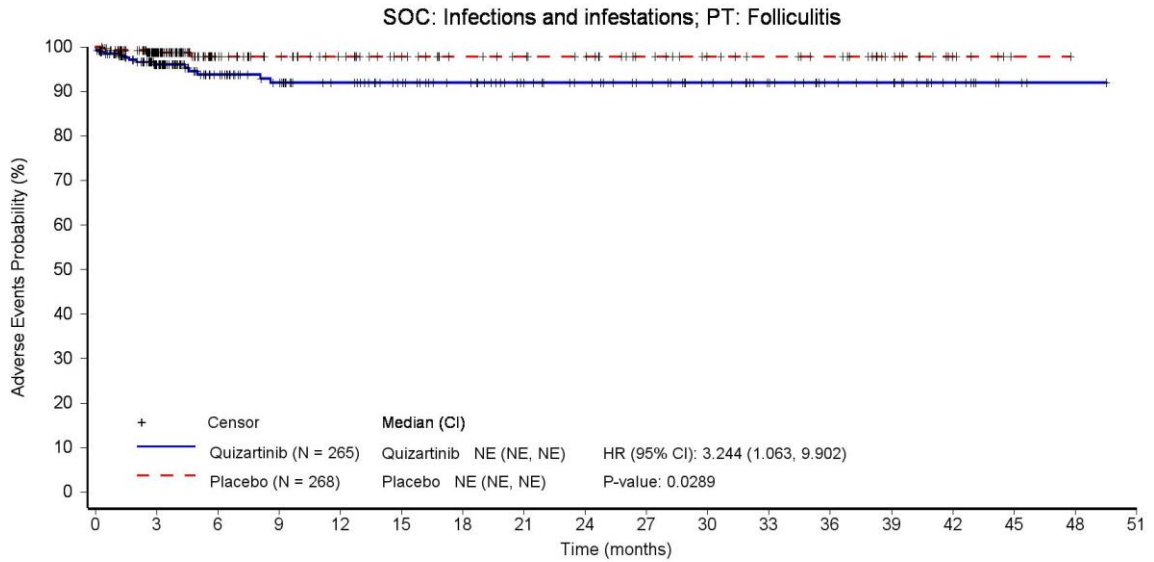
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	114	98	87	76	68	57	52	45	38	31	23	20	11	3	1	0
Placebo (N = 268)	268	154	96	82	71	61	52	49	46	37	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

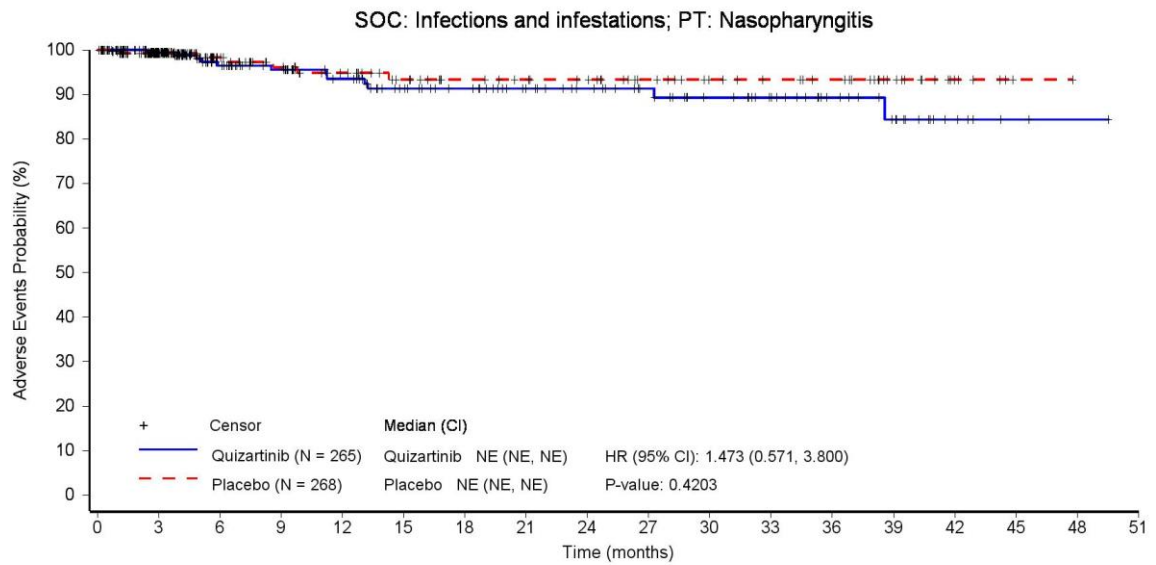
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	165	118	104	91	76	69	59	53	45	37	31	22	16	7	2	1	0
Placebo (N = 268)	268	155	97	81	70	60	51	48	45	36	30	27	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

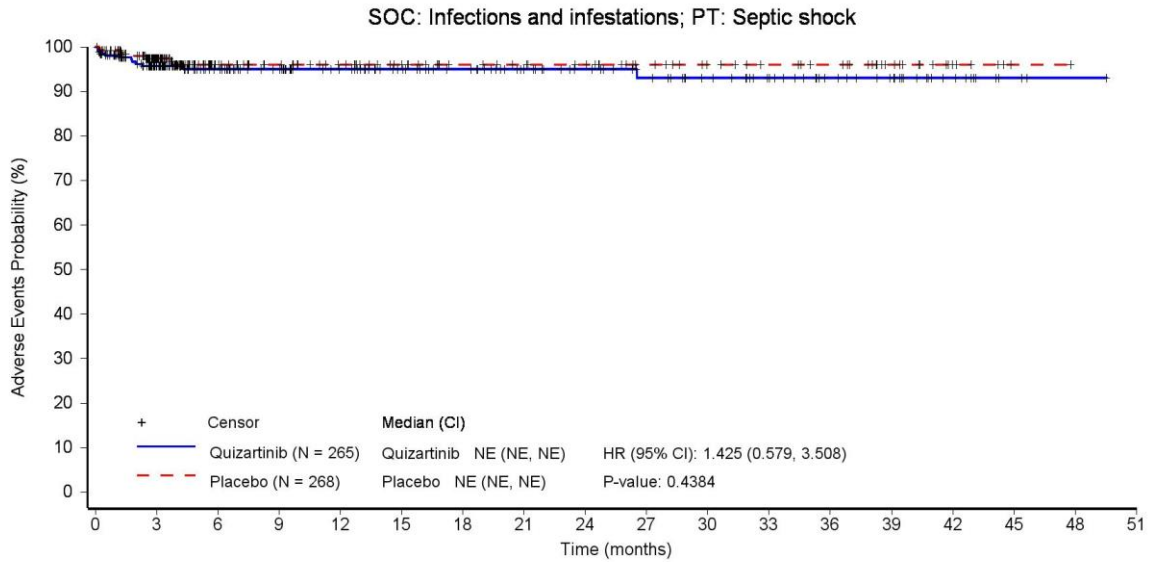
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	74	63	56	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	156	97	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

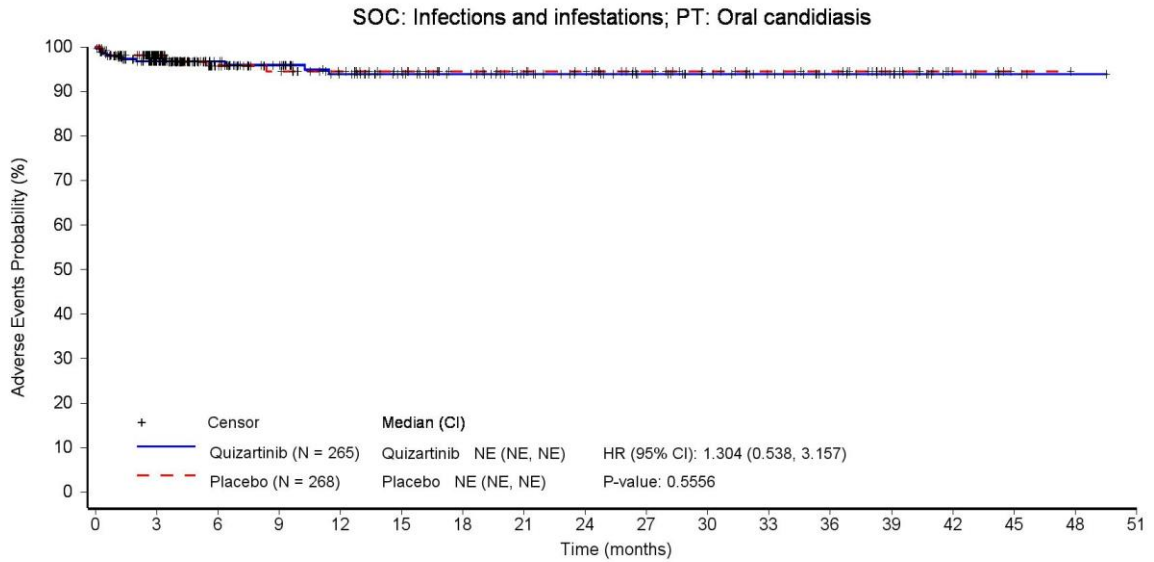
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	120	105	90	77	69	59	53	46	39	32	24	19	10	3	1	0
Placebo (N = 268)	268	153	91	76	65	56	46	43	40	31	26	23	22	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

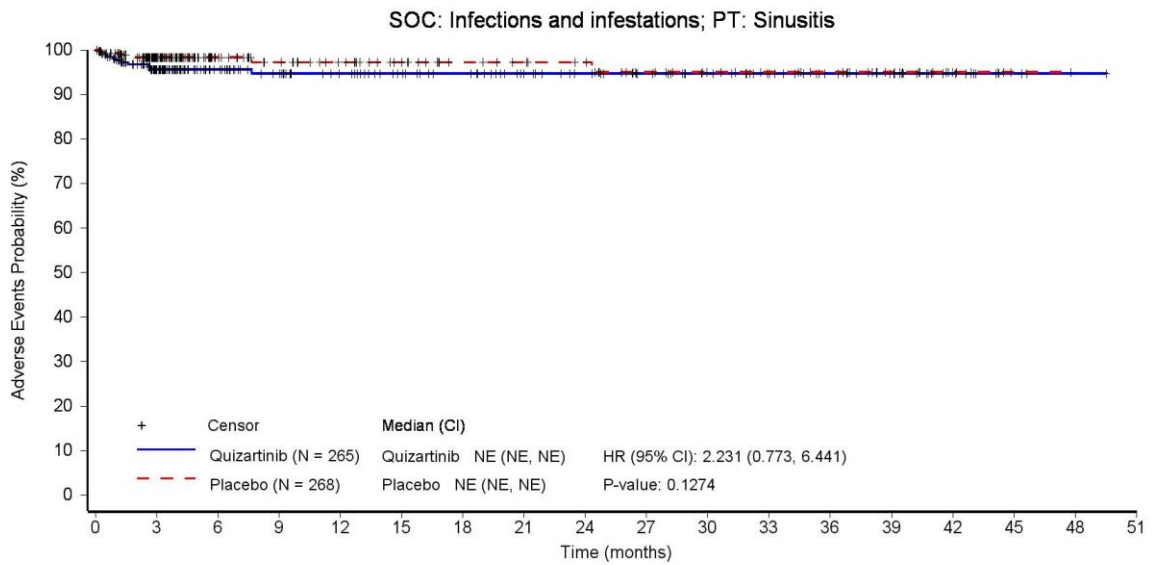
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	115	100	89	78	72	61	55	48	41	34	26	21	11	3	1	0
Placebo (N = 268)	268	154	97	82	71	61	51	48	45	35	30	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

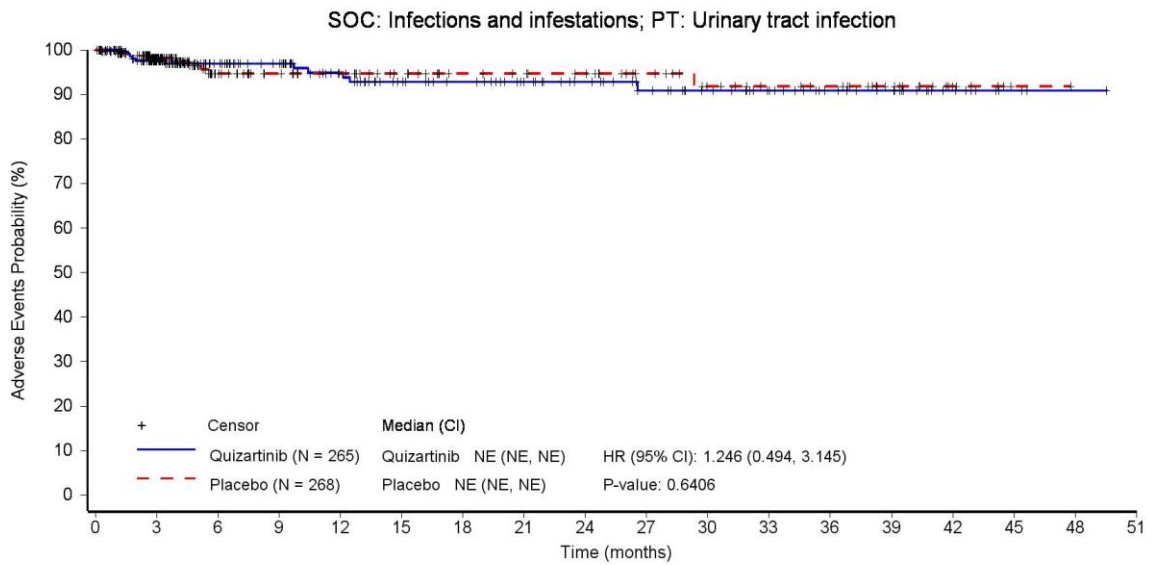
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	120	106	91	77	71	62	55	46	39	32	24	20	10	3	1	0
Placebo (N = 268)	268	154	95	81	70	61	51	49	46	37	30	26	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

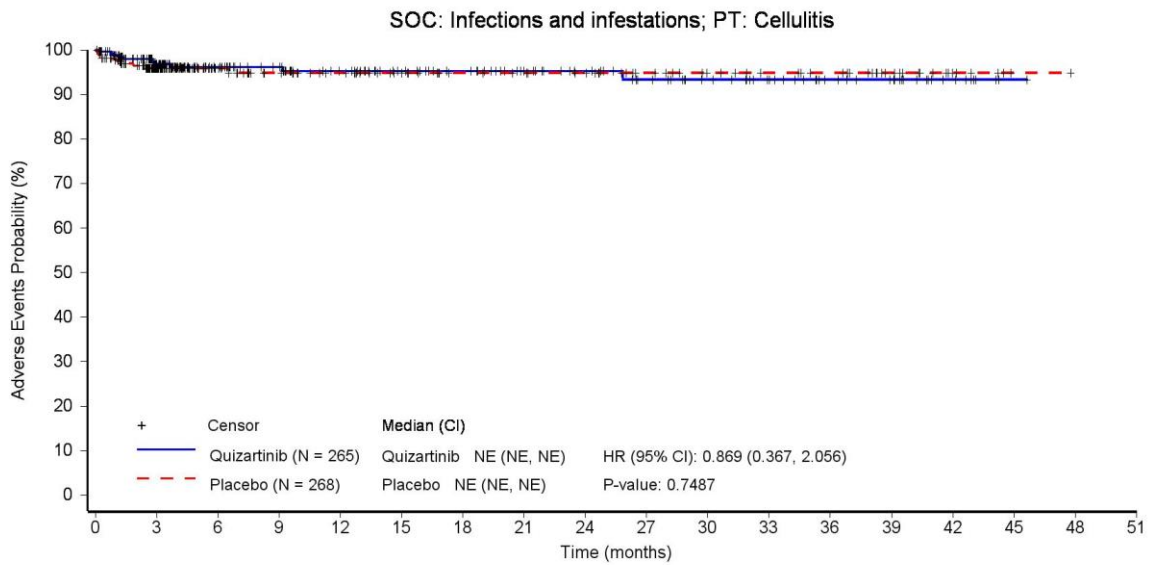
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	119	106	92	79	72	61	54	46	39	32	23	19	9	1	0	0
Placebo (N = 268)	268	151	96	81	71	61	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

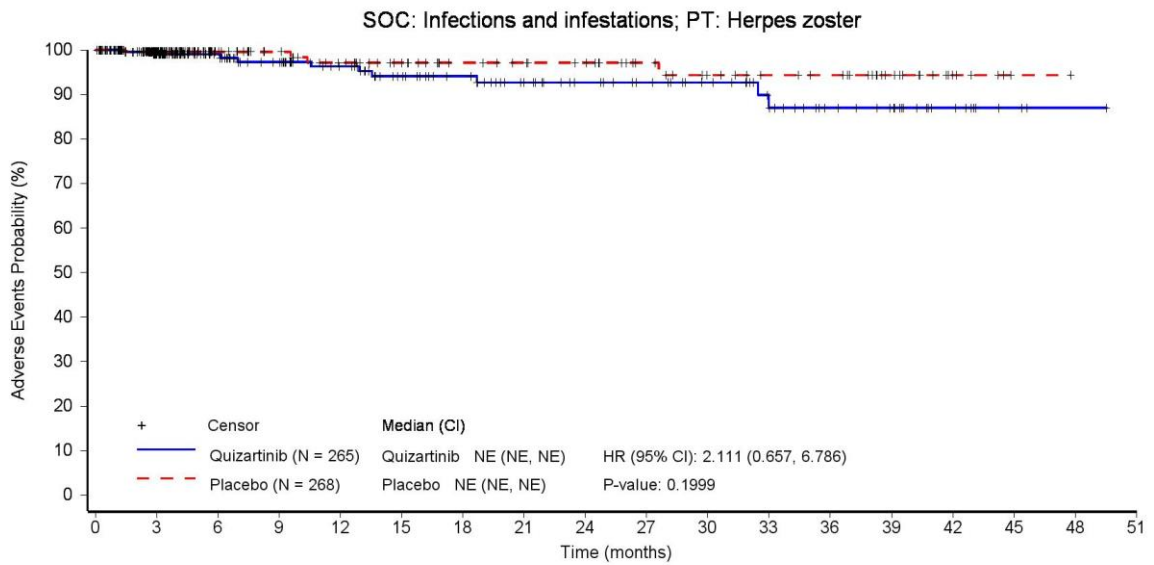
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	164	122	106	92	77	69	58	51	45	39	30	22	18	9	3	1	0
Placebo (N = 268)	268	156	97	83	71	61	51	48	45	36	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

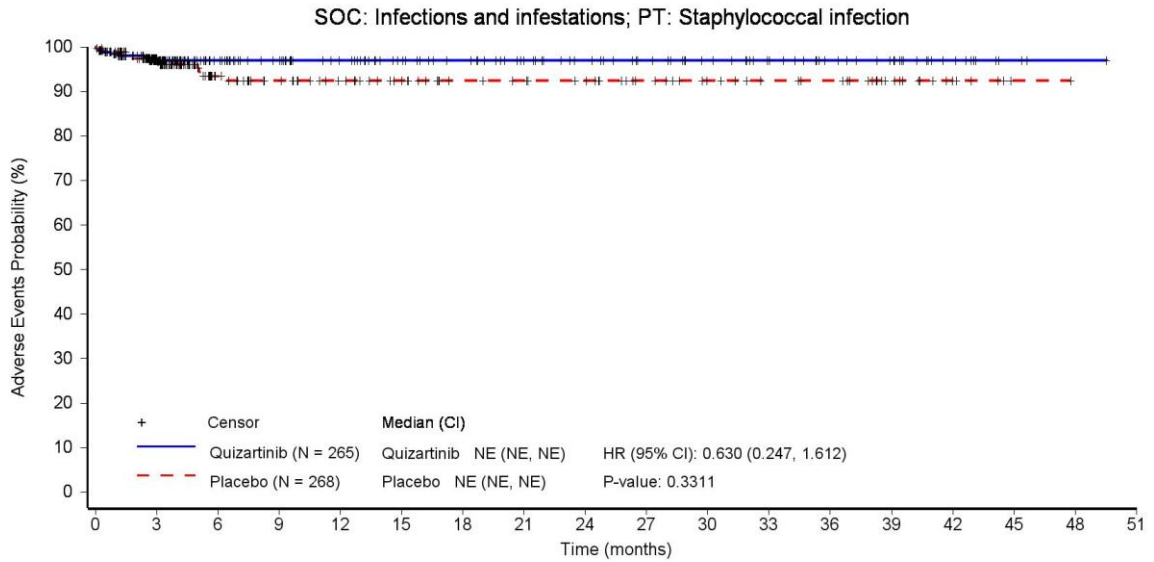
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	162	119	105	93	80	73	63	56	48	41	34	26	21	11	3	1	0
Placebo (N = 268)	268	154	94	80	69	60	50	48	45	36	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

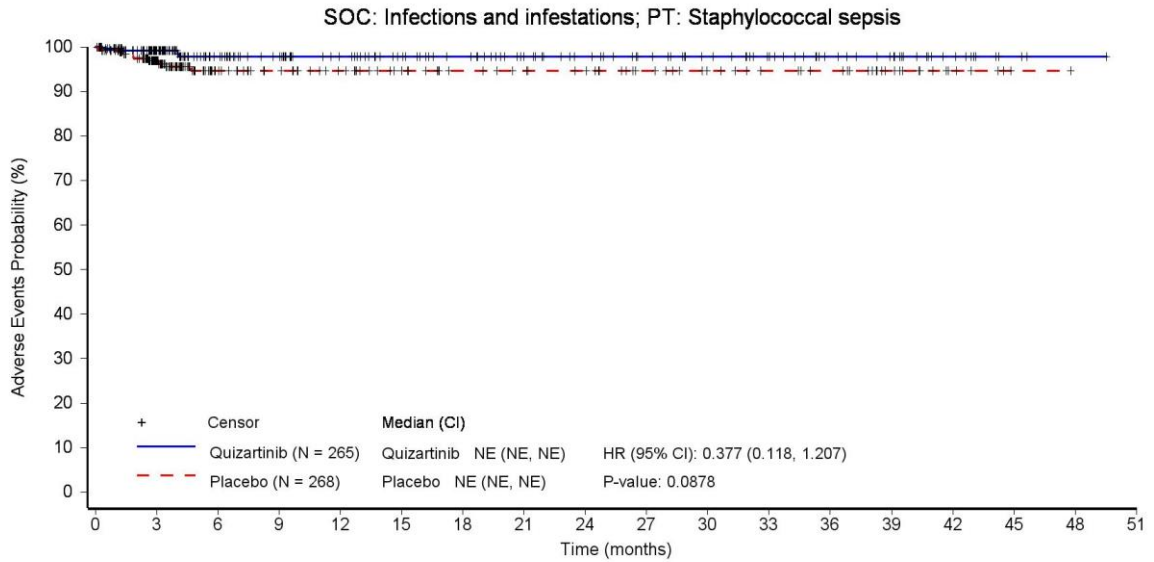
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	166	122	108	95	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	151	93	80	69	59	51	48	45	37	31	27	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

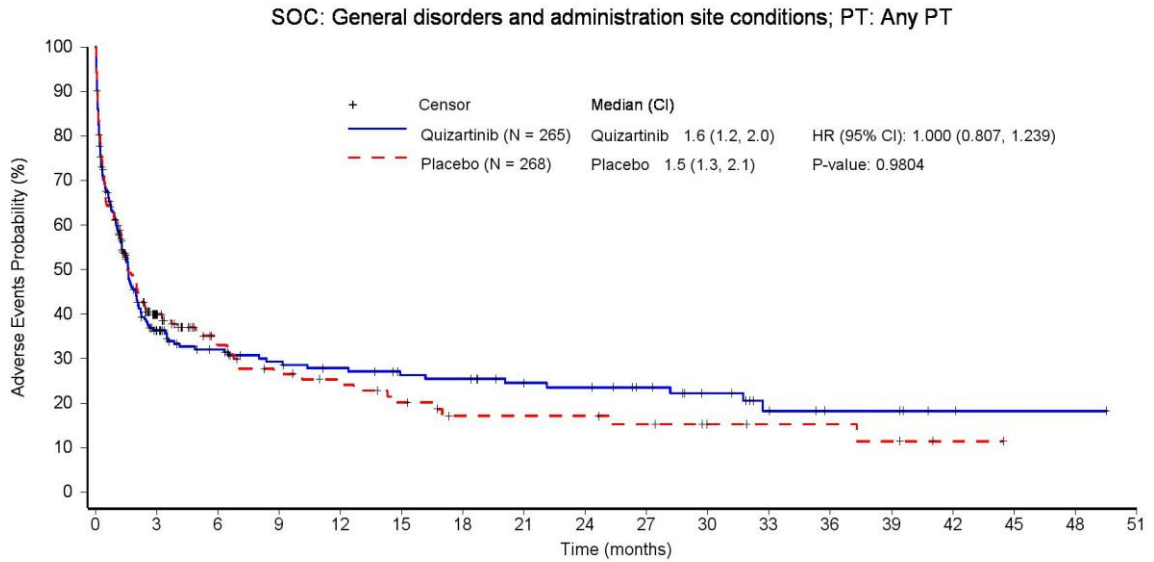
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	66	49	41	37	32	31	25	24	19	14	8	5	5	2	1	1	0
Placebo (N = 268)	268	58	32	23	19	15	10	10	10	8	5	4	4	3	1	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

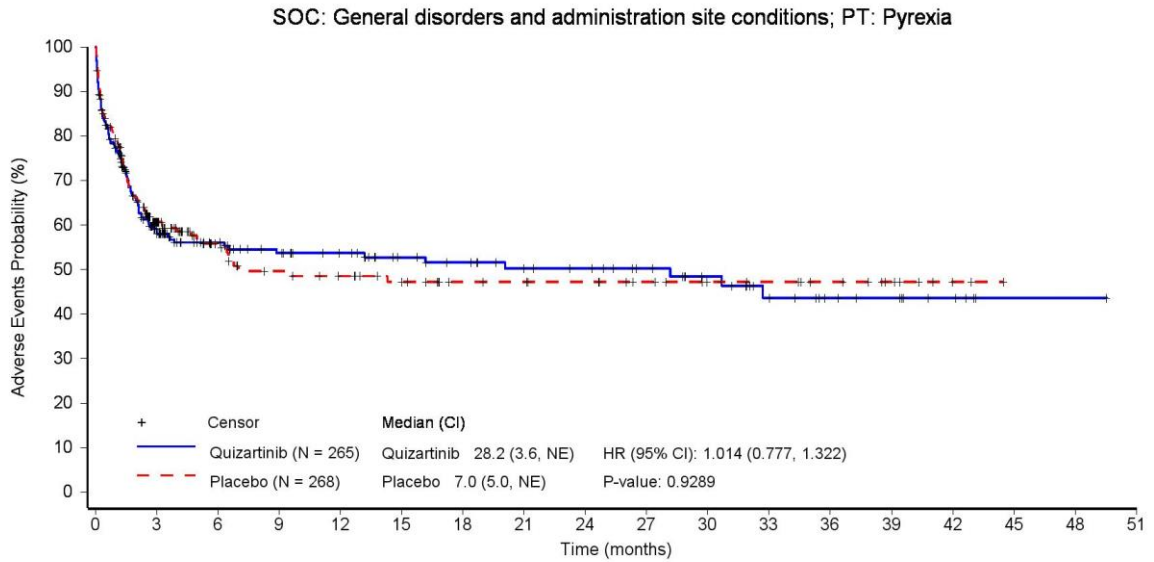
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	102	76	64	57	47	43	37	35	29	23	16	11	9	5	1	1	0
Placebo (N = 268)	268	92	55	44	40	34	28	27	25	21	17	15	12	8	2	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

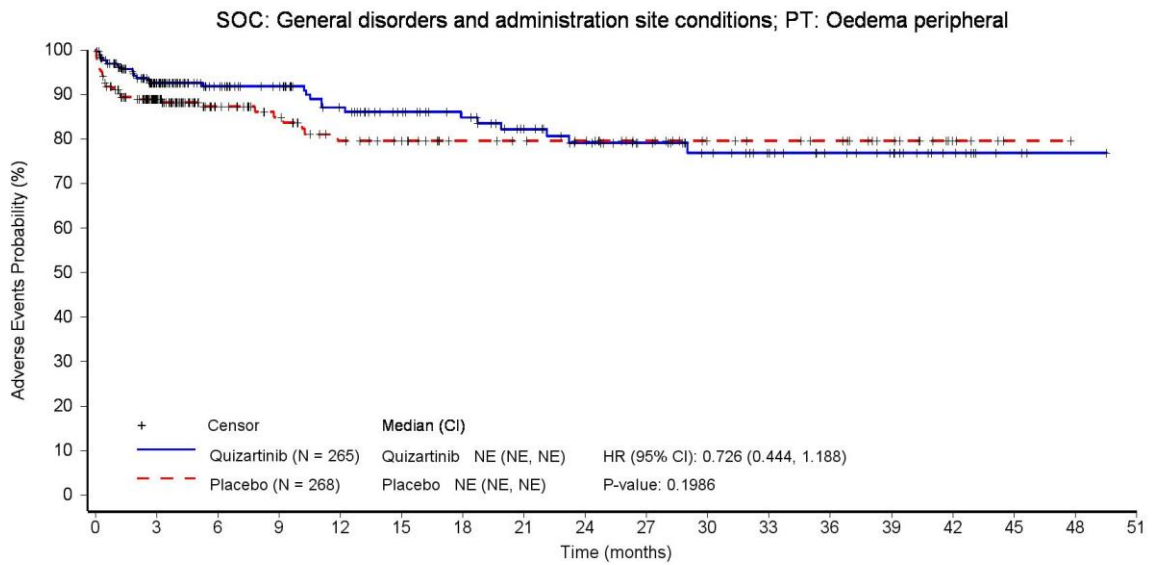
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	155	117	105	89	76	68	57	49	41	33	27	21	17	9	3	1	0
Placebo (N = 268)	268	137	85	70	56	50	40	38	36	29	23	21	19	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

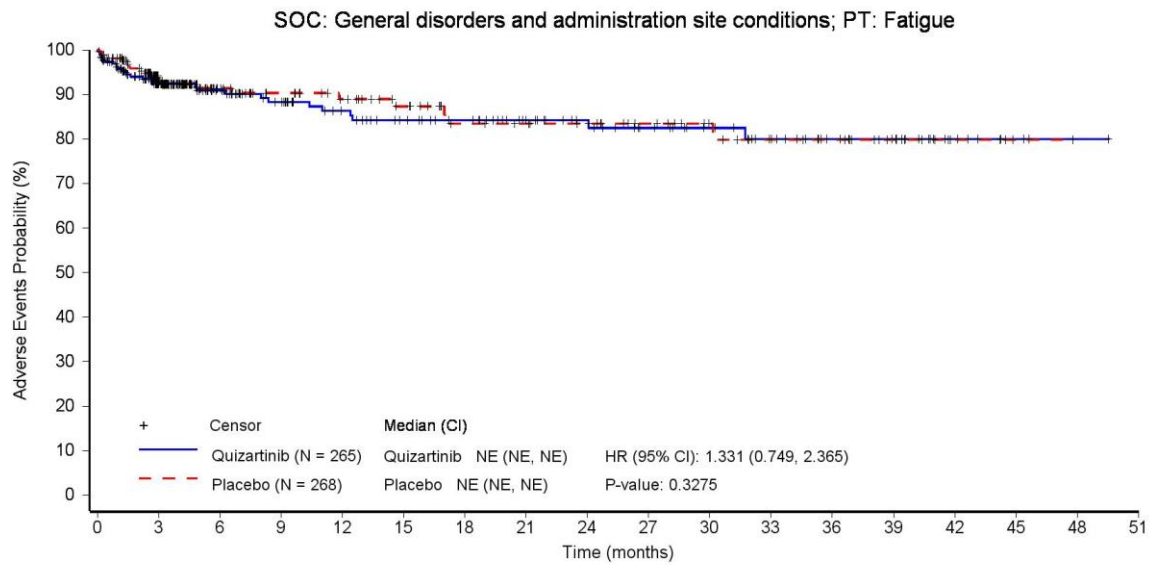
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	154	112	97	83	73	67	56	49	41	35	28	19	16	7	3	1	0
Placebo (N = 268)	268	145	88	73	63	54	42	40	37	29	23	19	18	12	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

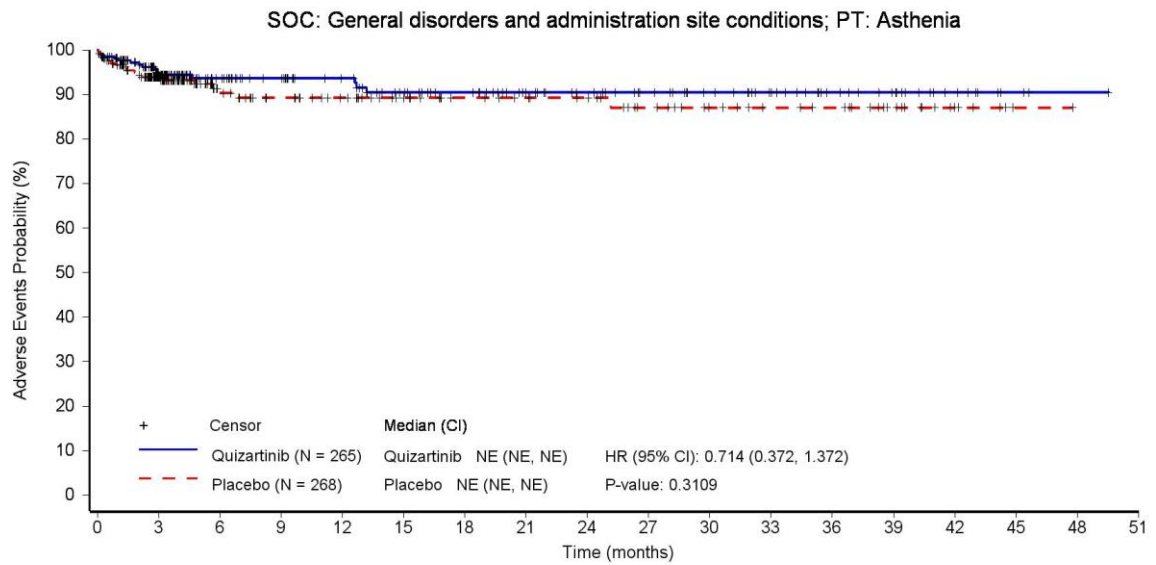
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	155	115	102	91	78	71	60	54	46	39	32	23	18	10	3	1	0
Placebo (N = 268)	268	147	87	76	67	57	49	46	43	34	28	24	22	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

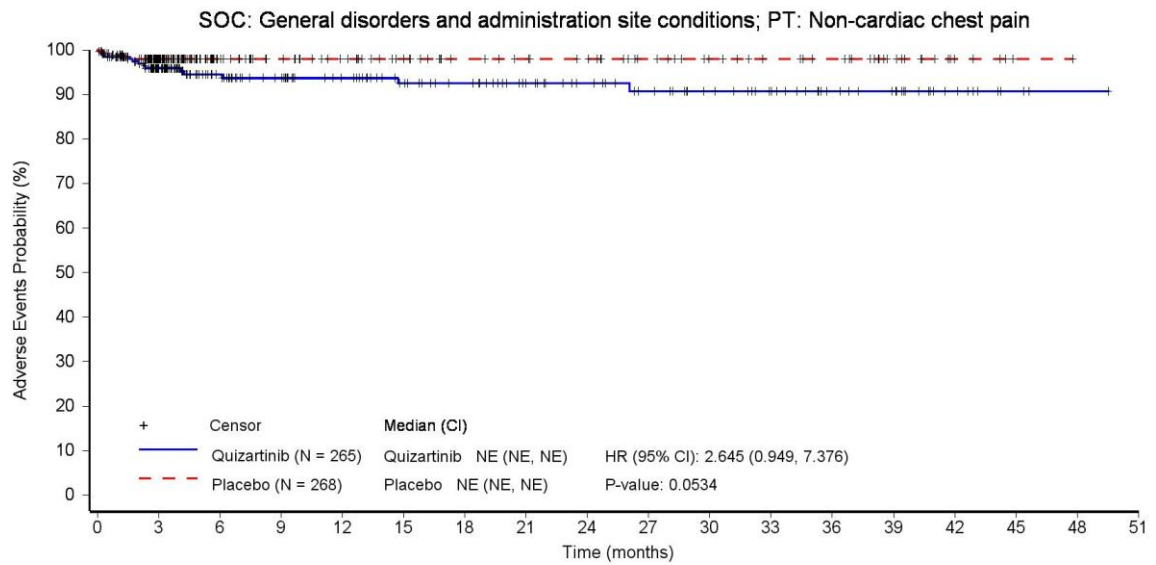
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	119	104	92	79	72	61	54	46	39	33	24	20	10	3	1	0
Placebo (N = 268)	268	154	96	82	72	62	52	49	46	37	31	27	24	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

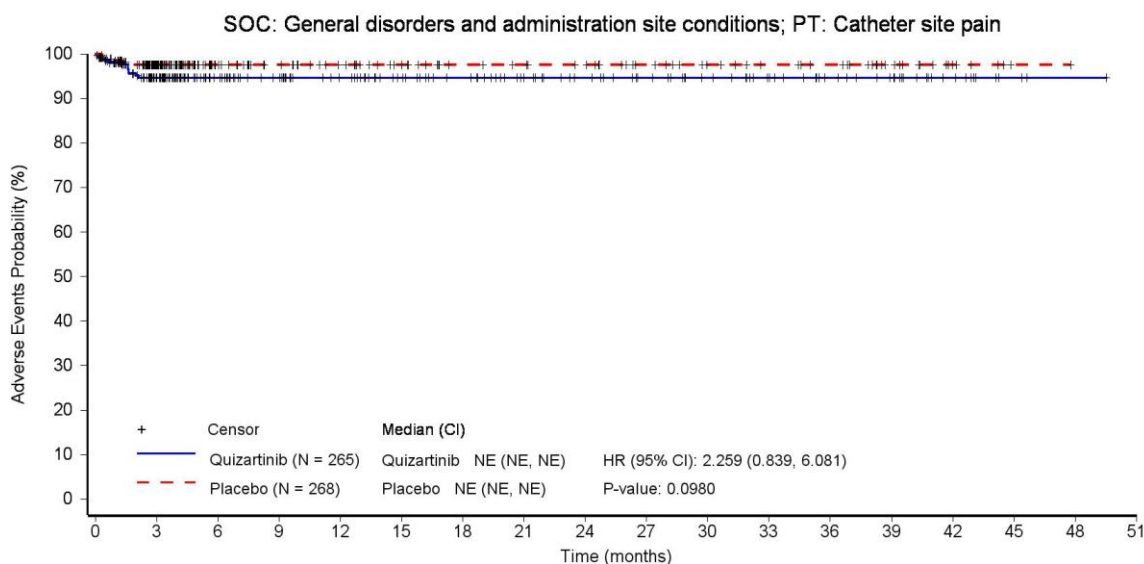
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	121	107	95	82	74	63	56	48	41	34	26	21	11	3	1	0
Placebo (N = 268)	268	153	97	83	72	62	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

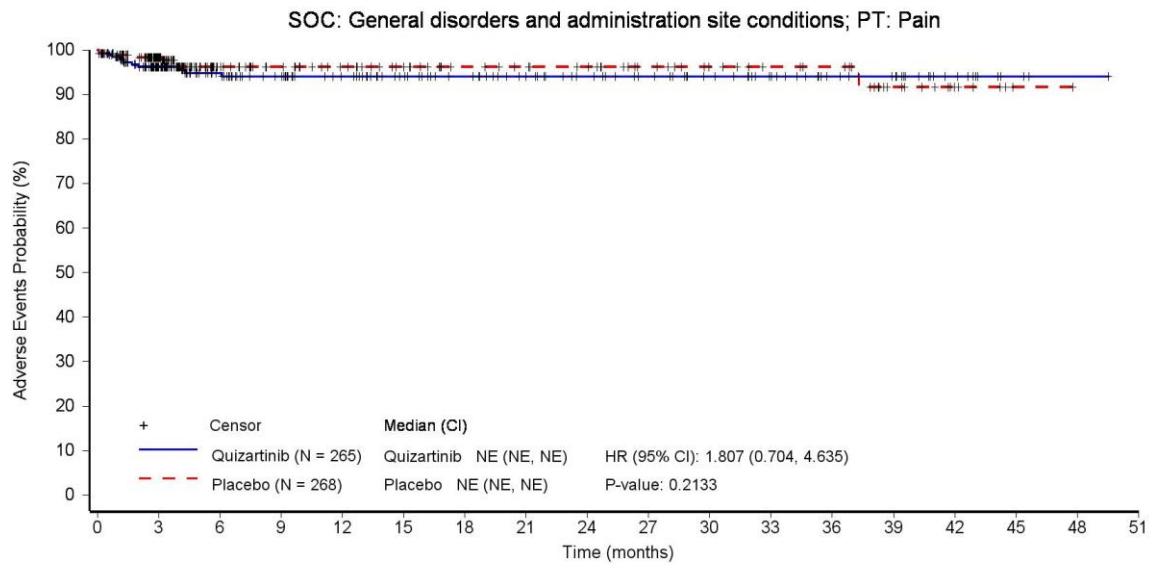
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	160	119	104	92	79	71	62	55	48	41	34	25	21	11	3	1	0
Placebo (N = 268)	268	155	95	81	70	61	51	48	45	36	30	26	24	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

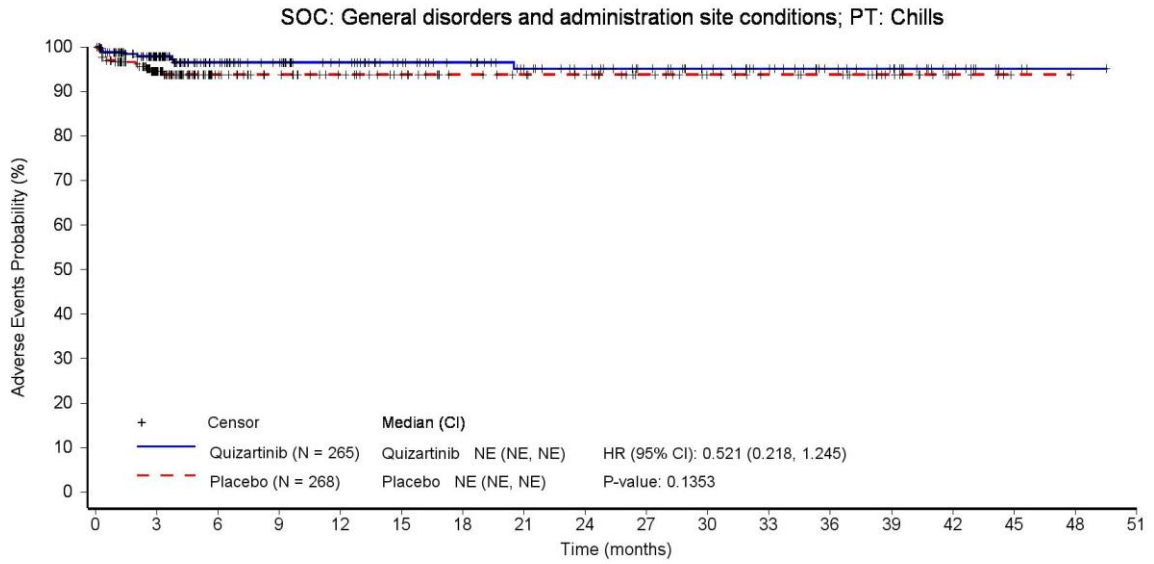
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	120	106	93	80	72	62	56	48	41	35	26	21	11	3	1	0
Placebo (N = 268)	268	147	93	80	69	60	51	48	45	36	30	26	24	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

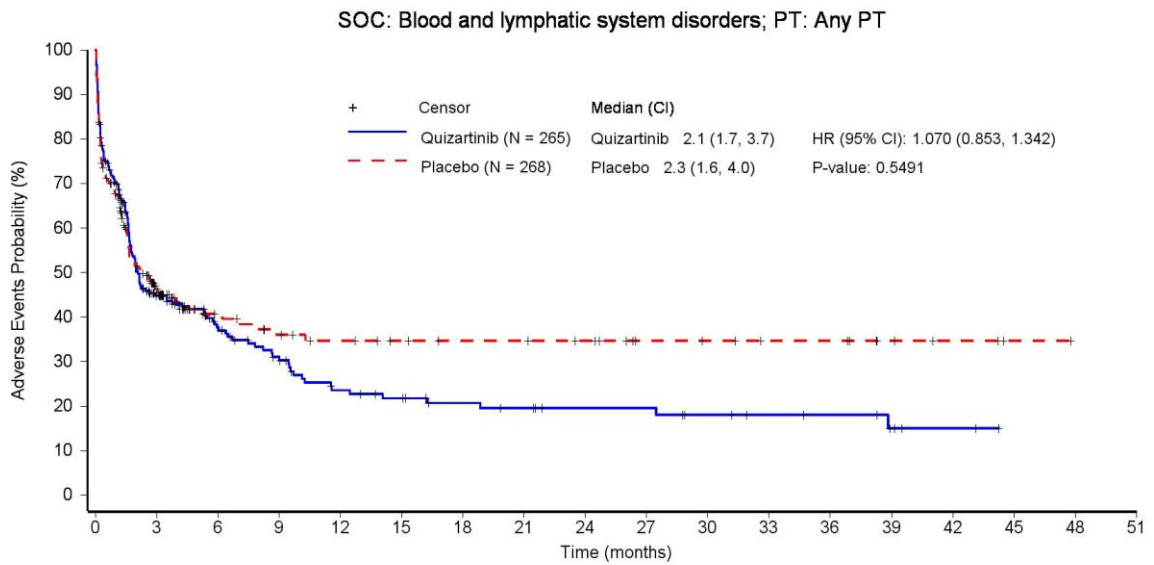
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	81	54	40	27	23	18	16	13	13	10	8	7	4	2	0	0	0
Placebo (N = 268)	268	70	36	29	25	22	20	20	18	12	11	9	9	5	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

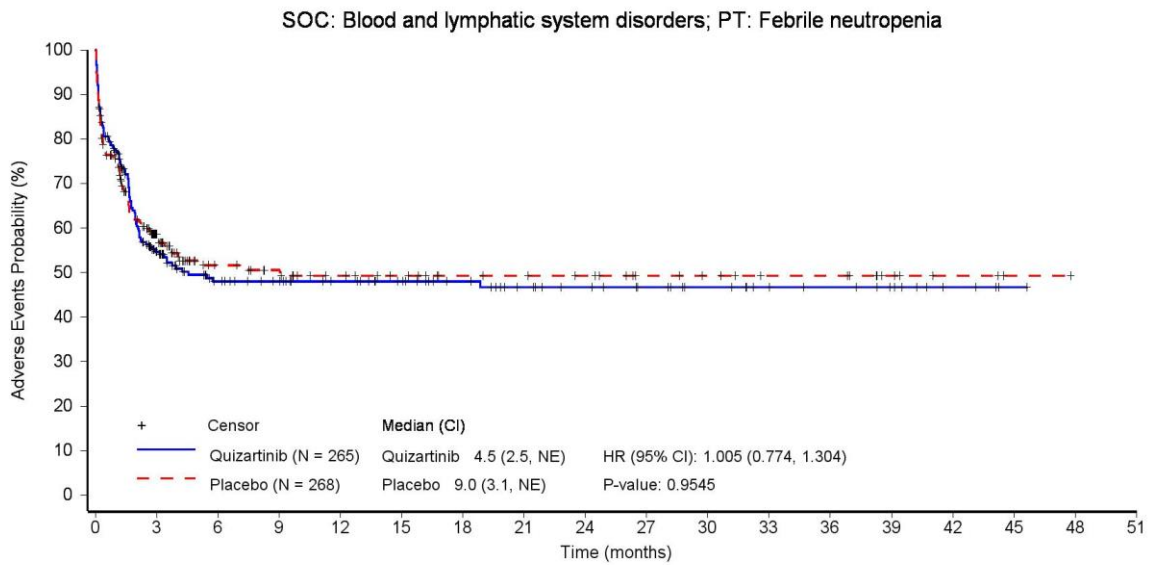
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	93	64	57	50	44	37	30	26	22	18	14	12	9	4	1	0	0
Placebo (N = 268)	268	86	47	41	34	30	25	24	22	16	14	11	11	6	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

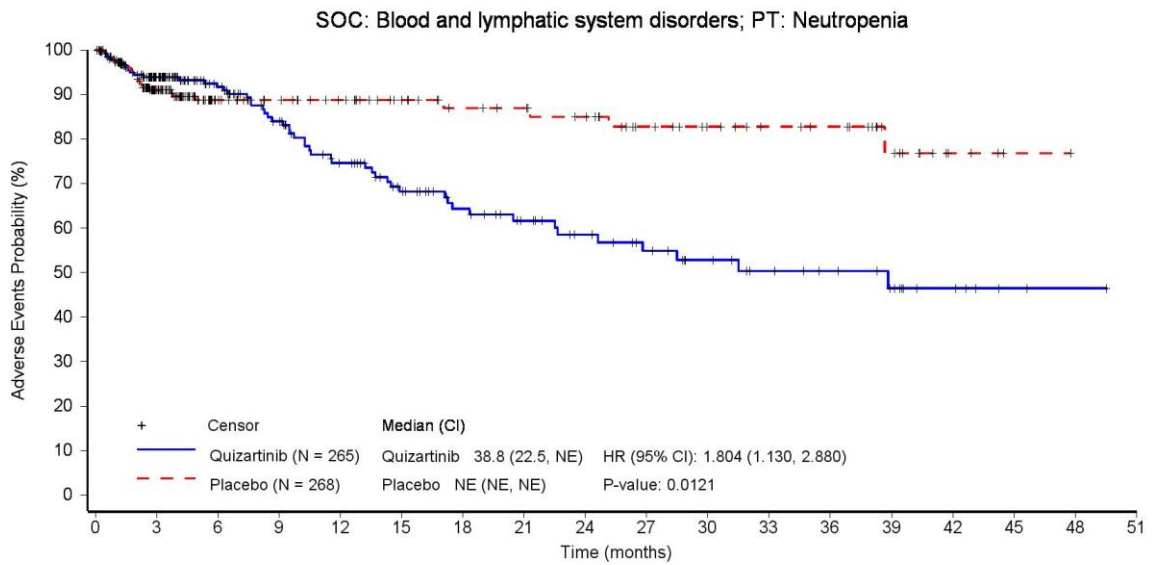
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	117	95	76	61	50	42	35	29	23	18	15	11	6	2	1	0
Placebo (N = 268)	268	146	89	76	67	57	48	46	42	32	27	23	21	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

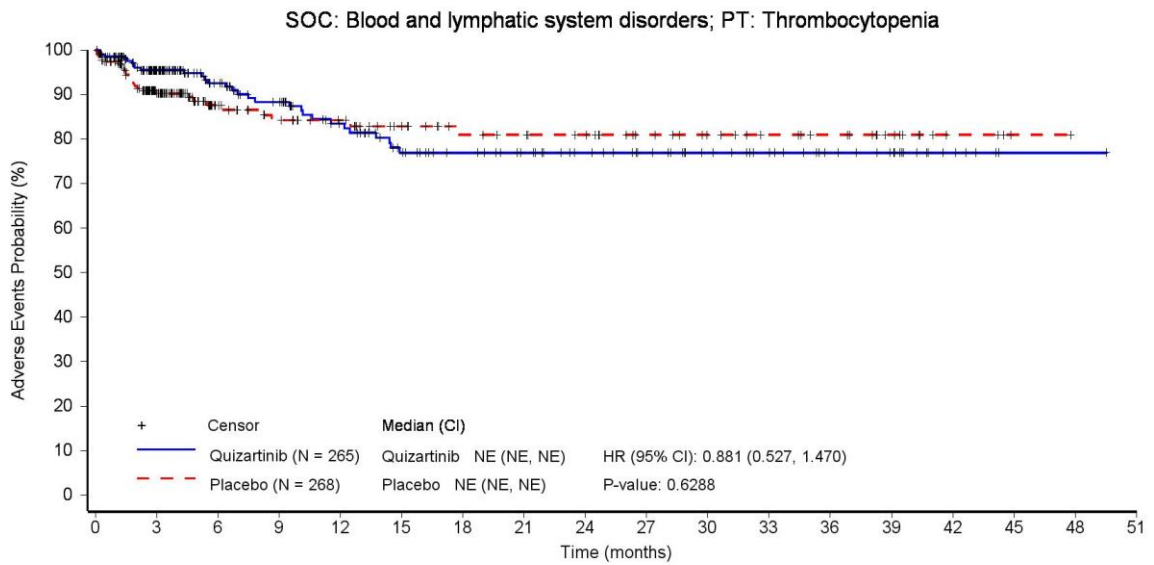
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	117	100	82	67	59	53	46	39	32	27	20	16	7	1	1	0
Placebo (N = 268)	268	142	85	71	62	51	43	41	38	30	25	21	18	12	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

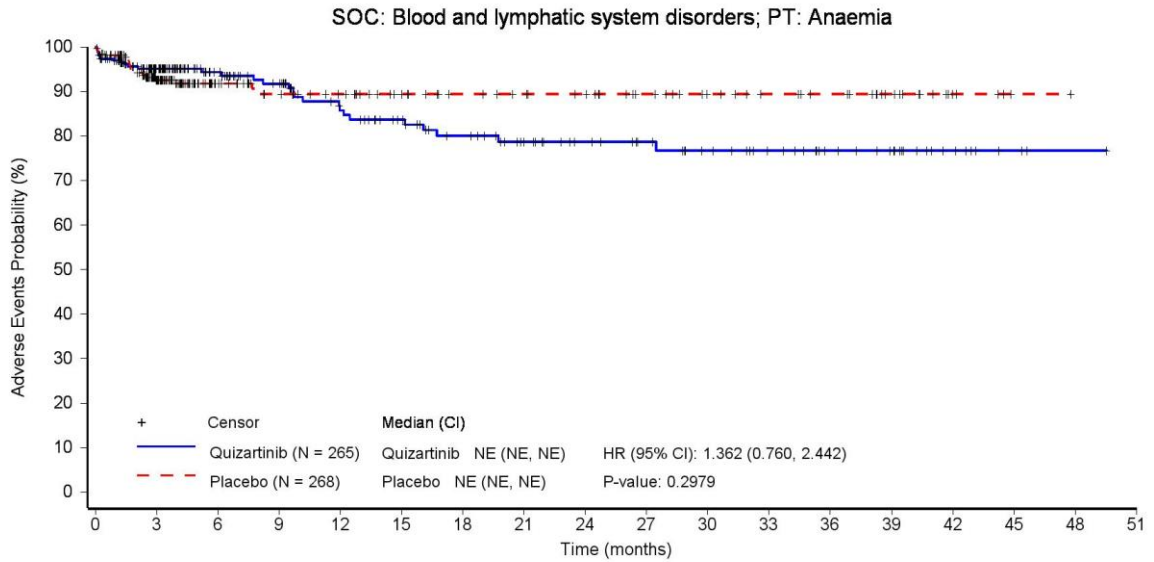
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	117	101	84	73	63	53	46	41	35	29	22	18	9	3	1	0
Placebo (N = 268)	268	146	90	74	65	55	48	45	42	34	28	24	21	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

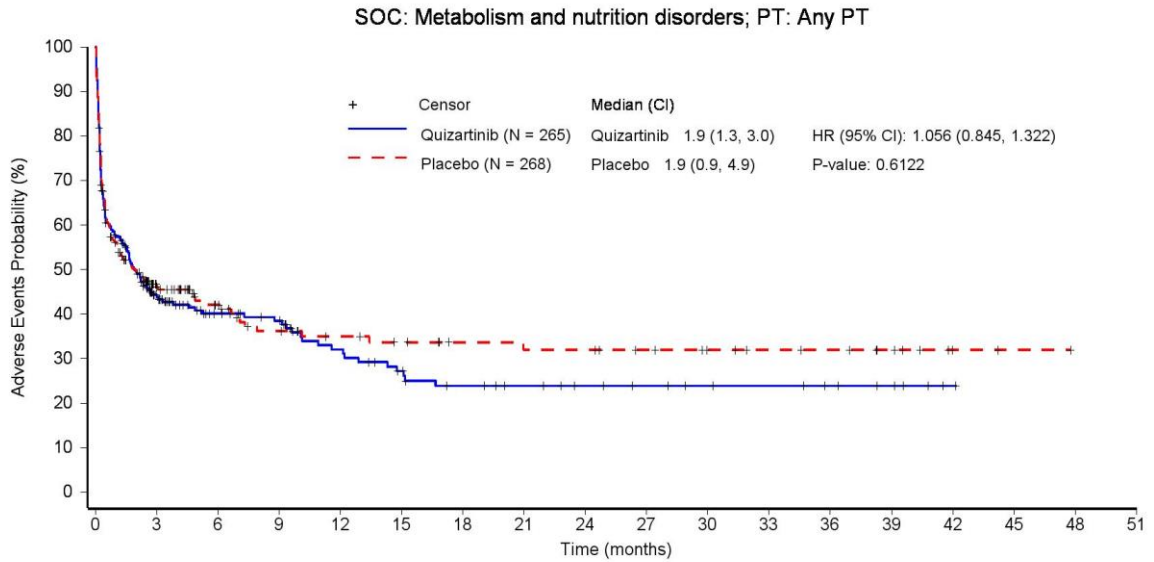
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	82	54	47	34	26	20	17	14	12	10	9	7	5	1	0	0	0
Placebo (N = 268)	268	70	46	35	28	25	20	19	19	16	13	11	10	7	2	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

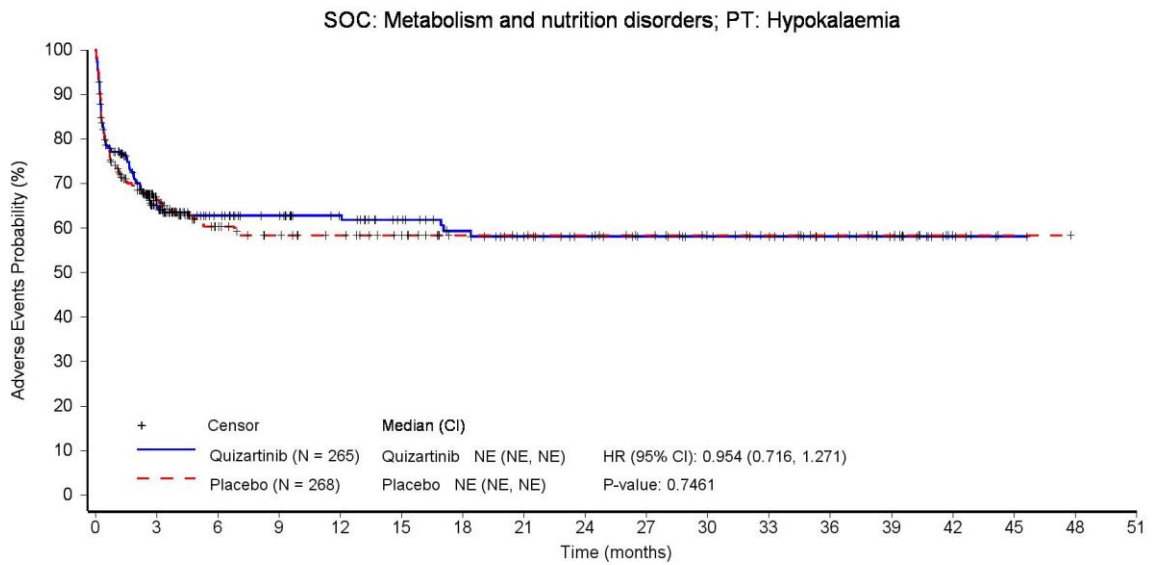
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	117	84	75	65	55	47	39	33	29	26	24	17	13	4	1	0	0
Placebo (N = 268)	268	102	65	56	49	42	33	32	31	27	22	19	16	11	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

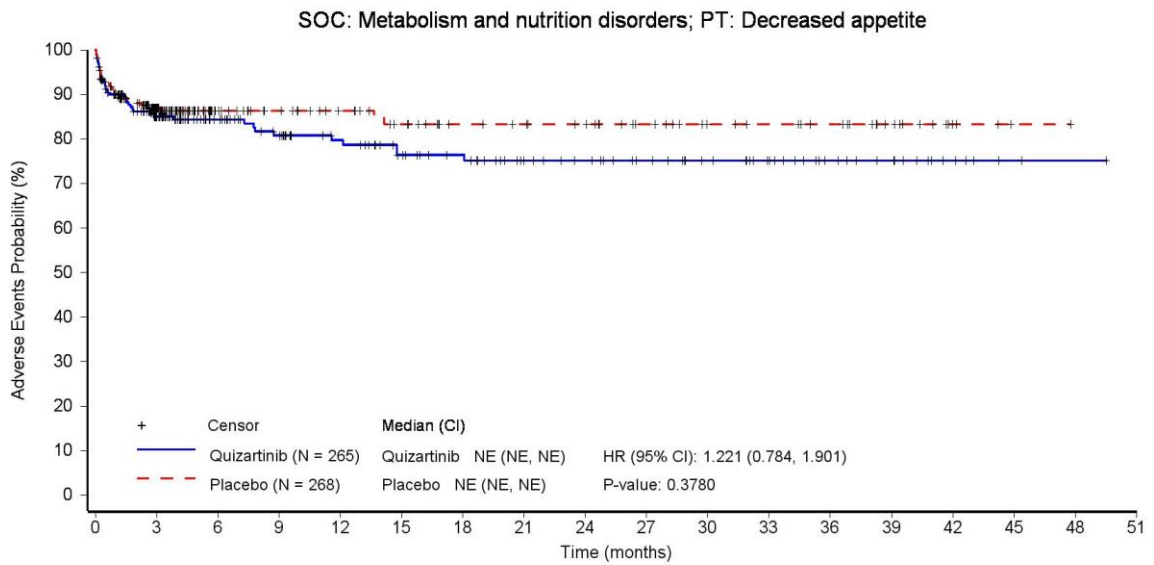
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	140	104	89	77	65	59	48	44	37	31	25	17	13	6	2	1	0
Placebo (N = 268)	268	137	81	70	61	53	44	42	39	31	25	23	20	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

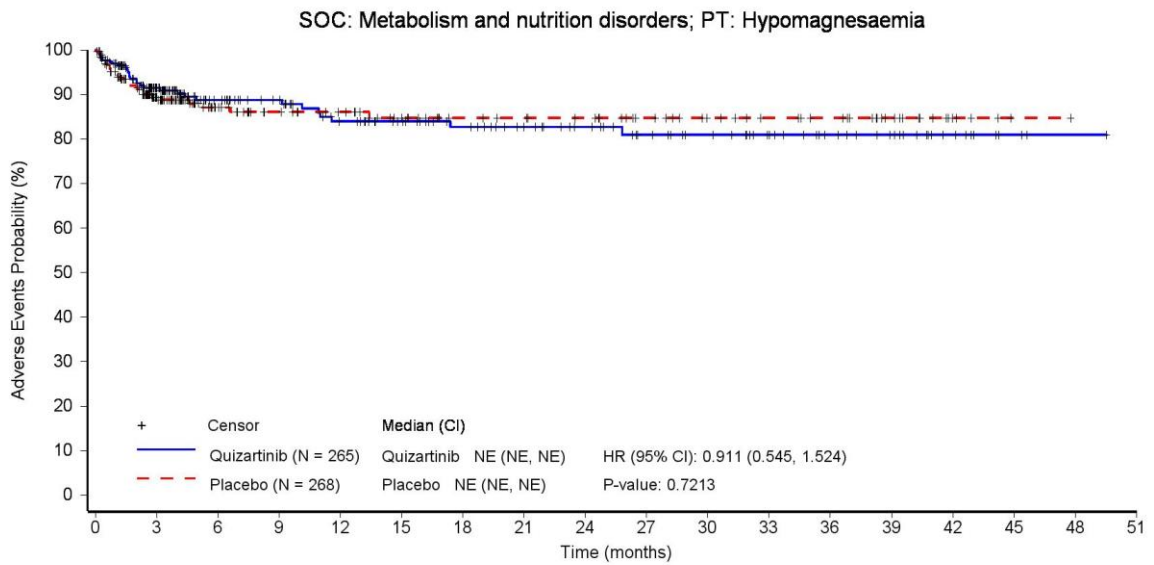
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	155	111	99	84	74	65	57	51	42	37	30	23	18	10	3	1	0
Placebo (N = 268)	268	139	91	77	68	58	48	46	43	35	29	25	22	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

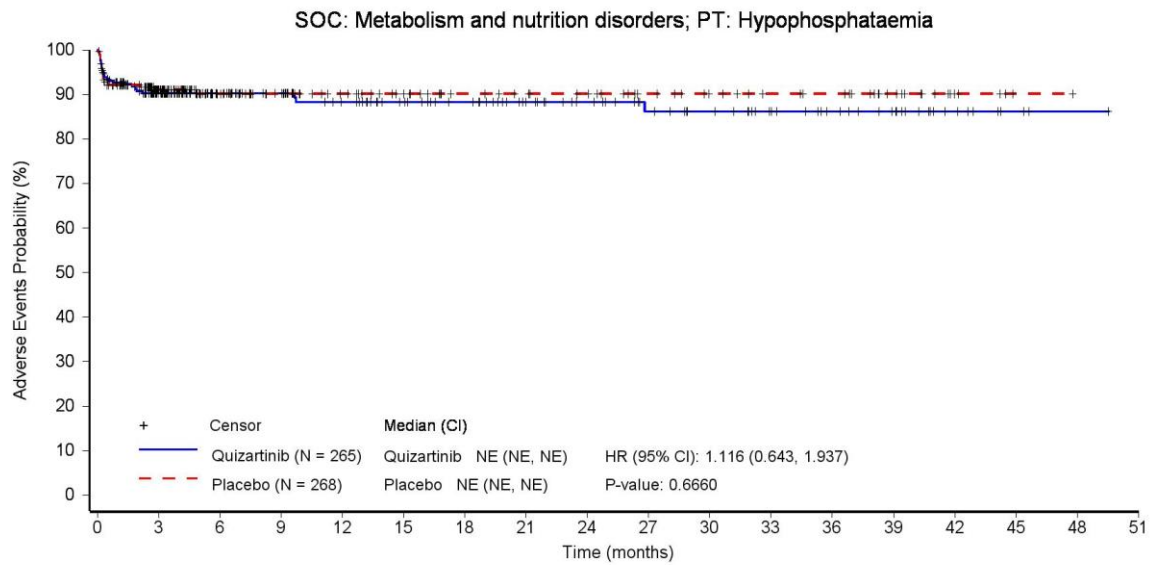
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	154	113	100	86	75	68	57	50	41	36	29	23	18	9	3	1	0
Placebo (N = 268)	268	139	89	75	65	56	47	44	41	33	28	24	22	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

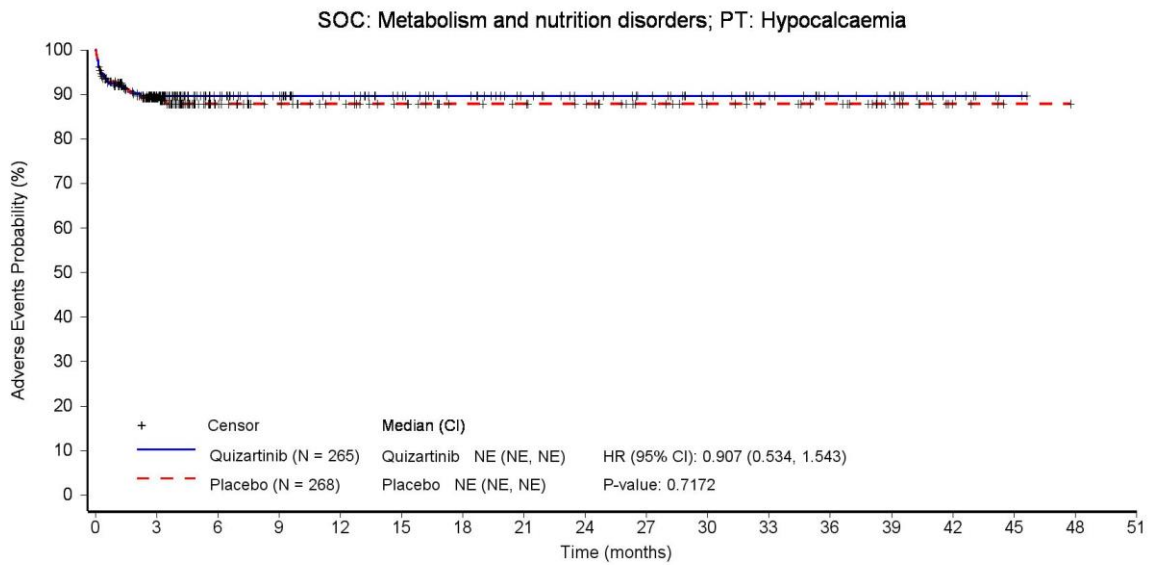
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	151	108	96	83	73	66	56	50	43	36	30	23	19	9	2	0	0
Placebo (N = 268)	268	137	87	75	66	59	49	47	44	35	29	26	23	14	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

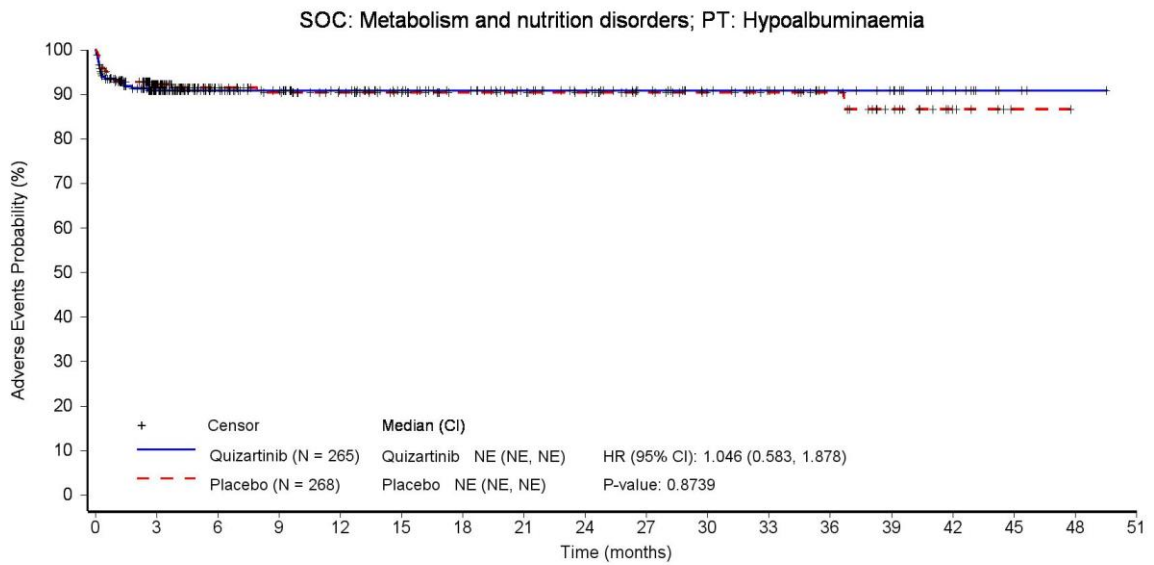
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	114	101	91	79	71	61	54	46	39	33	24	20	11	3	1	0
Placebo (N = 268)	268	146	93	80	69	59	51	49	46	37	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

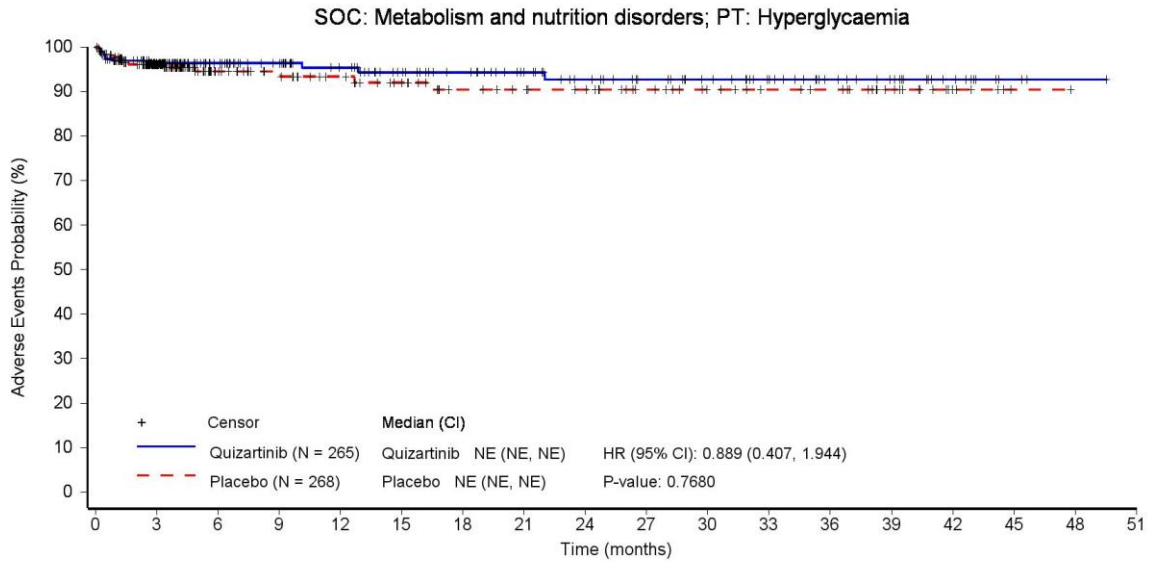
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	120	106	93	80	72	62	54	46	40	33	24	19	11	3	1	0
Placebo (N = 268)	268	152	95	82	71	62	51	48	45	36	30	26	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

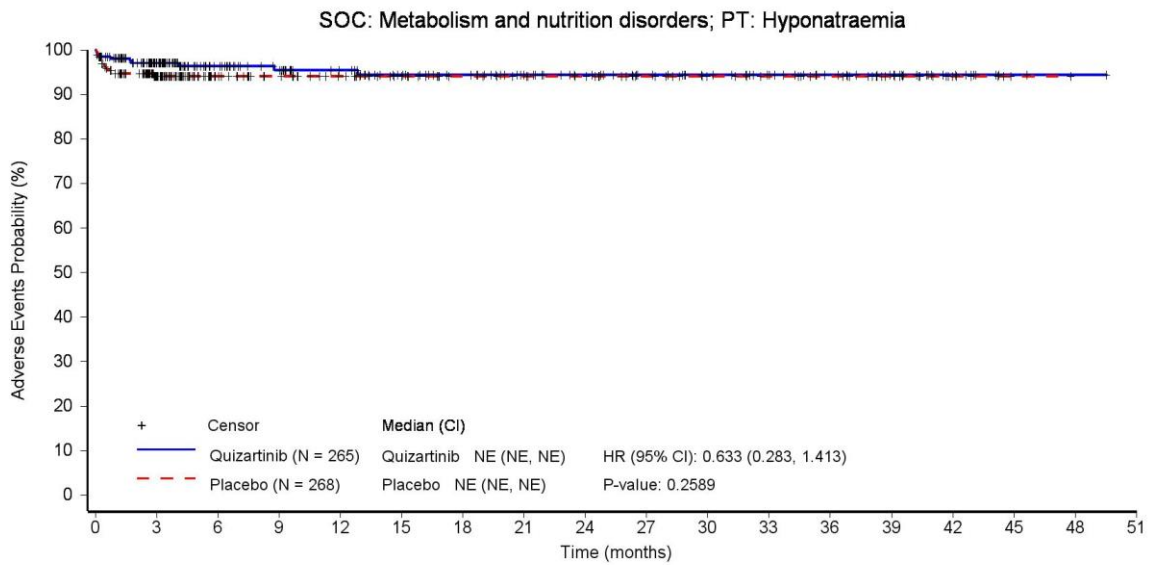
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	119	104	92	79	72	61	54	46	40	33	25	20	10	2	1	0
Placebo (N = 268)	268	147	96	82	71	61	51	48	45	37	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

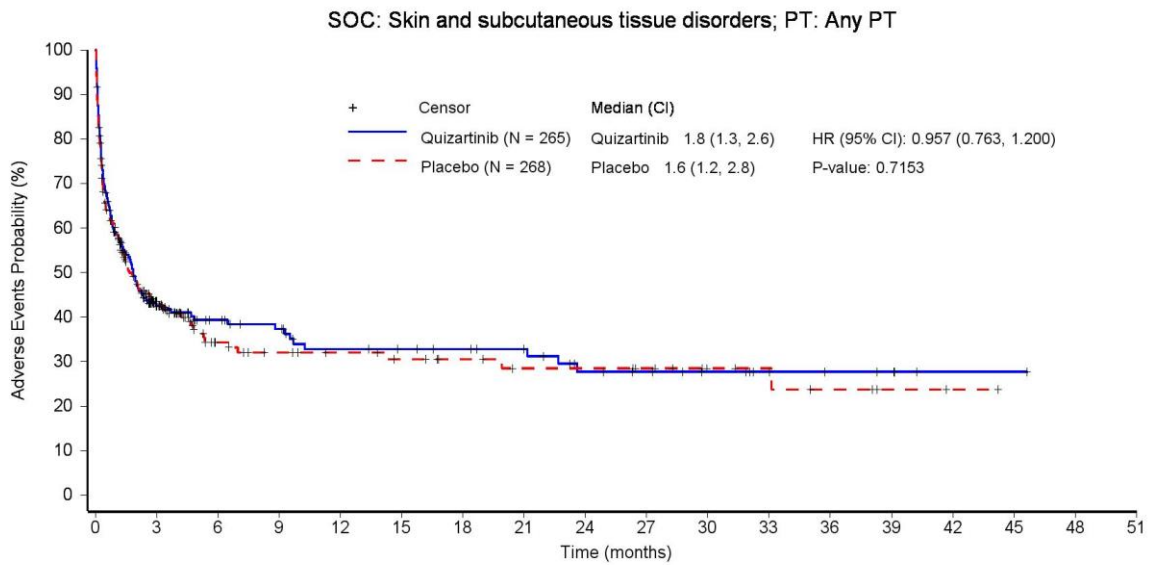
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	63	42	36	28	26	24	21	15	13	10	7	5	4	1	1	0	0
Placebo (N = 268)	268	66	31	25	22	19	16	13	13	11	7	6	4	2	1	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

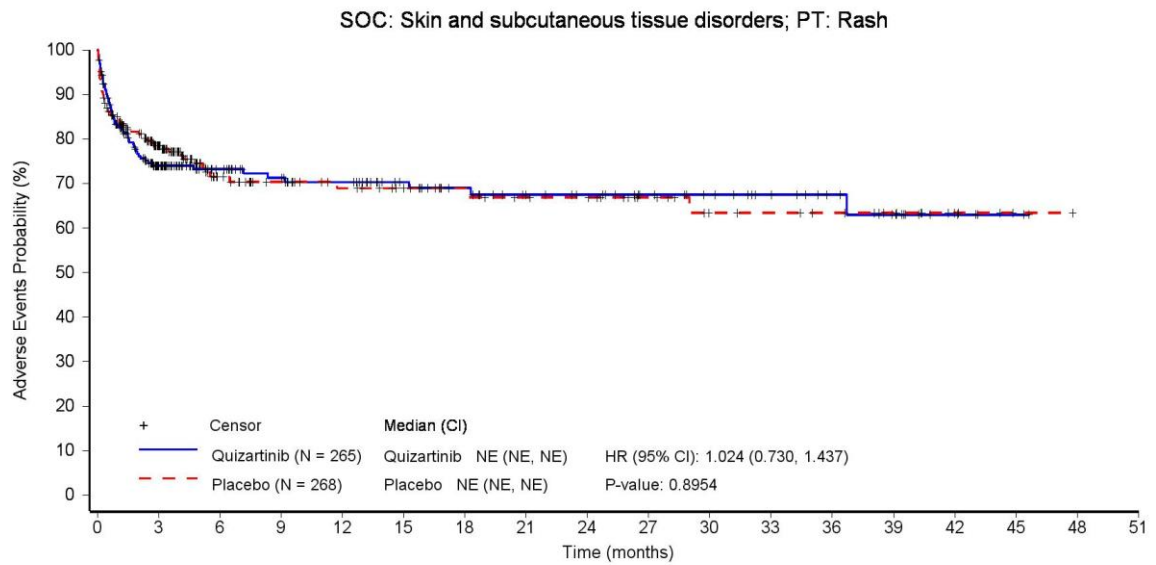
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	118	85	74	65	53	47	39	36	30	26	21	16	12	5	2	0	0
Placebo (N = 268)	268	122	85	53	47	41	34	31	30	22	16	15	13	9	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

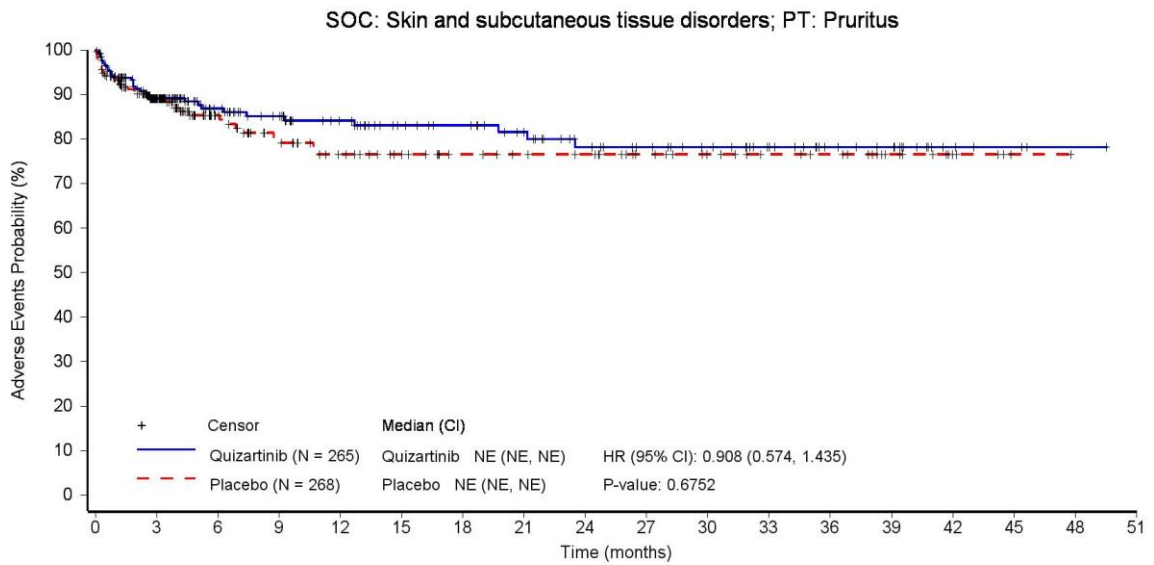
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	150	105	91	77	64	60	52	43	38	33	26	18	15	5	3	1	0
Placebo (N = 268)	268	141	88	71	58	50	43	40	38	30	25	21	19	12	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

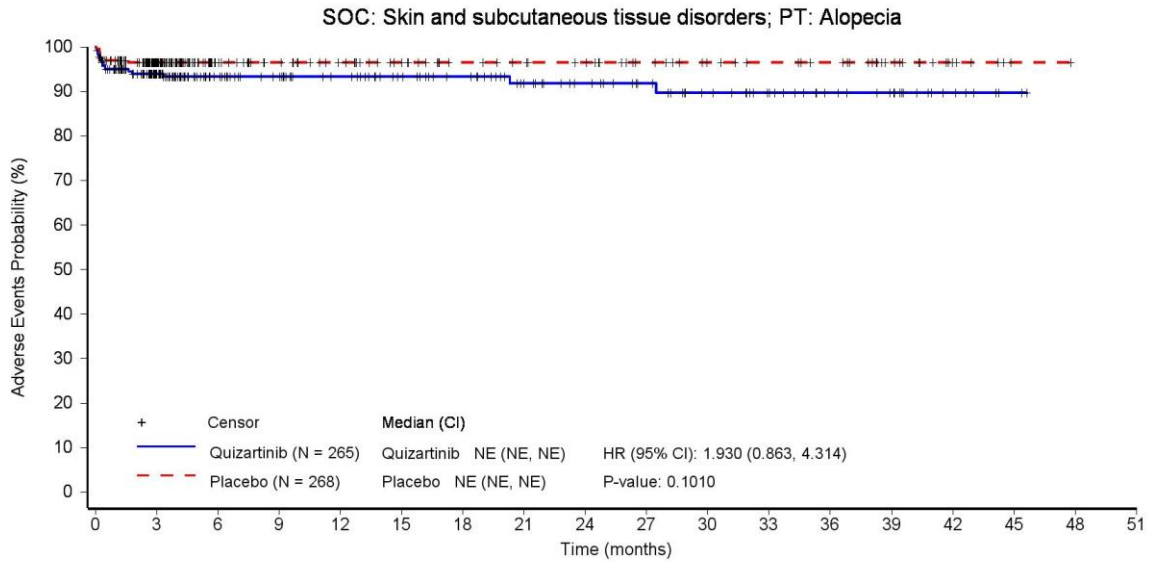
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	151	110	99	89	78	71	59	52	44	36	29	21	17	8	2	0	0
Placebo (N = 268)	268	151	95	83	72	62	52	49	46	37	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

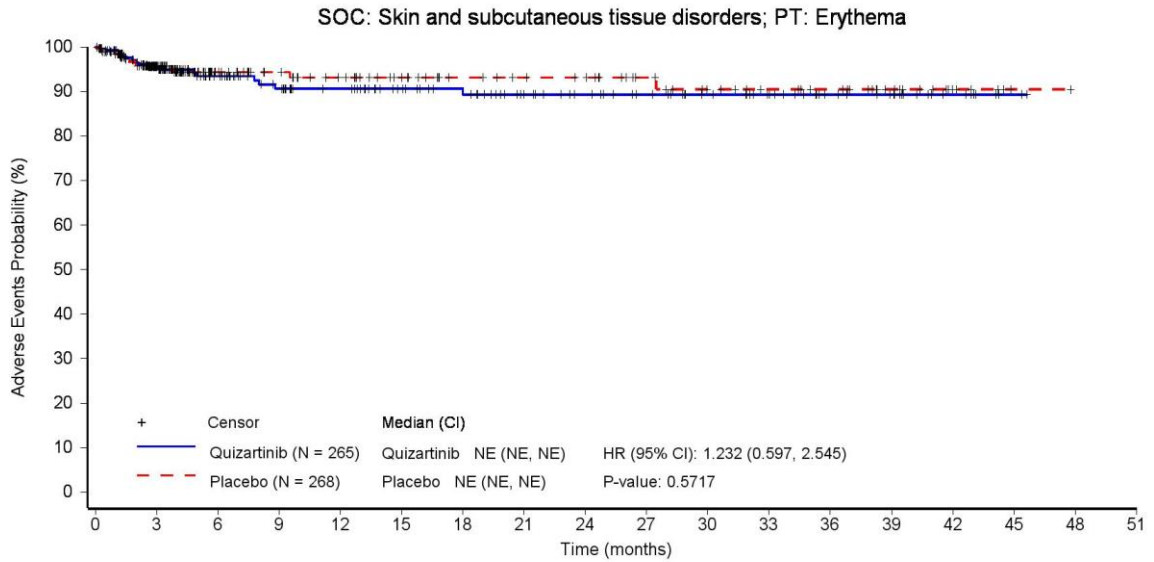
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	157	114	97	87	74	68	56	50	44	37	31	22	18	9	2	0	0
Placebo (N = 268)	268	153	94	81	70	60	50	47	45	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

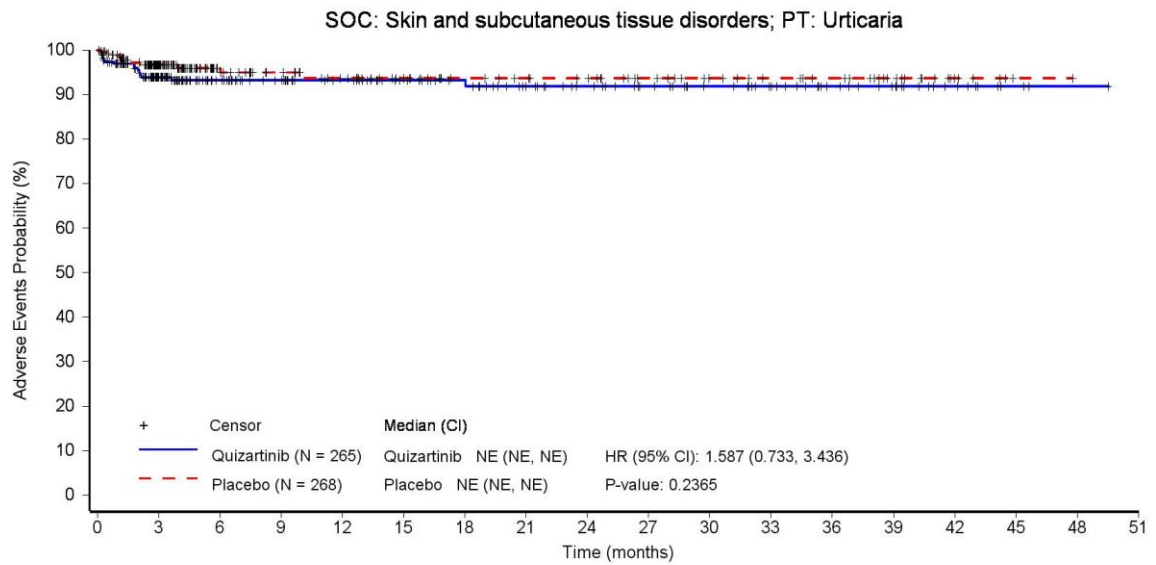
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	155	113	99	88	76	69	58	51	44	37	31	22	17	9	3	1	0
Placebo (N = 268)	268	153	96	82	71	61	51	48	45	36	30	26	23	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

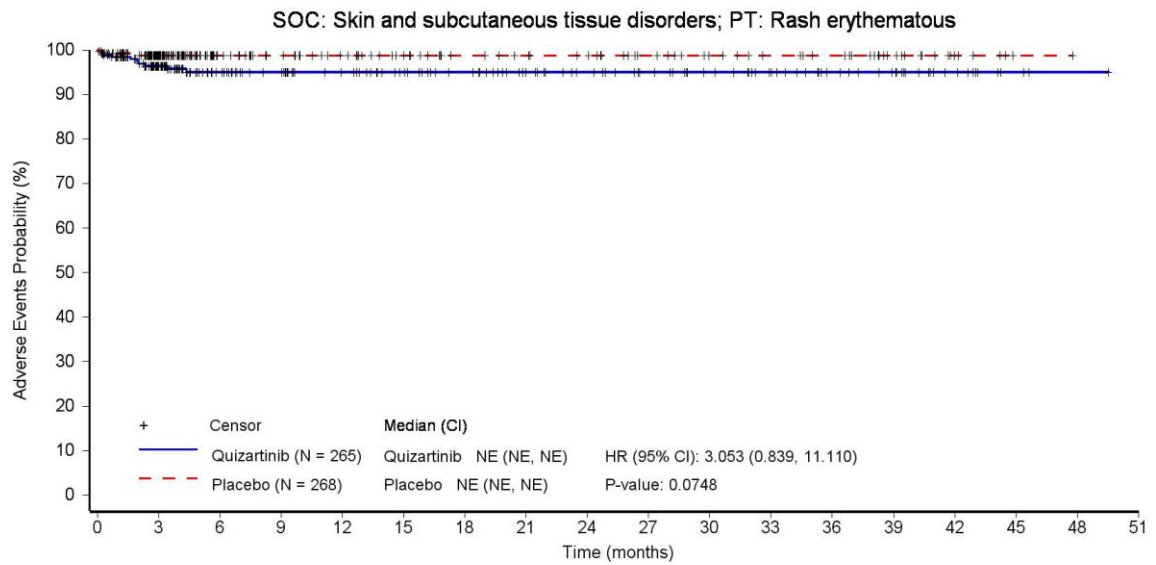
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	117	105	94	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	155	97	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

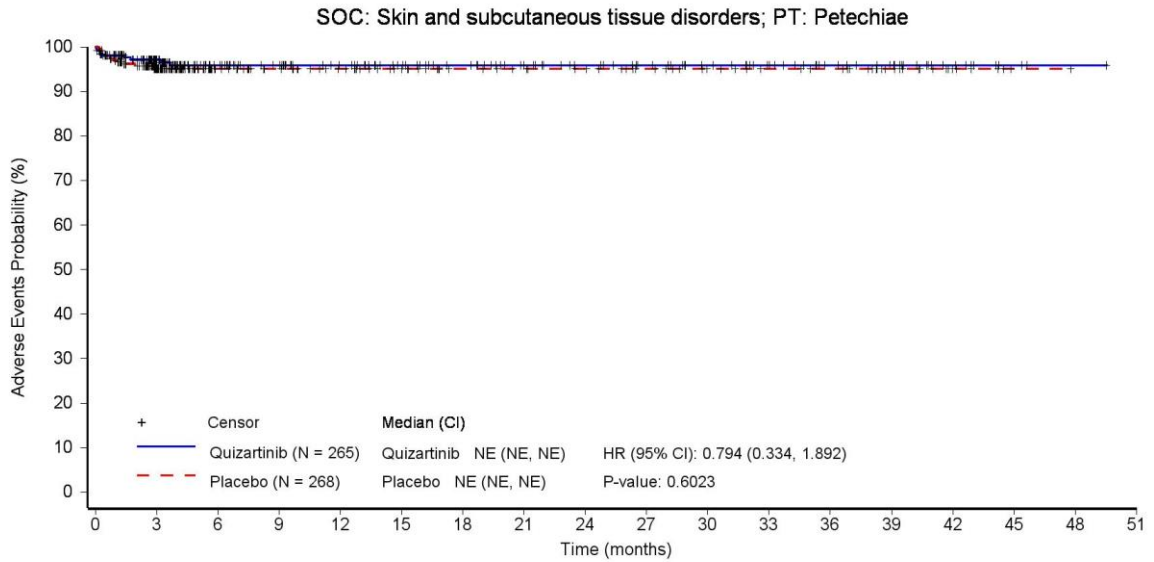
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	160	117	104	92	80	72	62	55	48	41	34	25	20	10	3	1	0
Placebo (N = 268)	268	151	94	81	70	60	50	47	44	37	31	27	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

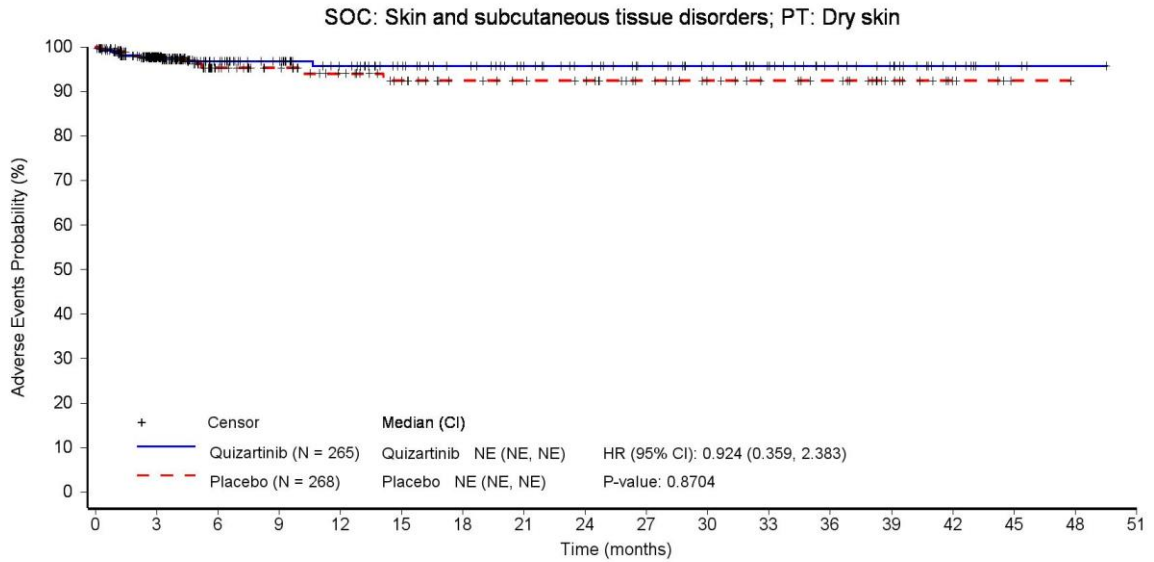
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	117	103	89	77	70	61	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	152	91	78	66	56	48	45	43	35	29	25	22	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

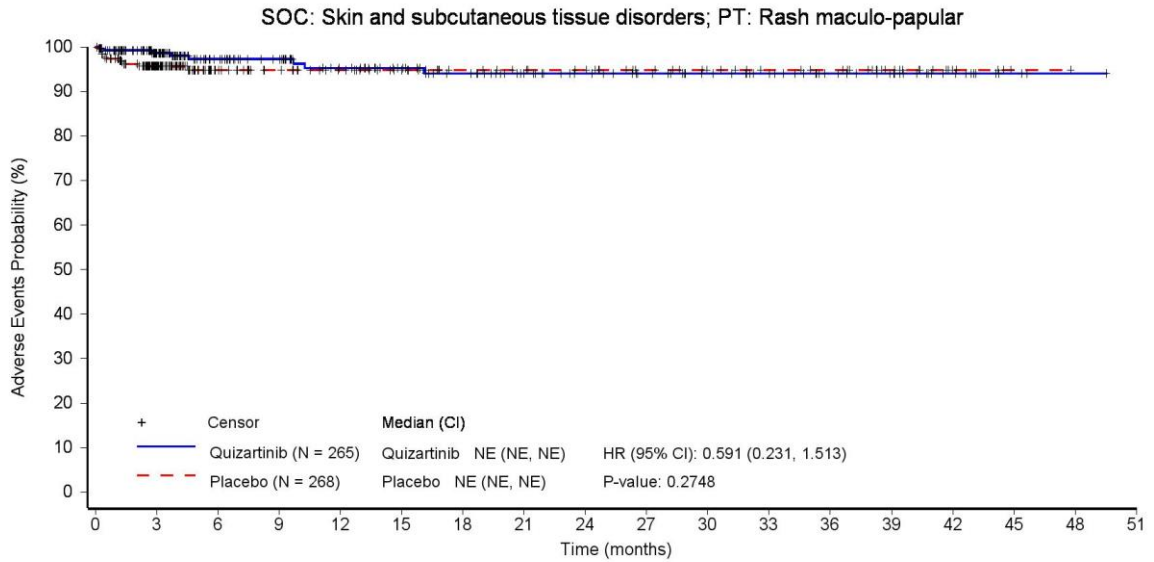
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	121	107	92	81	72	61	54	47	40	34	25	20	11	3	1	0
Placebo (N = 268)	268	149	93	79	68	59	49	46	43	35	30	26	24	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

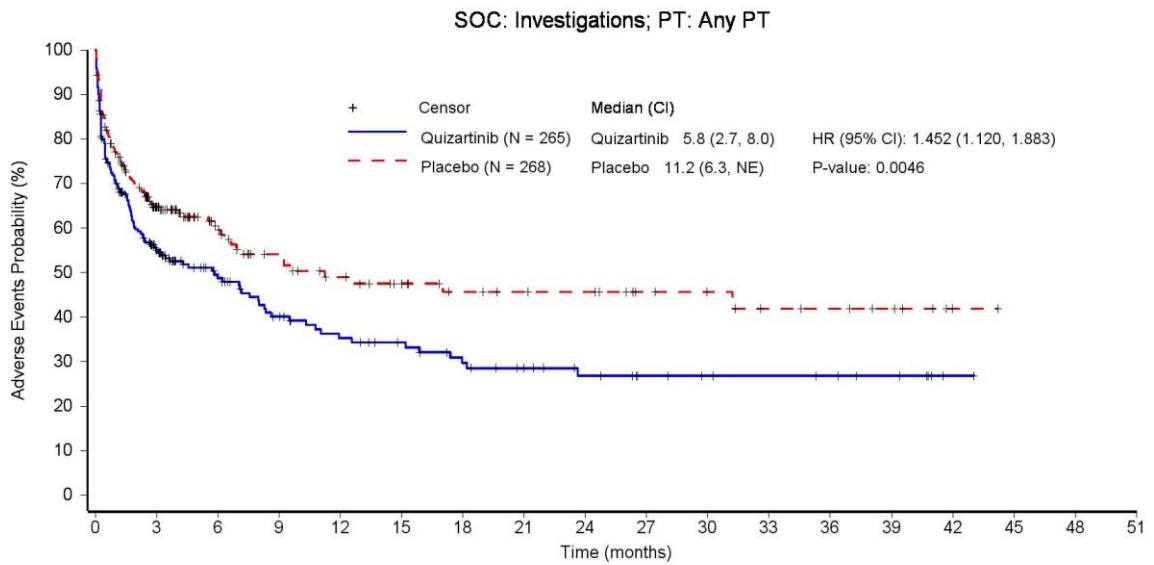
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	
Quizartinib (N = 265)	265	94	61	45	36	31	25	20	16	12	10	9	8	6	1	0	0
Placebo (N = 268)	268	98	59	43	35	28	23	21	20	14	12	9	8	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

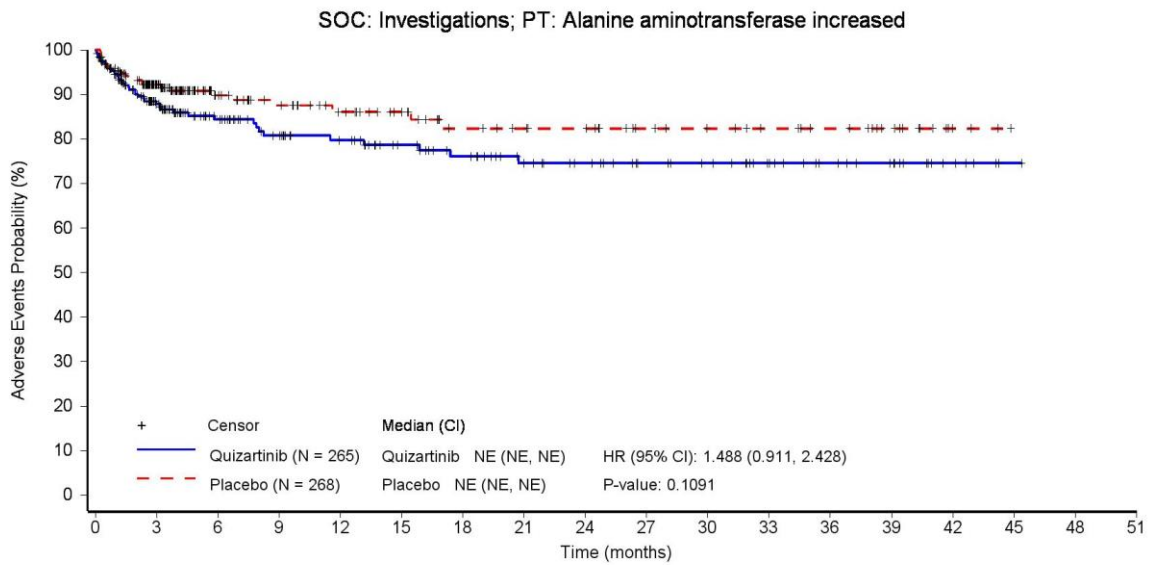
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	145	104	87	78	65	57	47	42	34	31	24	18	14	6	1	0	0
Placebo (N = 268)	268	144	87	72	60	51	40	37	35	27	24	21	18	13	3	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

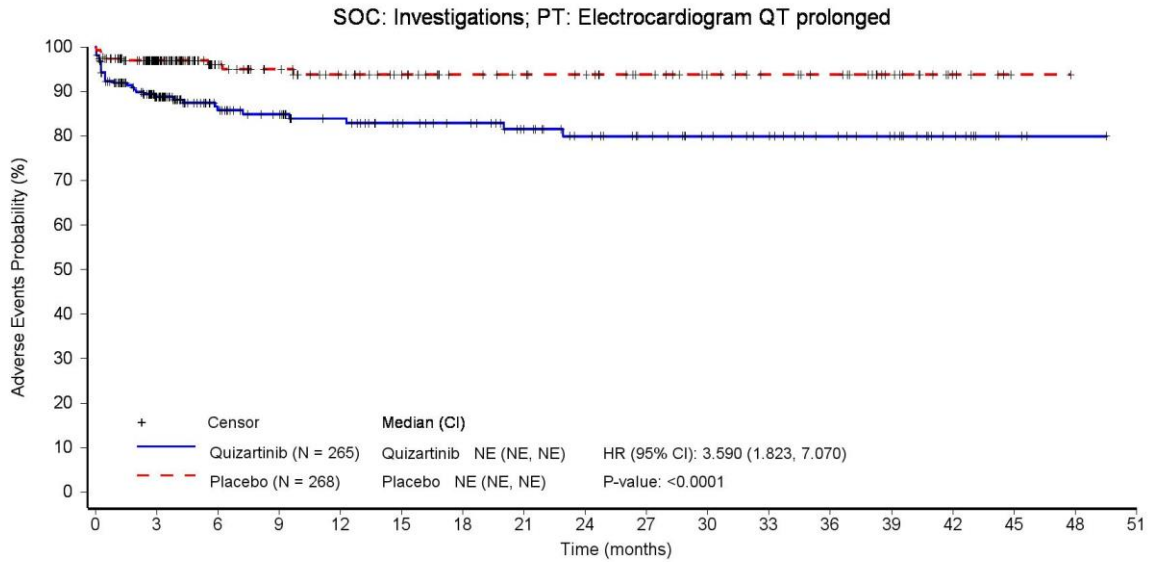
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	149	105	93	82	71	66	56	48	41	35	31	25	20	11	3	1	0
Placebo (N = 268)	268	153	96	82	70	61	52	49	46	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

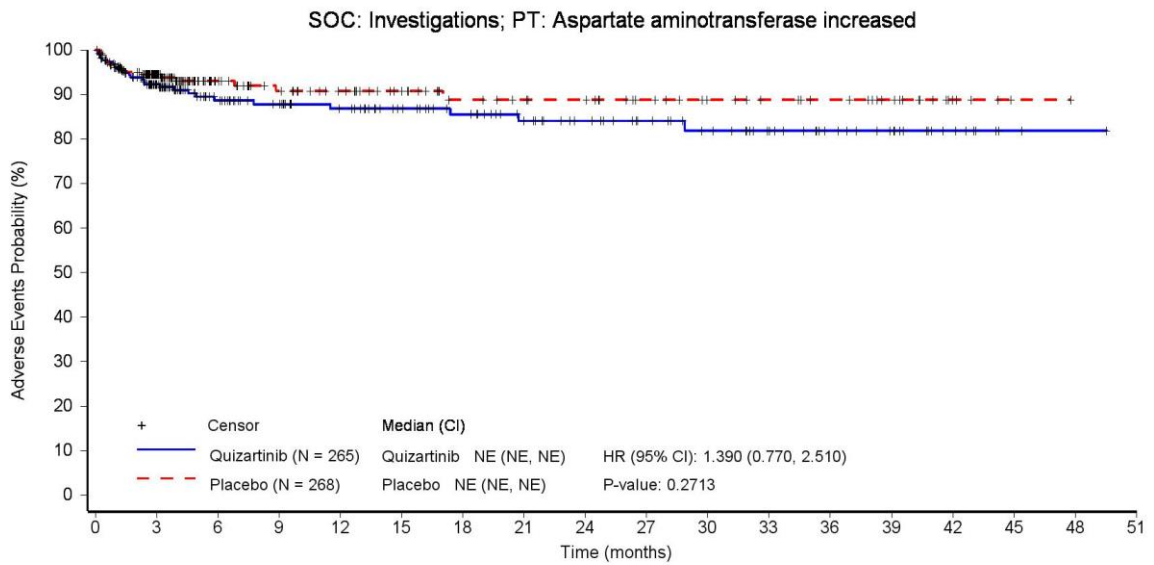
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	152	110	97	87	75	67	57	50	42	36	29	21	16	8	2	1	0
Placebo (N = 268)	268	148	91	76	65	55	44	41	39	31	26	23	20	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

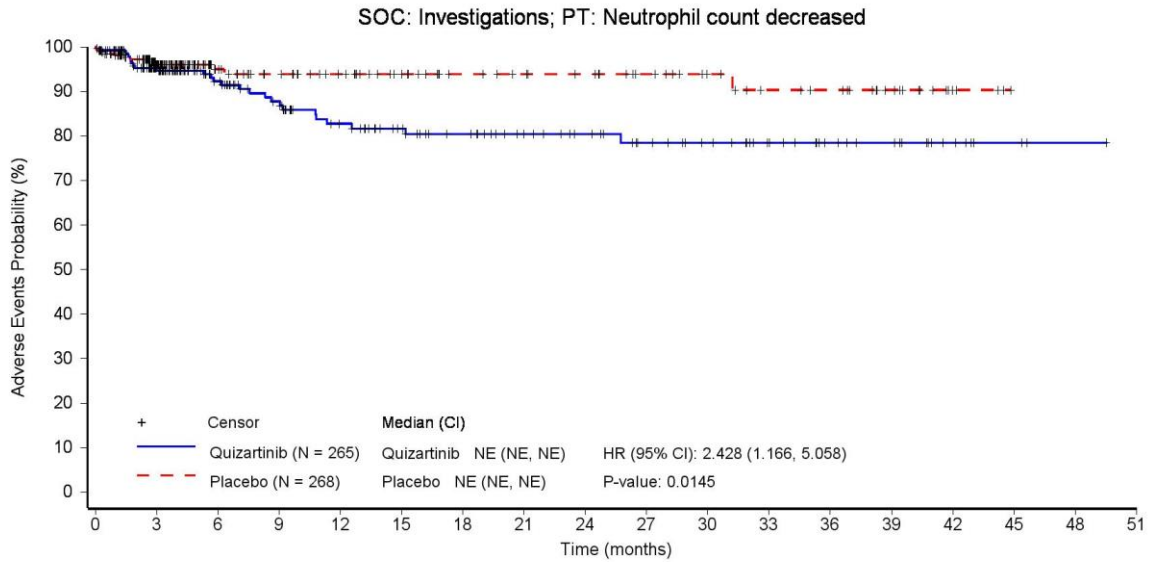
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	112	94	77	66	58	49	44	36	31	24	17	14	7	3	1	0
Placebo (N = 268)	268	150	91	77	66	56	46	43	40	33	27	22	20	13	4	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

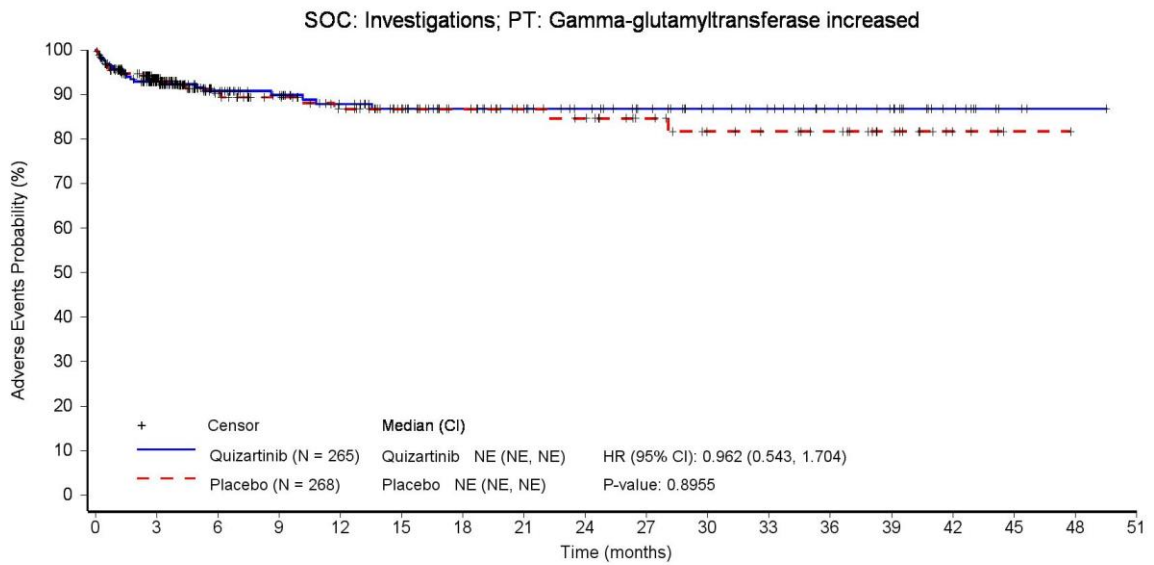
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	152	110	97	86	74	66	57	52	44	37	32	25	20	11	3	1	0
Placebo (N = 268)	268	146	90	76	64	55	46	43	39	31	25	23	20	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

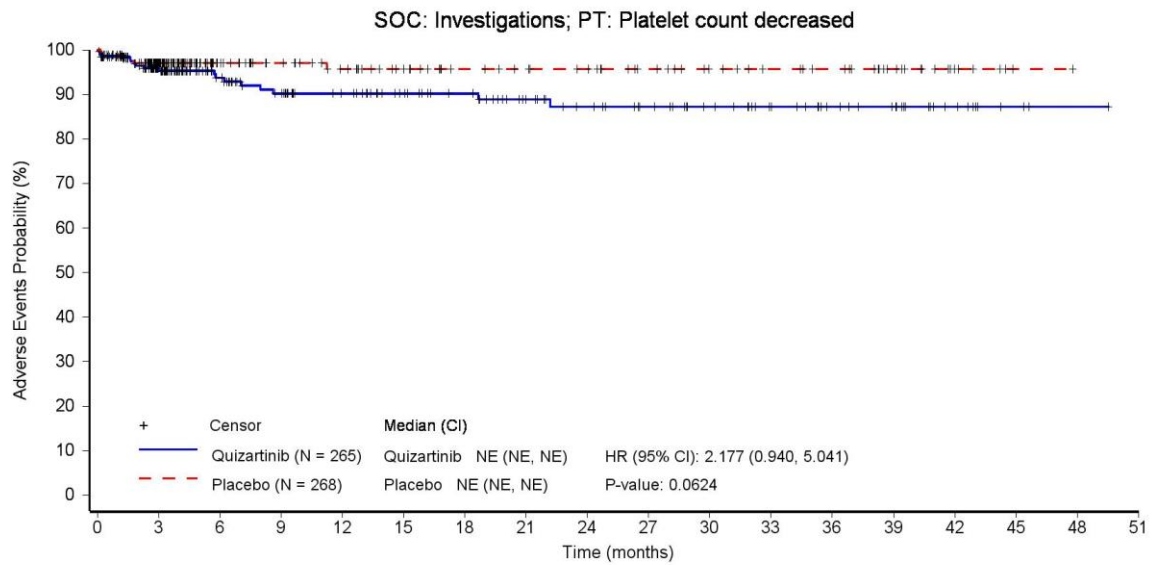
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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	115	99	87	76	69	57	50	43	36	29	22	18	9	3	1	0
Placebo (N = 268)	268	151	93	79	69	59	50	47	44	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

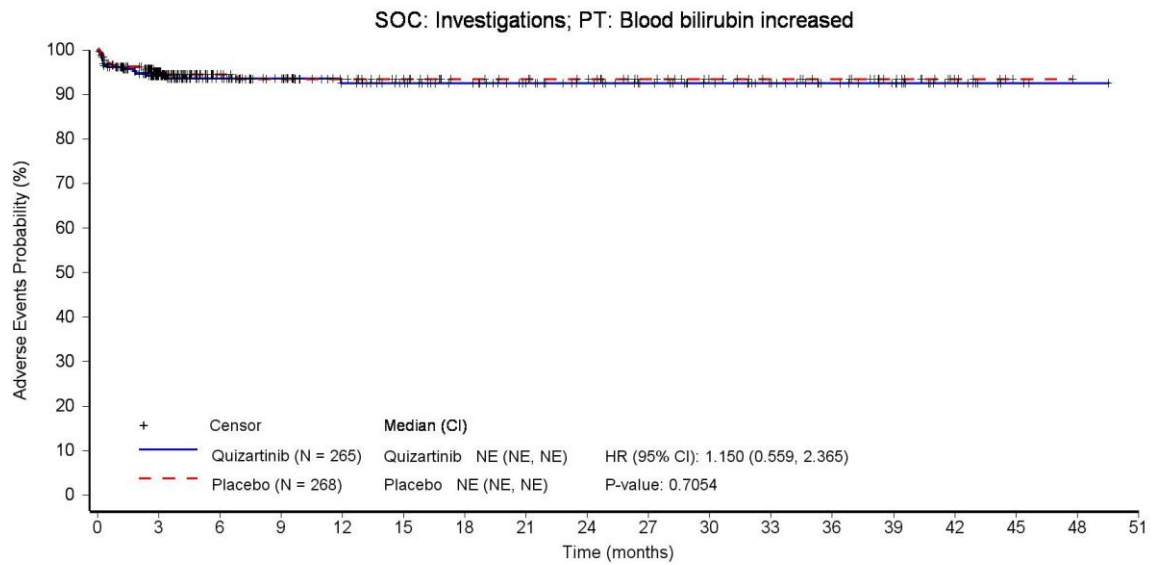
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	157	115	101	89	80	72	62	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	148	94	80	69	60	50	48	45	36	30	26	23	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

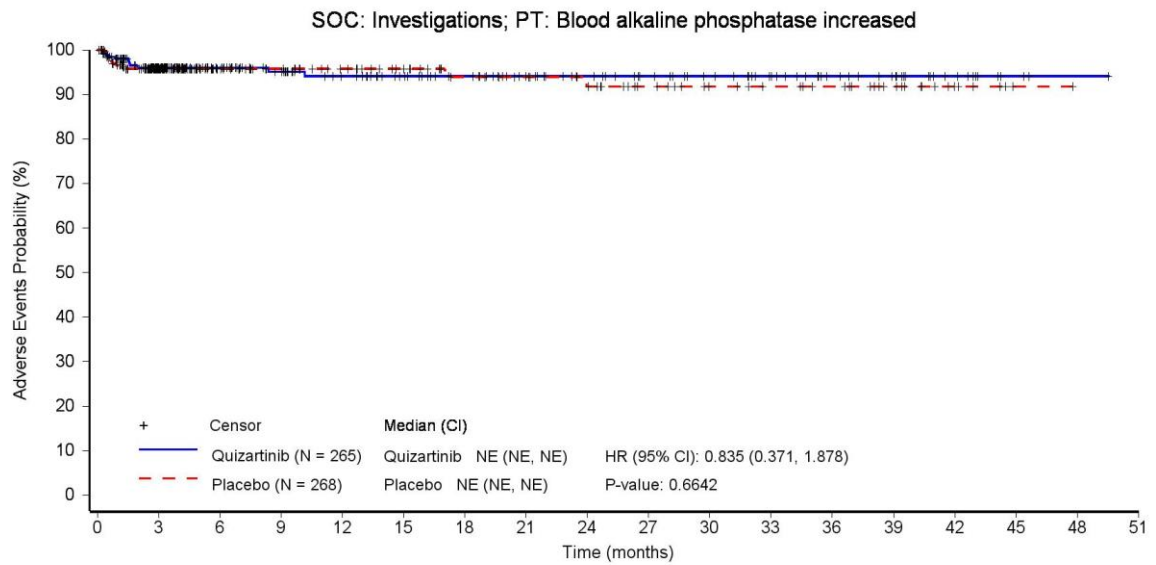
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	118	104	91	80	72	62	55	47	41	34	25	20	11	3	1	0
Placebo (N = 268)	268	150	95	81	70	61	50	47	43	34	28	25	22	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

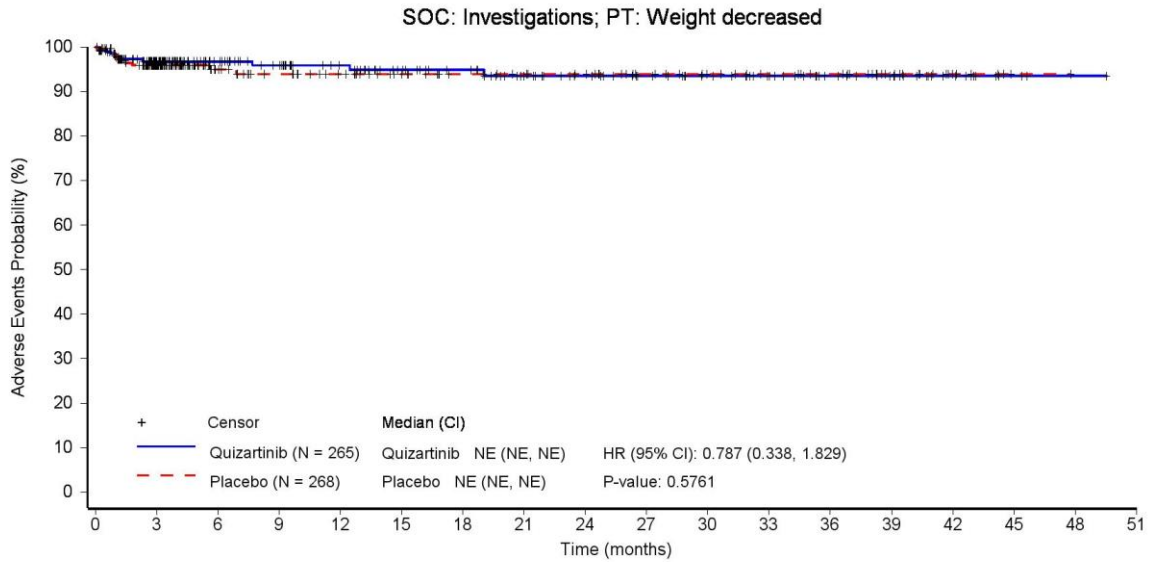
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	120	107	94	81	74	62	55	47	41	34	25	20	11	3	1	0
Placebo (N = 268)	268	150	93	80	70	60	51	48	45	36	31	27	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

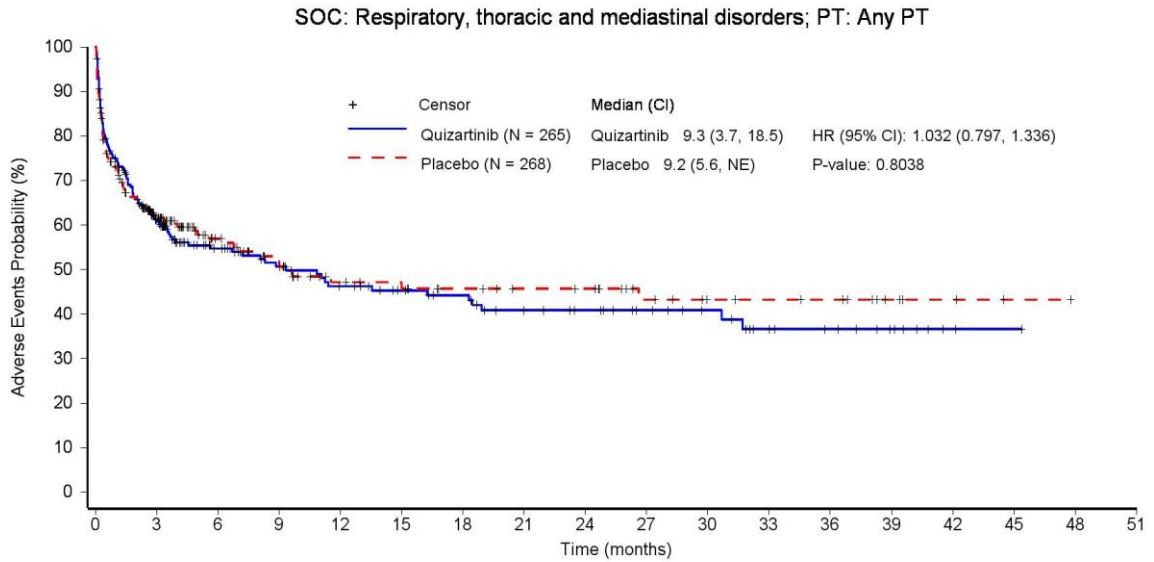
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	115	75	62	51	44	40	32	29	24	20	14	11	7	2	1	0	0
Placebo (N = 268)	268	101	60	46	36	33	29	26	25	17	13	12	11	6	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

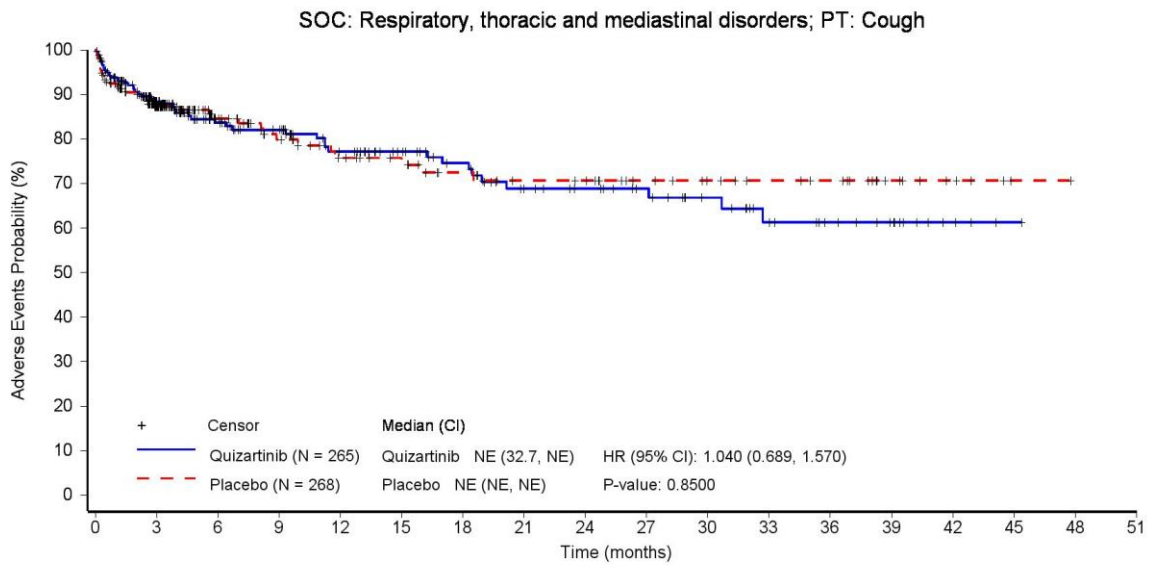
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	151	107	94	77	65	55	43	39	34	27	20	15	11	4	1	0	0
Placebo (N = 268)	268	137	82	65	53	47	40	36	35	27	23	20	18	10	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

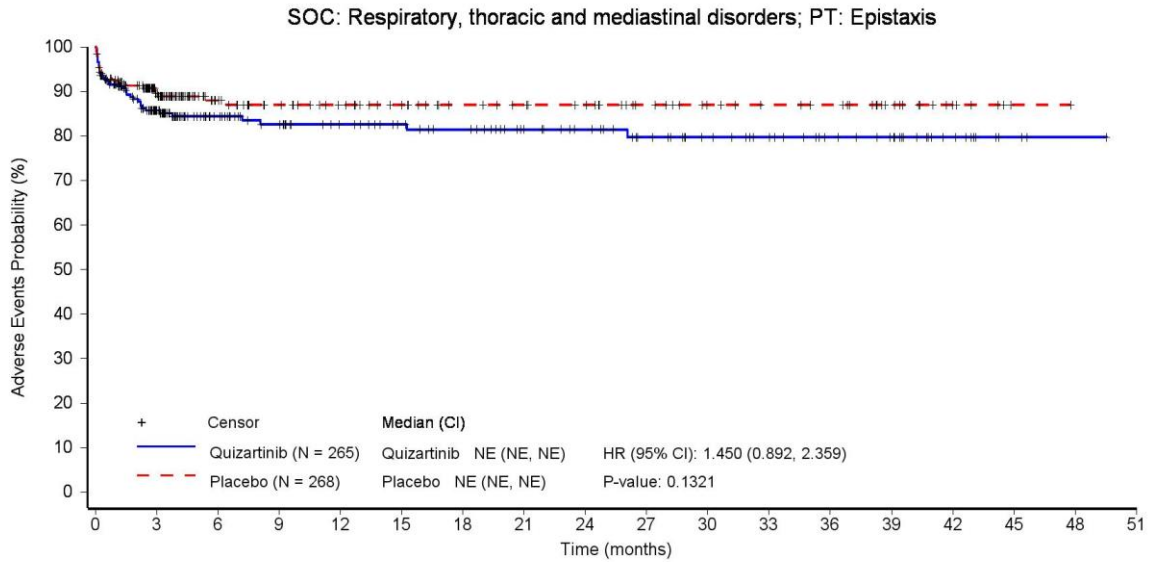
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	143	102	89	79	72	67	57	52	44	37	32	25	21	11	3	1	0
Placebo (N = 268)	268	140	90	76	66	58	49	46	43	34	28	25	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

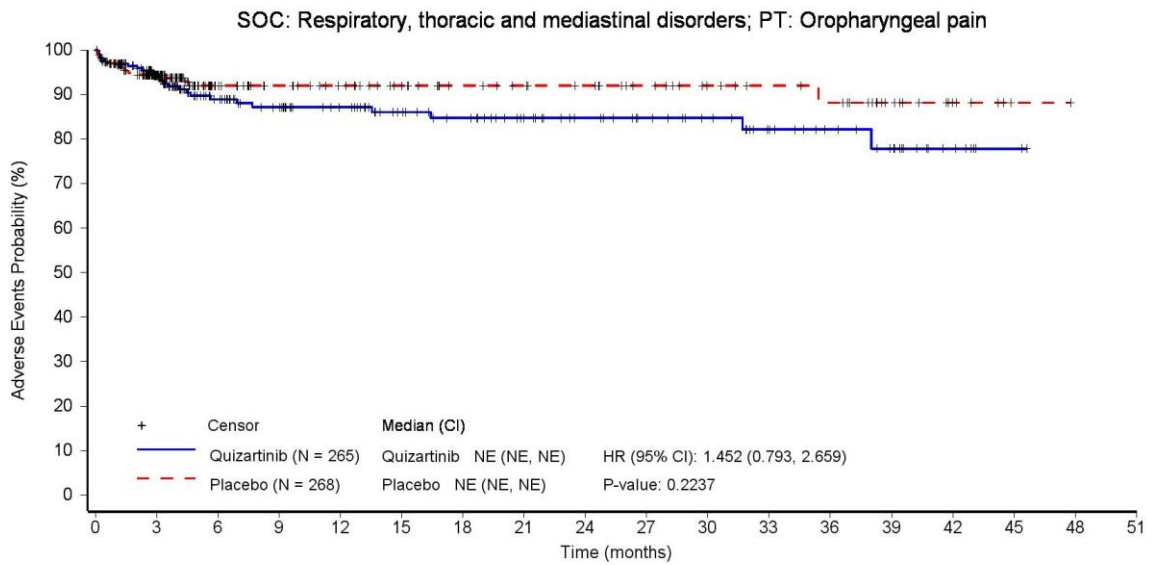
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	111	96	84	70	63	53	46	40	35	27	21	16	7	2	0	0
Placebo (N = 268)	268	146	87	74	65	56	47	44	41	34	28	25	23	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

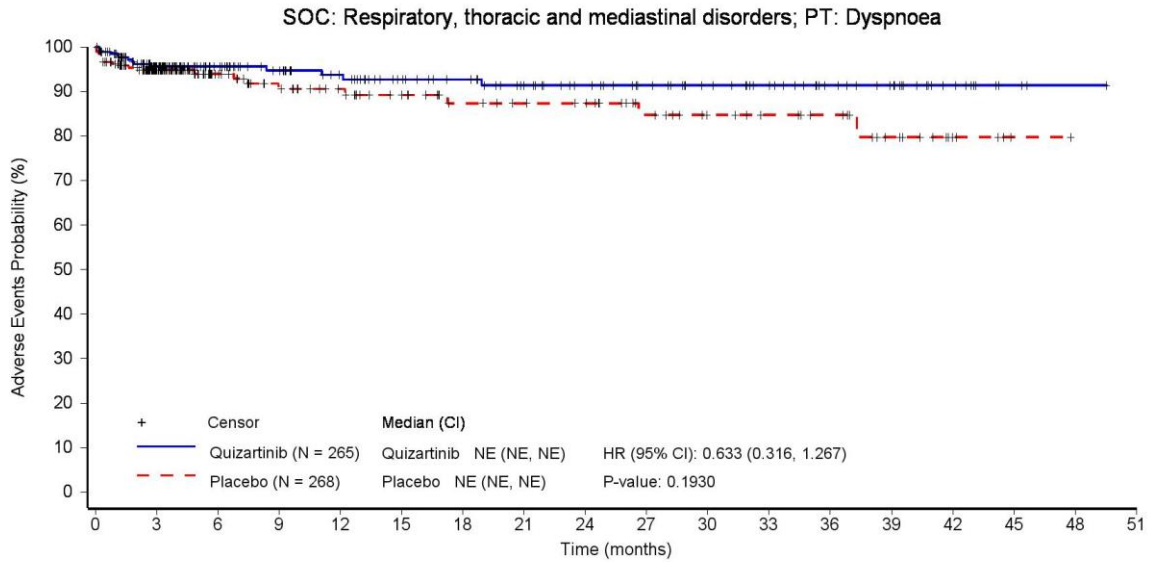
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	119	104	92	79	73	63	56	48	41	35	26	21	11	3	1	0
Placebo (N = 268)	268	150	92	75	64	55	47	44	42	32	26	23	20	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

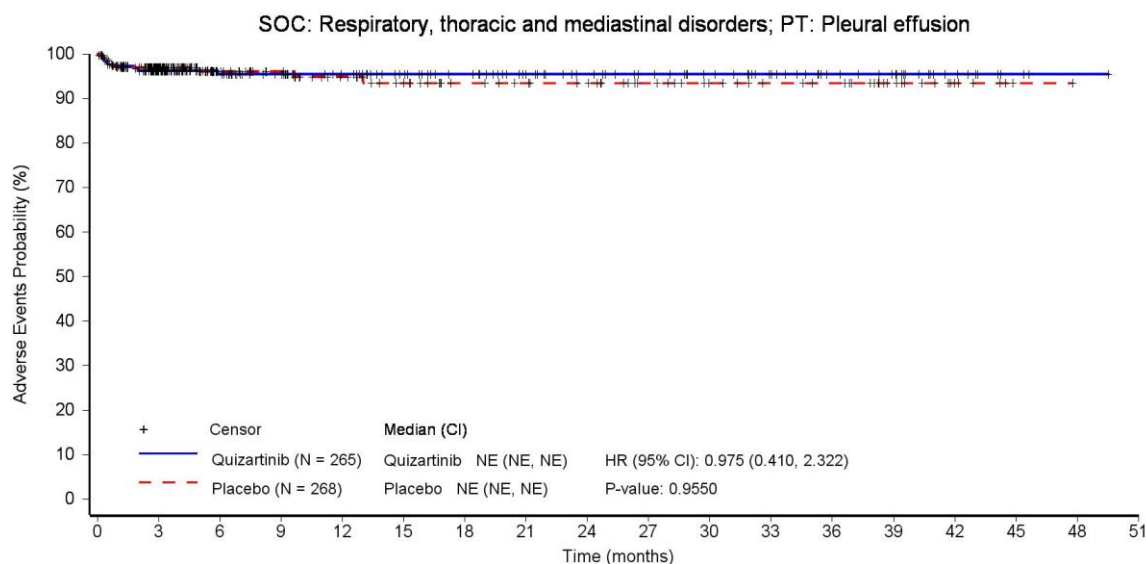
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	117	103	91	79	71	60	53	46	40	33	24	20	10	3	1	0
Placebo (N = 268)	268	154	96	82	70	61	51	48	45	36	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

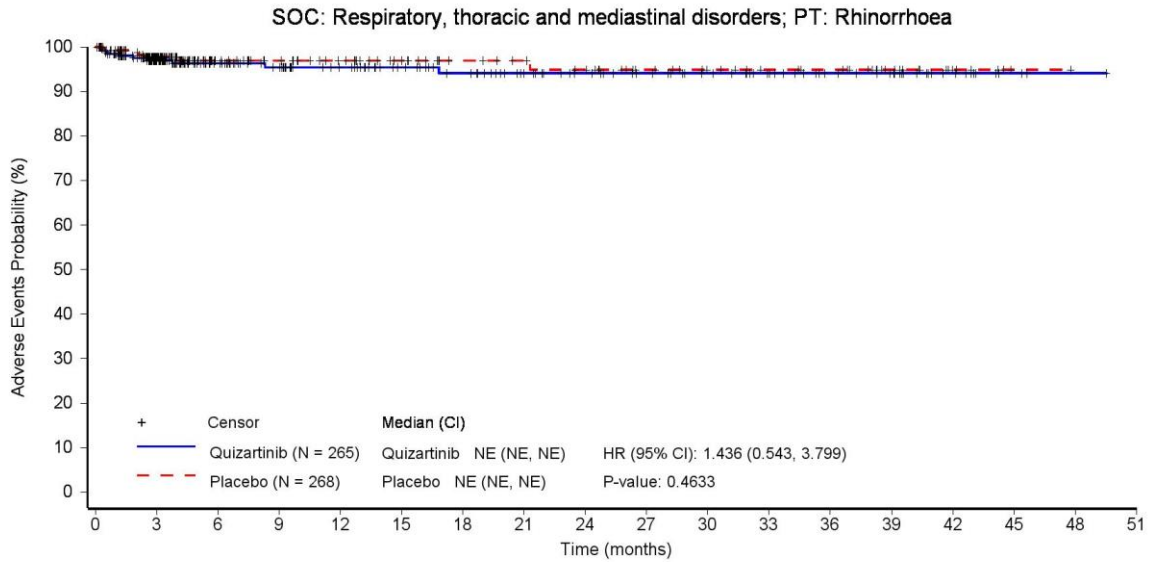
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	119	104	91	78	70	59	52	45	39	32	24	20	10	3	1	0
Placebo (N = 268)	268	152	93	81	70	60	50	47	44	35	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

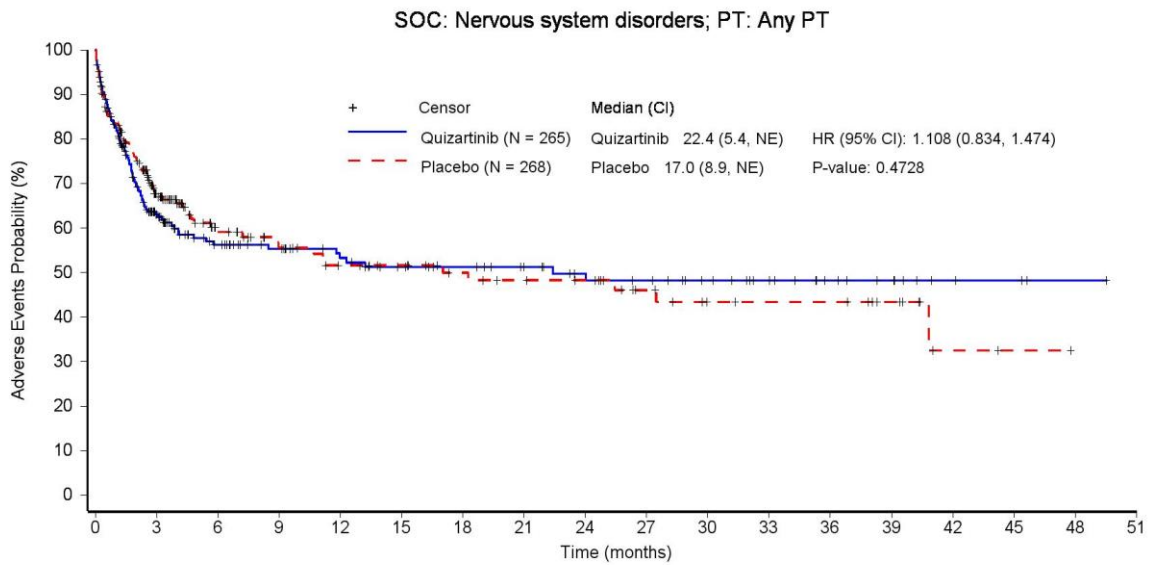
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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	105	72	61	52	45	42	37	32	28	23	18	12	9	4	3	1	0
Placebo (N = 268)	268	102	57	45	38	35	29	26	24	18	13	12	12	8	2	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

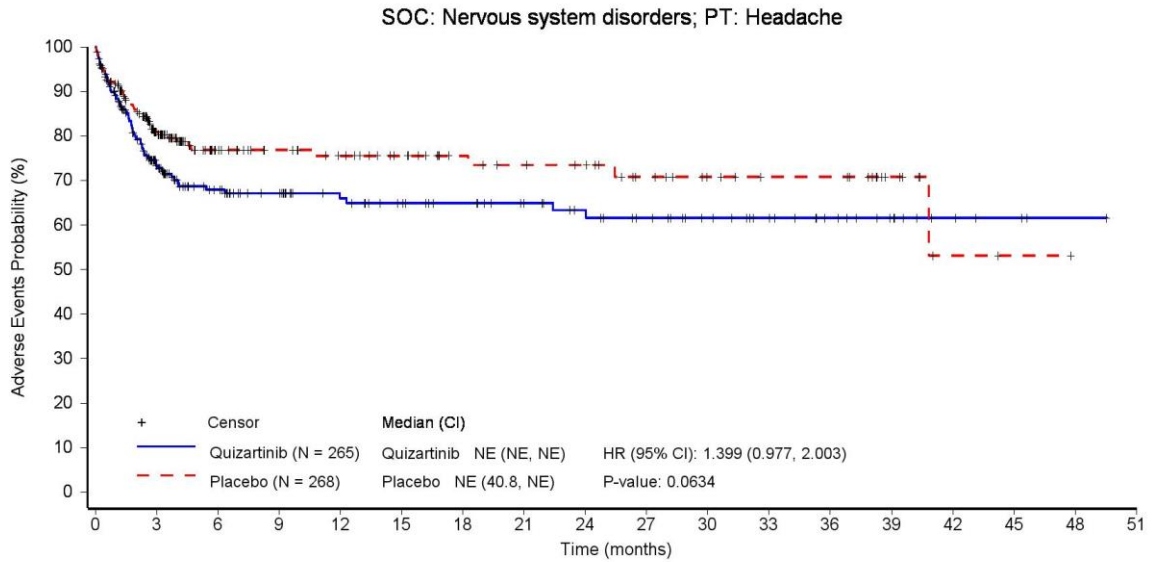
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	120	85	72	61	53	48	42	37	32	26	21	15	10	5	3	1	0
Placebo (N = 268)	268	122	72	61	53	46	36	33	31	24	19	16	16	8	2	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

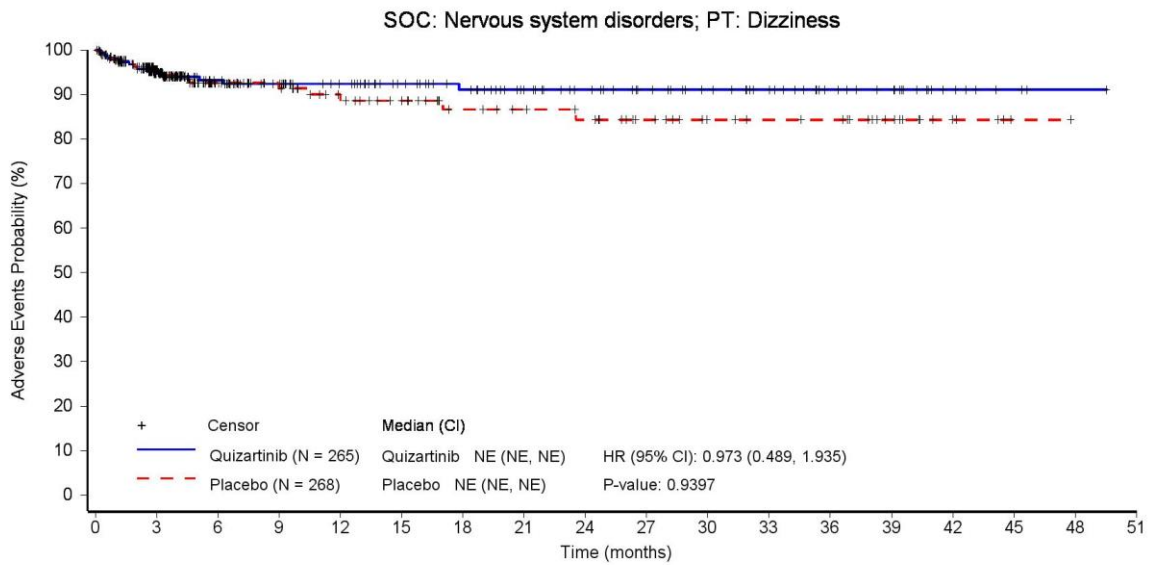
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	157	115	101	89	77	69	58	51	43	37	31	22	18	8	3	1	0
Placebo (N = 268)	268	149	89	74	61	54	43	40	37	29	23	21	20	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

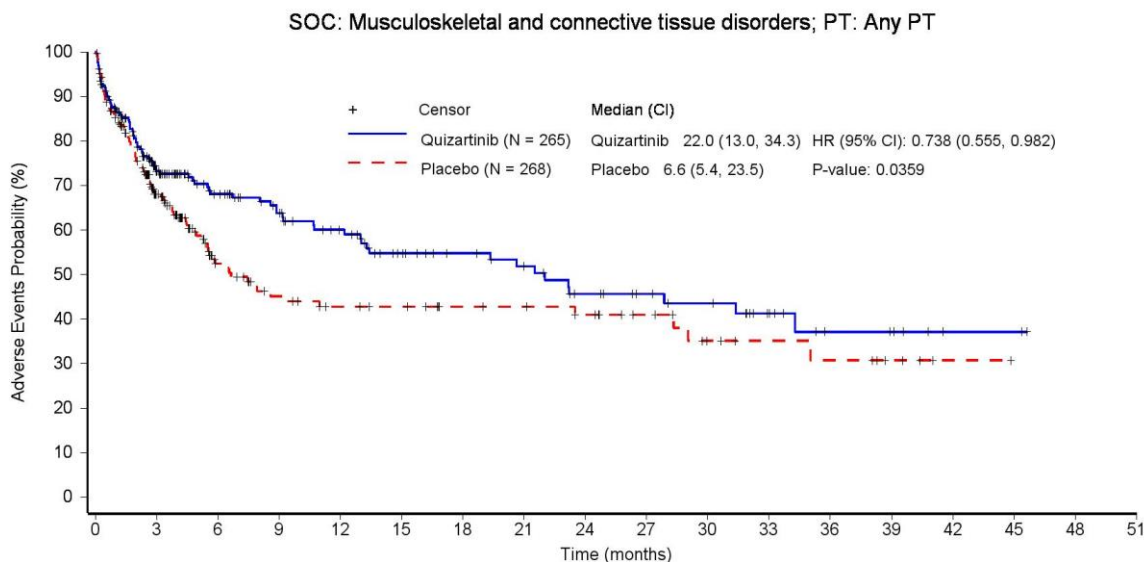
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	122	87	72	60	45	39	34	27	23	20	13	7	6	2	2	0	0
Placebo (N = 268)	268	109	53	40	33	31	26	25	22	16	10	8	7	4	1	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

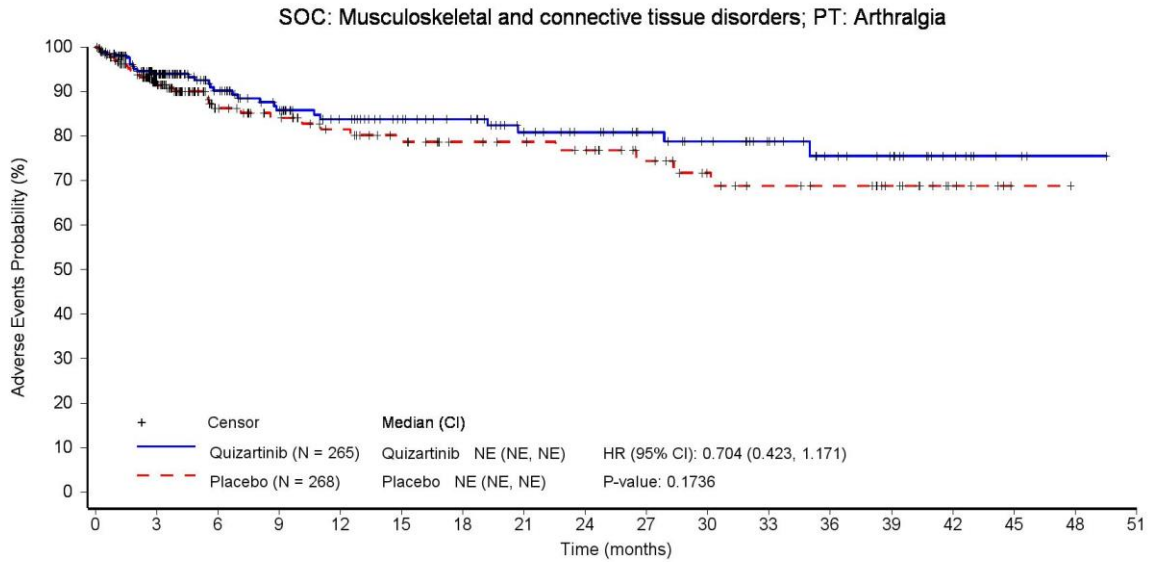
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	113	95	81	70	64	52	47	40	34	28	20	16	8	3	1	0
Placebo (N = 268)	268	145	86	73	61	53	45	43	40	31	24	20	18	13	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

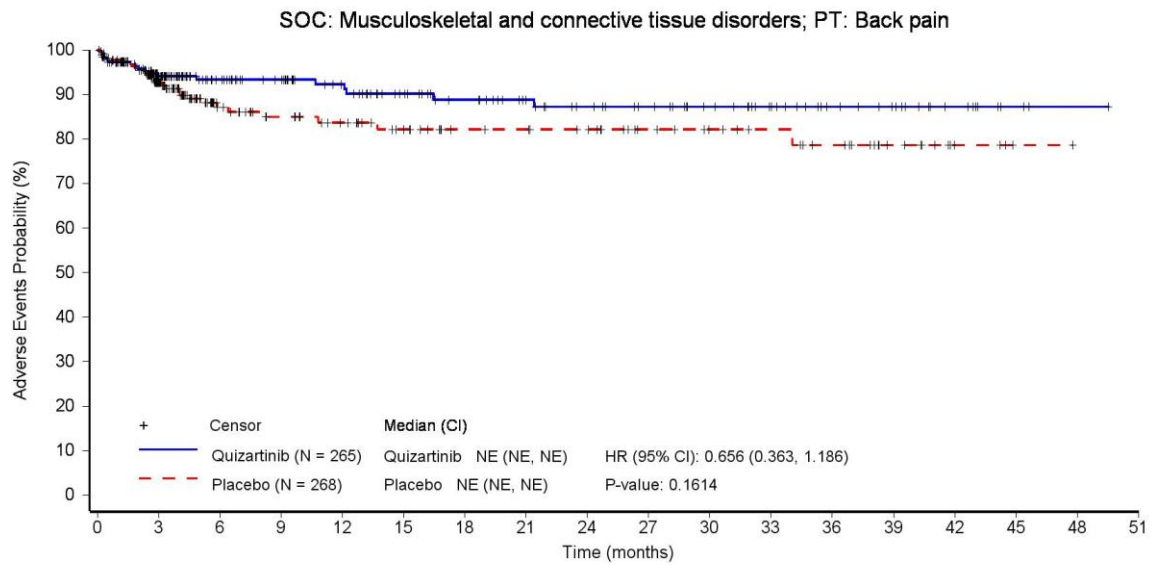
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	153	113	101	87	73	64	55	49	43	36	29	21	17	10	3	1	0
Placebo (N = 268)	268	146	86	72	62	52	43	42	39	30	26	23	19	11	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

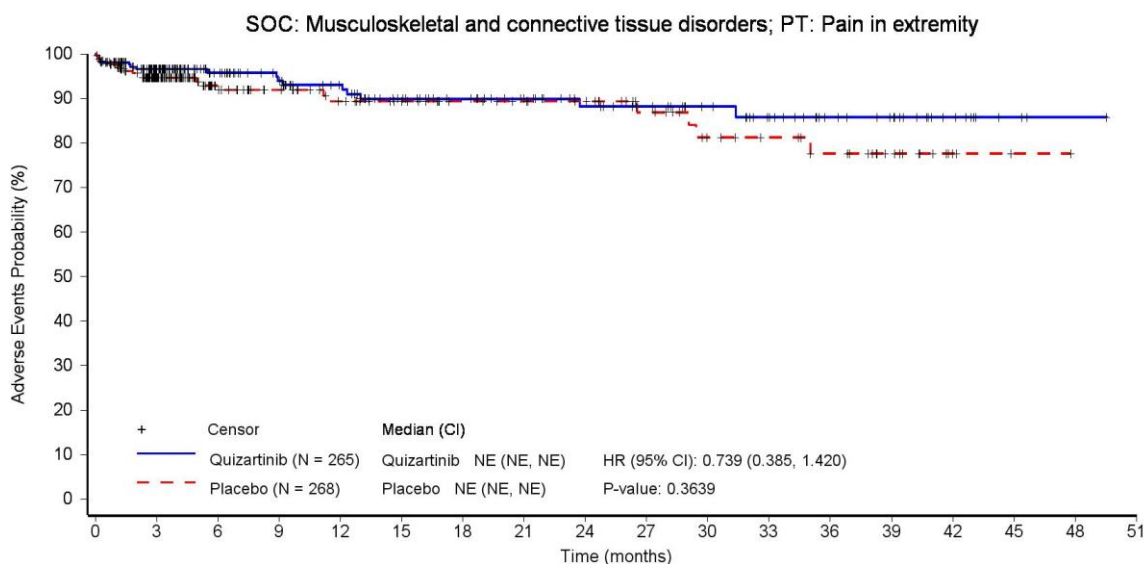
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	162	119	103	90	75	67	59	51	45	38	31	22	18	9	3	1	0
Placebo (N = 268)	268	151	94	80	68	60	51	48	45	35	27	24	20	13	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

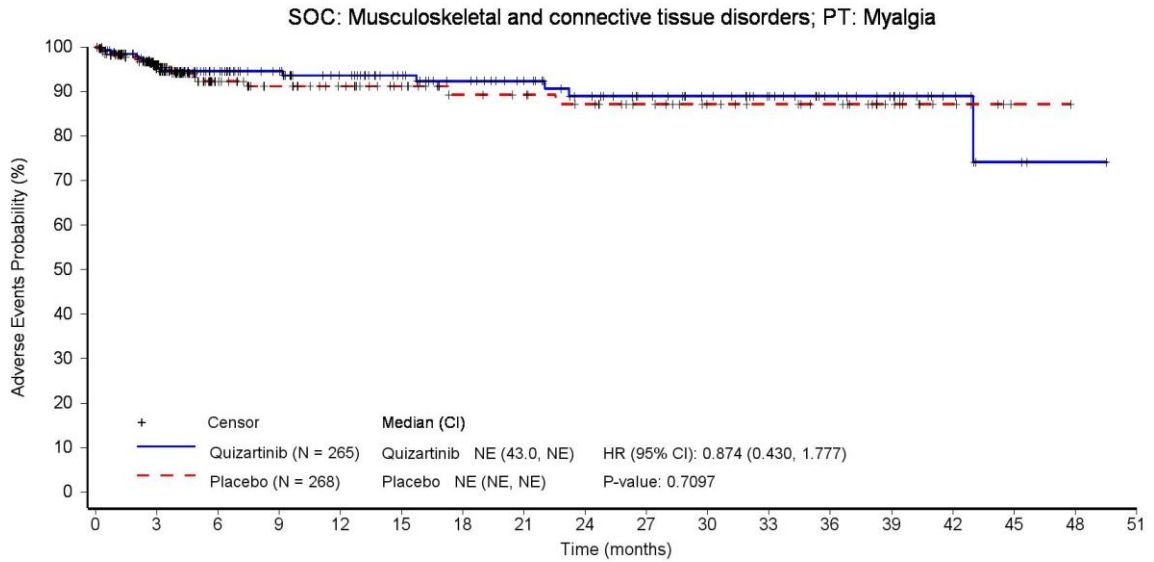
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	116	102	89	76	67	59	50	42	36	29	21	16	8	3	1	0
Placebo (N = 268)	268	152	90	76	67	57	46	44	40	33	27	24	21	13	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

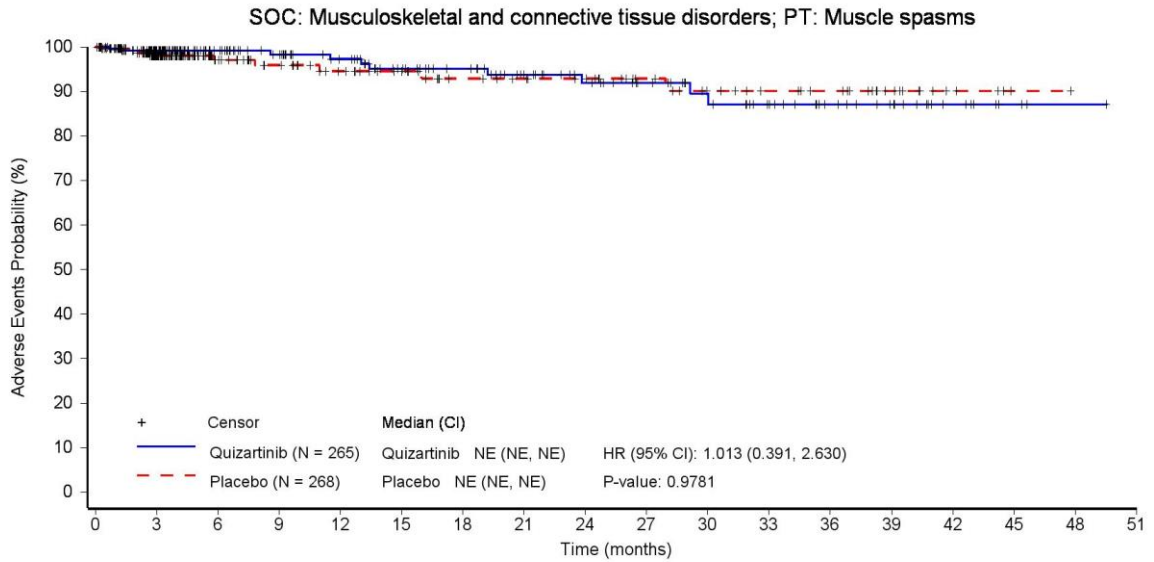
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	166	123	108	95	80	72	60	52	44	37	30	22	17	9	3	1	0
Placebo (N = 268)	268	153	95	80	68	60	49	46	43	34	28	24	21	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

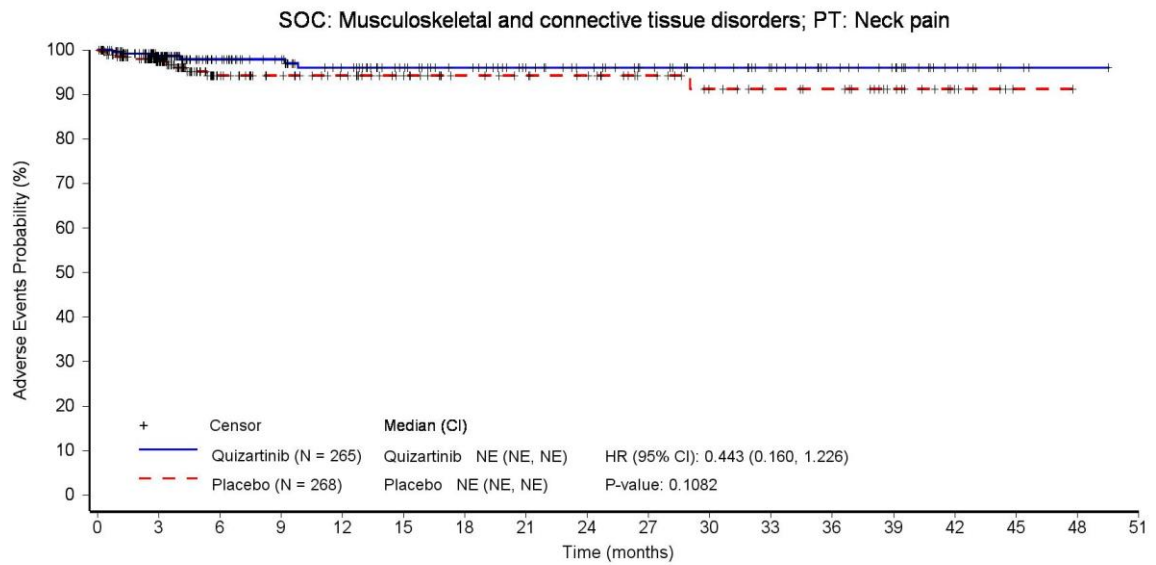
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	164	121	107	93	80	72	62	56	48	41	34	25	20	10	3	1	0
Placebo (N = 268)	268	154	94	80	70	60	50	47	44	35	28	24	22	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

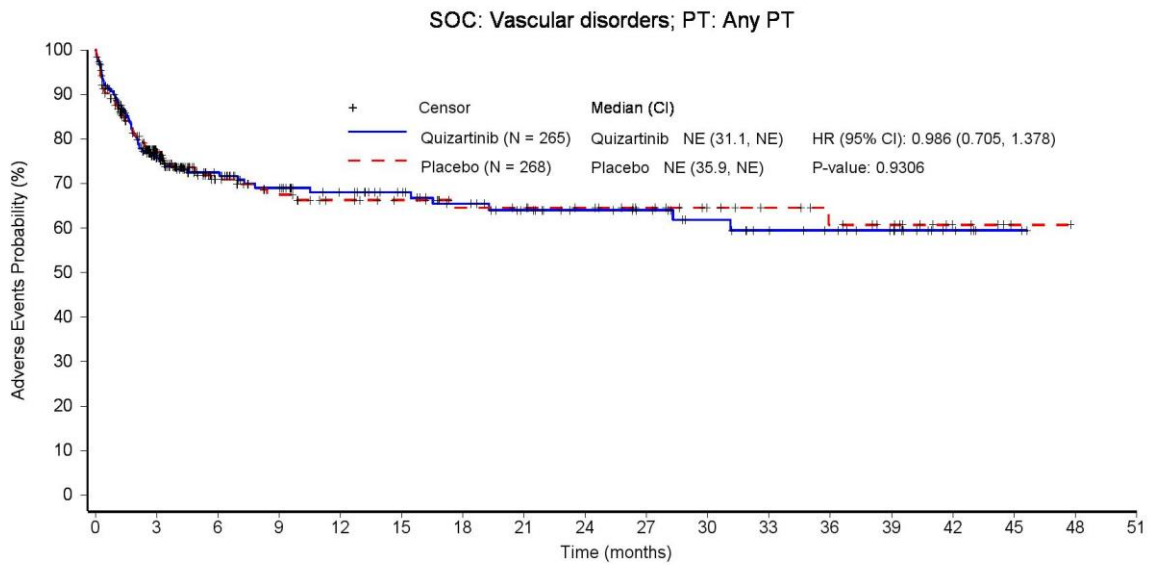
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	129	92	77	66	57	49	41	35	32	26	21	18	14	6	2	0	0
Placebo (N = 268)	268	122	69	57	48	44	37	36	33	27	22	19	16	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

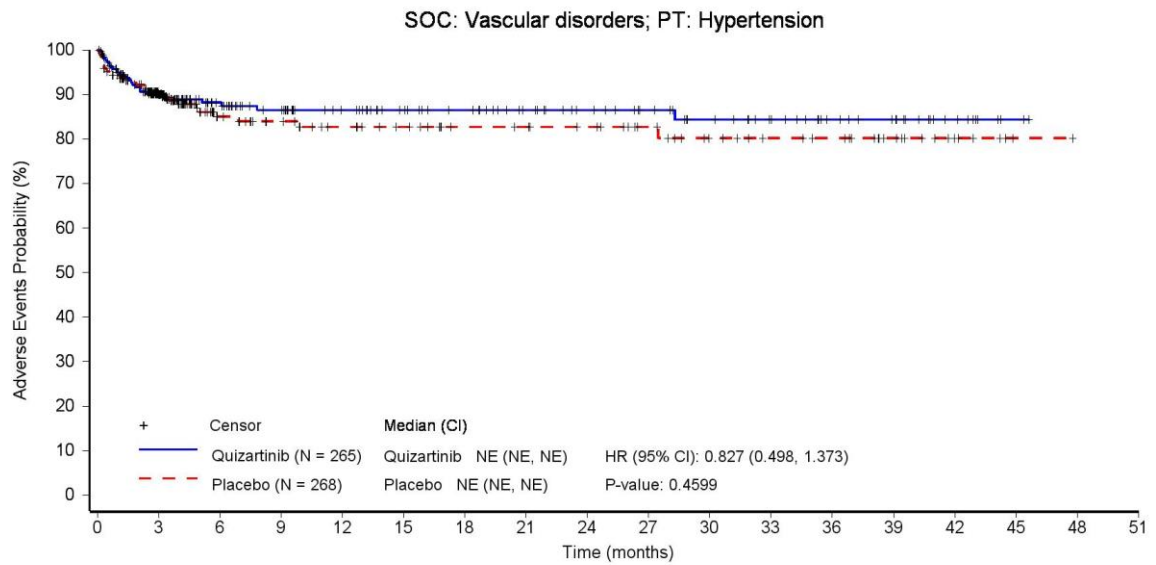
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	153	111	96	83	72	66	57	50	43	36	30	22	18	9	2	0	0
Placebo (N = 268)	268	140	81	69	59	54	45	44	41	34	27	23	21	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

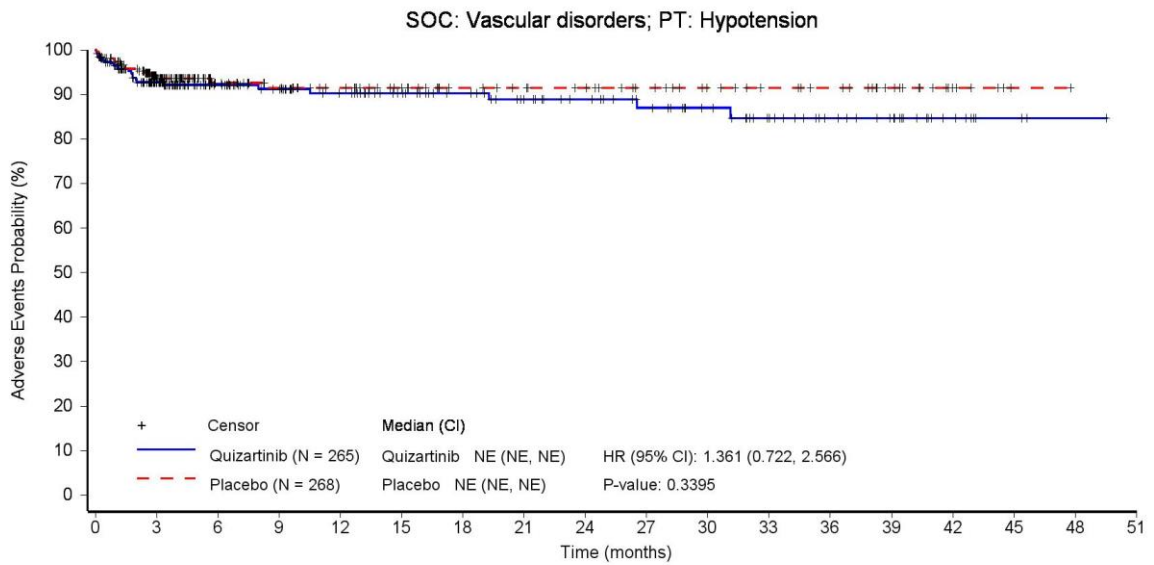
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	115	101	89	77	69	60	54	46	39	31	23	18	8	3	1	0
Placebo (N = 268)	268	148	92	79	69	59	49	46	43	36	30	26	23	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

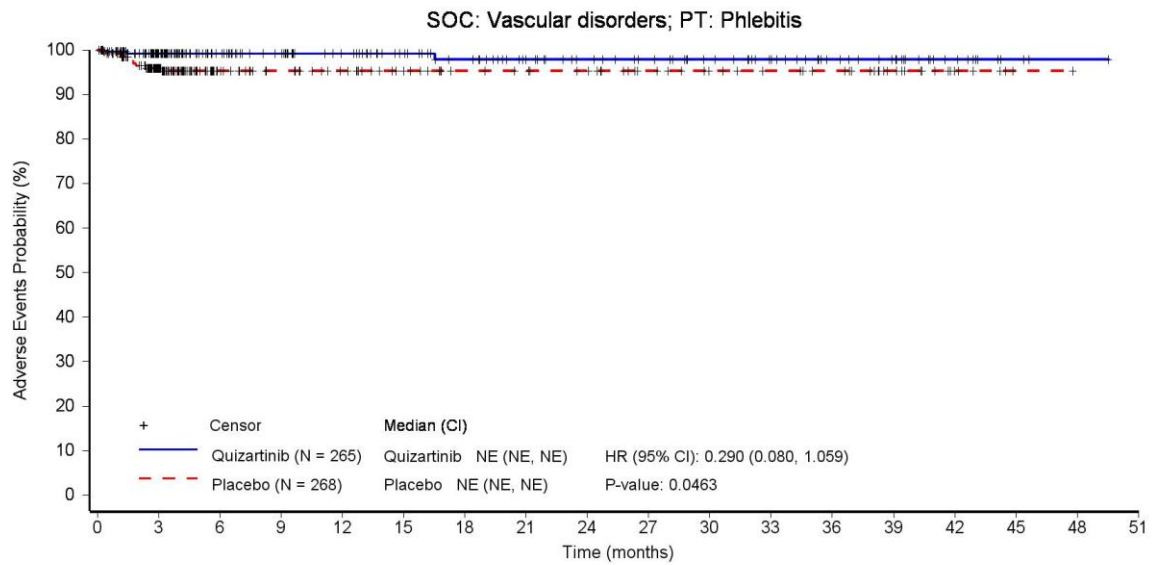
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	73	62	55	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	150	92	79	69	59	50	48	45	36	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

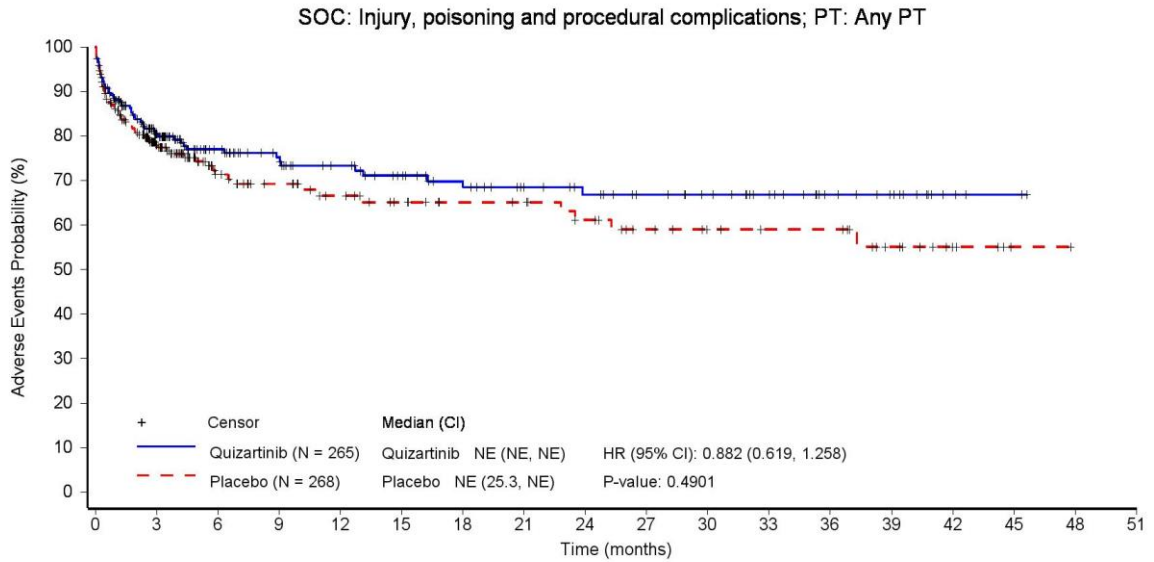
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Quizartinib (N = 265)	265	132	93	79	69	59	52	44	40	34	30	24	16	12	4	2	0	0
Placebo (N = 268)	268	121	69	57	48	41	36	35	30	24	20	18	18	11	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

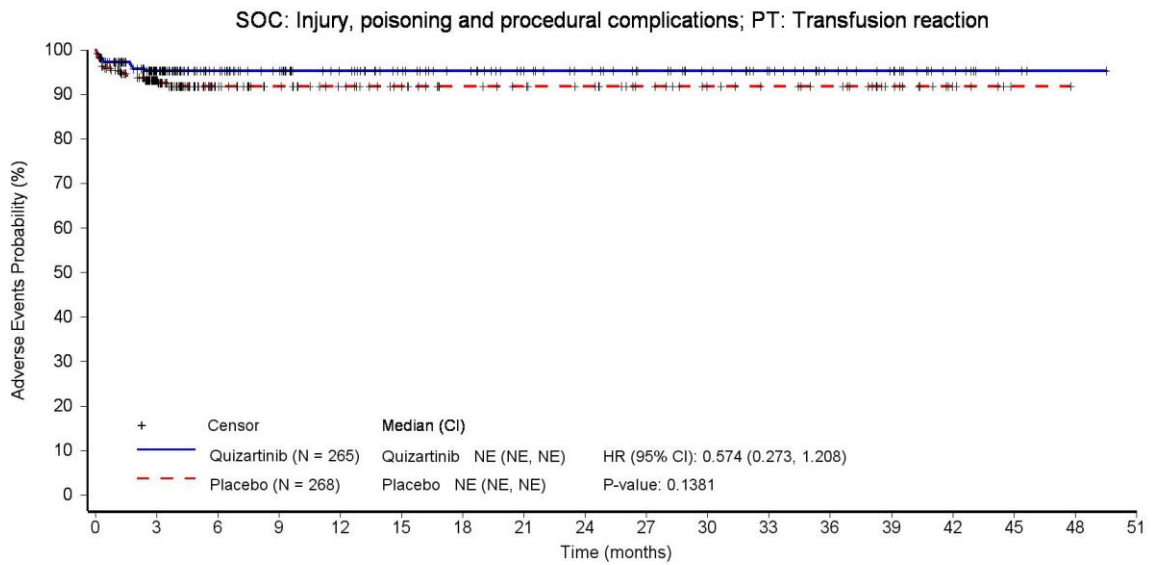
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	118	104	91	79	71	61	56	48	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	147	93	80	69	60	51	48	45	37	31	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

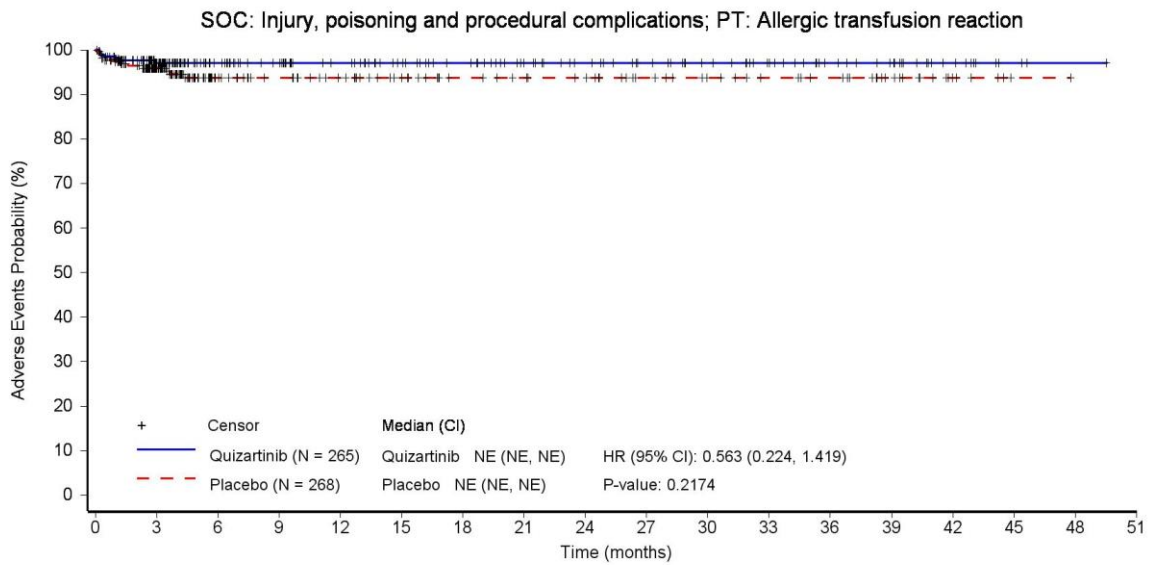
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Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	120	107	95	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	150	90	79	69	59	50	47	44	35	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

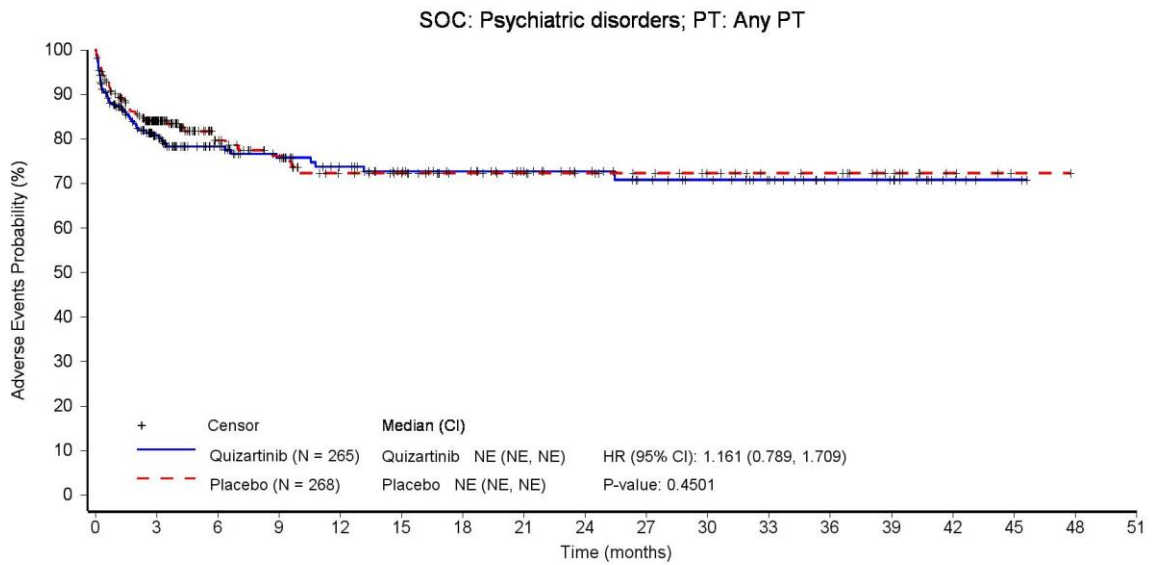
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	134	99	85	71	60	55	47	41	34	30	24	16	13	5	2	0	0
Placebo (N = 268)	268	131	75	61	50	45	36	33	30	26	22	18	17	11	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

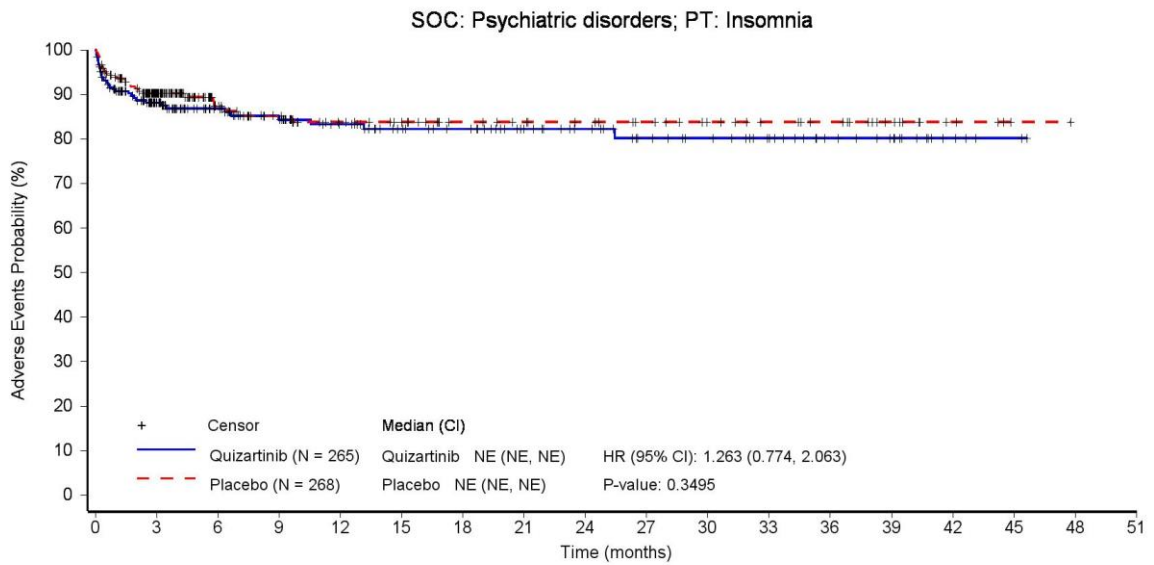
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	145	109	94	80	67	62	51	45	36	32	26	18	14	5	2	0	0
Placebo (N = 268)	268	141	81	67	57	51	42	39	36	31	26	22	19	12	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

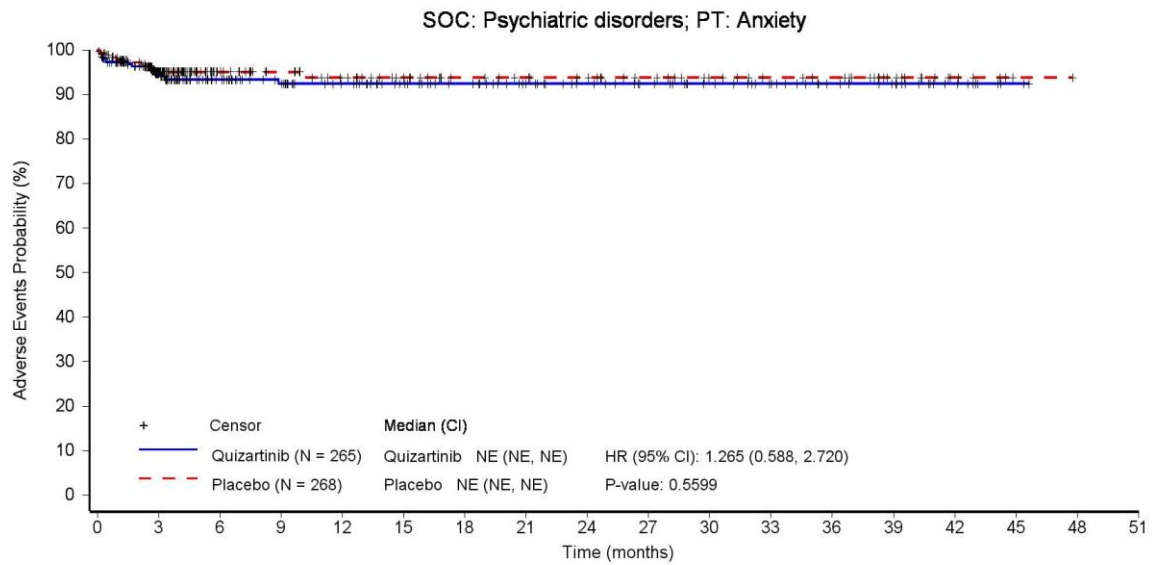
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	155	115	100	88	76	68	58	51	44	37	31	23	19	10	2	0	0
Placebo (N = 268)	268	149	93	79	68	59	49	46	43	36	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

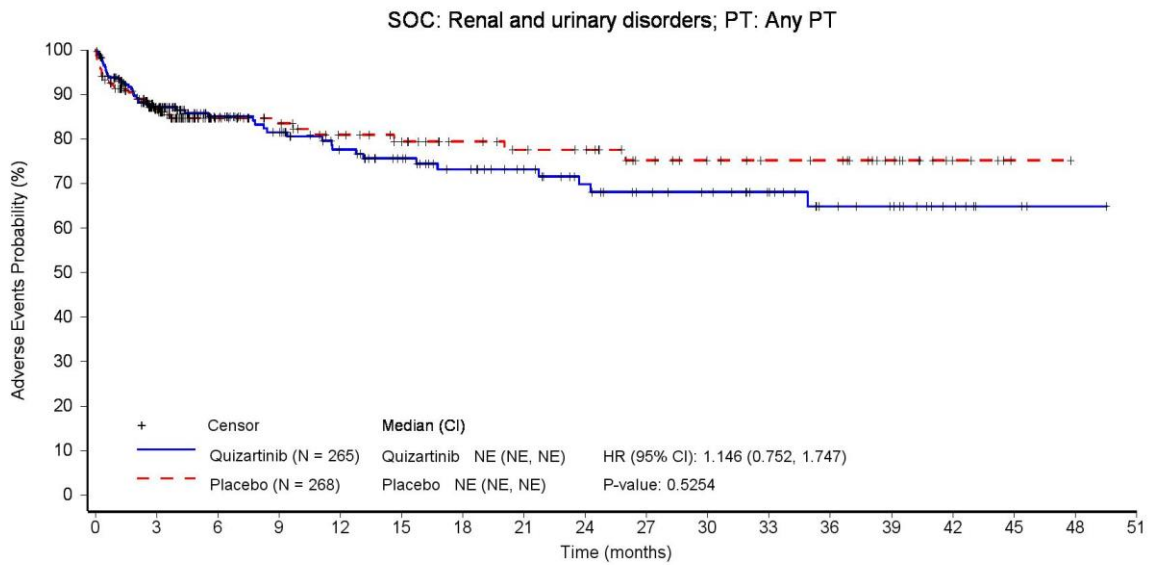
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	150	106	92	78	66	56	48	40	34	31	25	17	14	7	3	1	0
Placebo (N = 268)	268	138	84	70	58	51	44	40	38	28	24	21	20	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

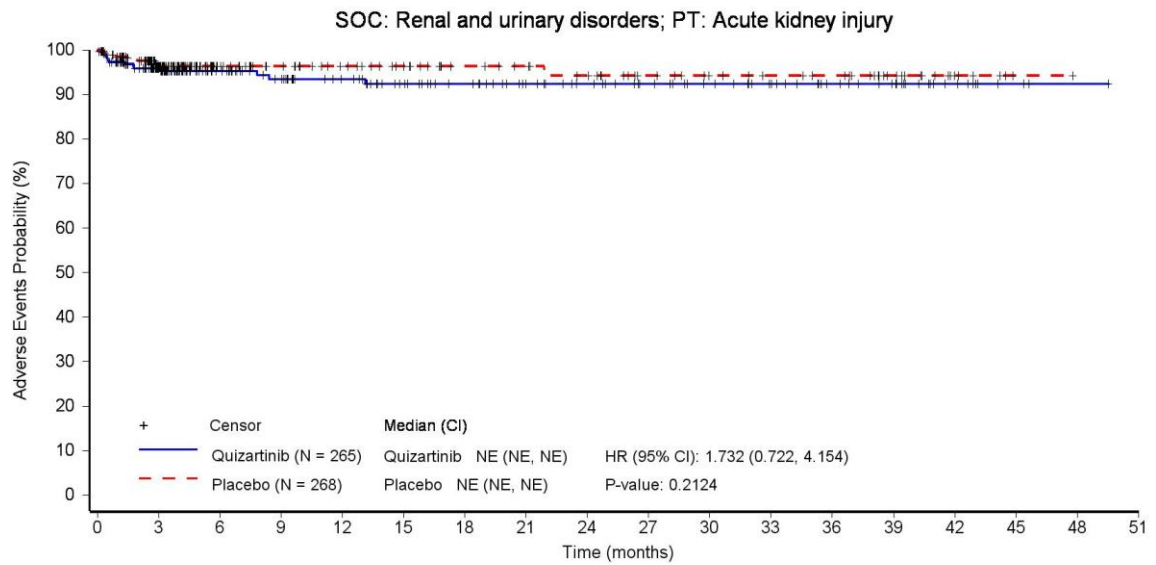
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	161	117	102	90	77	69	59	53	45	39	33	25	20	10	3	1	0
Placebo (N = 268)	268	151	93	79	68	60	51	48	44	35	30	27	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

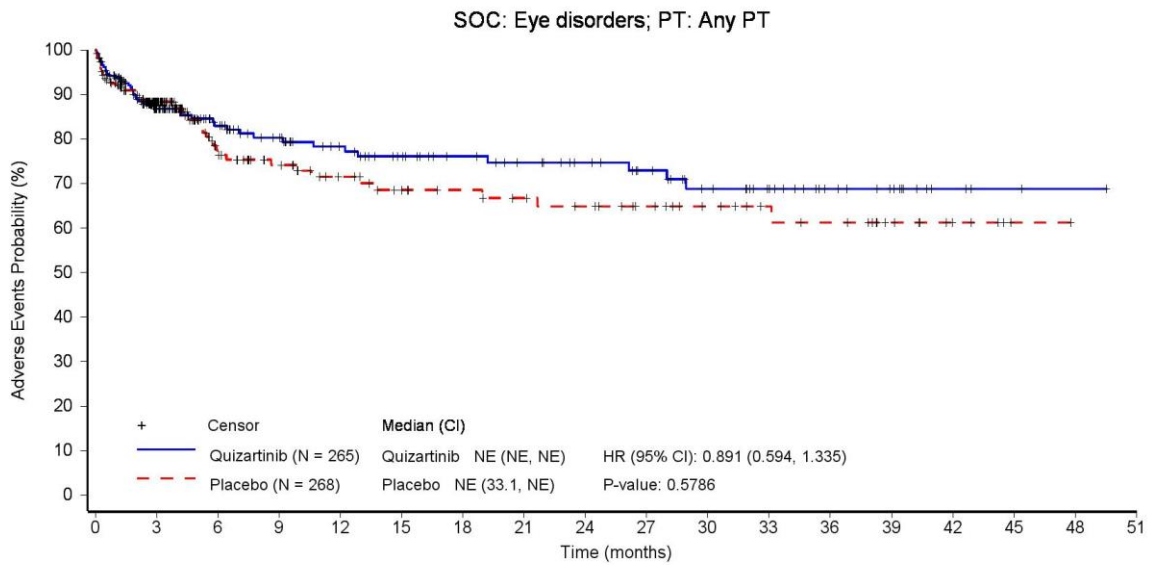
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	141	101	85	72	62	55	50	45	38	30	24	16	12	5	2	1	0
Placebo (N = 268)	268	138	75	61	50	42	39	36	33	27	22	18	16	10	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

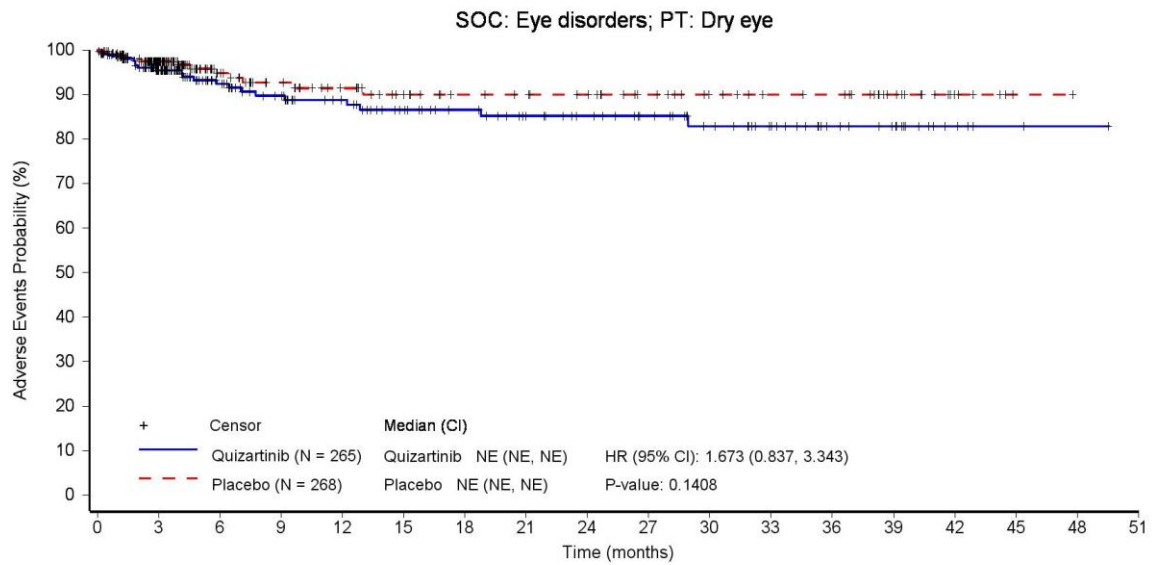
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	111	95	82	70	63	55	50	43	35	28	19	15	6	2	1	0
Placebo (N = 268)	268	151	92	77	66	56	49	47	44	36	30	26	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

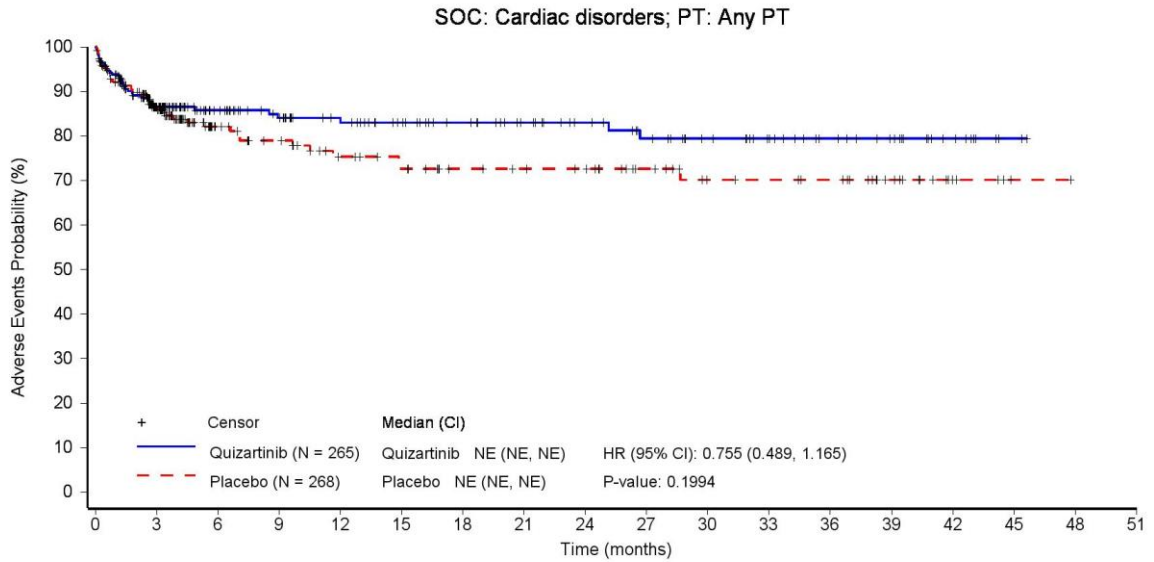
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	150	109	94	82	73	65	57	50	43	36	30	23	18	10	2	0	0
Placebo (N = 268)	268	138	81	71	58	53	46	44	42	33	26	25	23	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

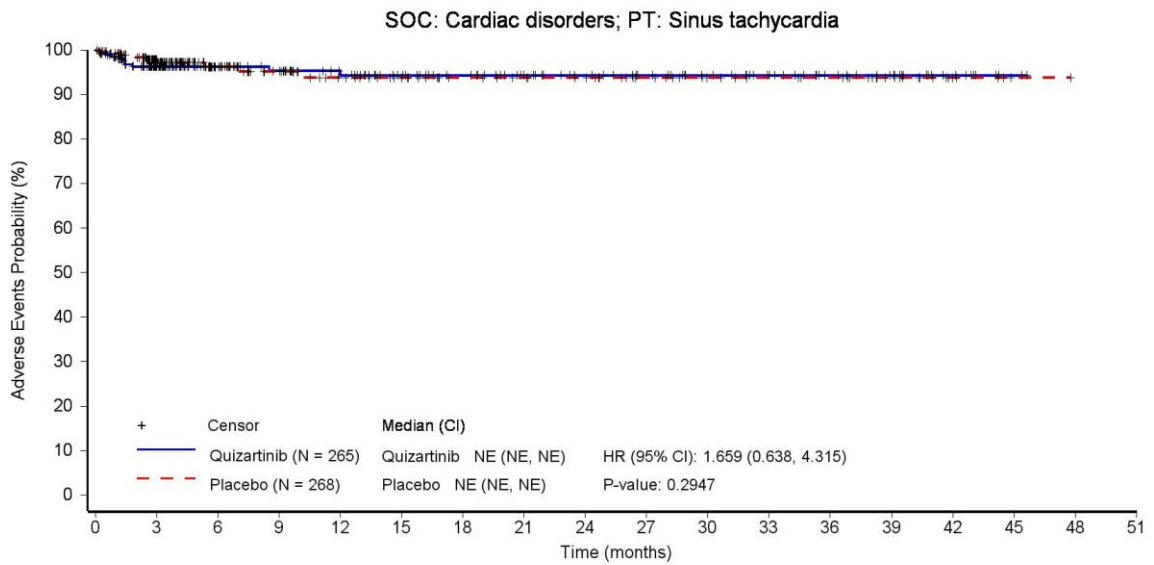
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	118	103	90	78	70	60	53	47	40	33	24	19	10	2	0	0
Placebo (N = 268)	268	153	94	79	67	59	49	46	43	34	28	25	23	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

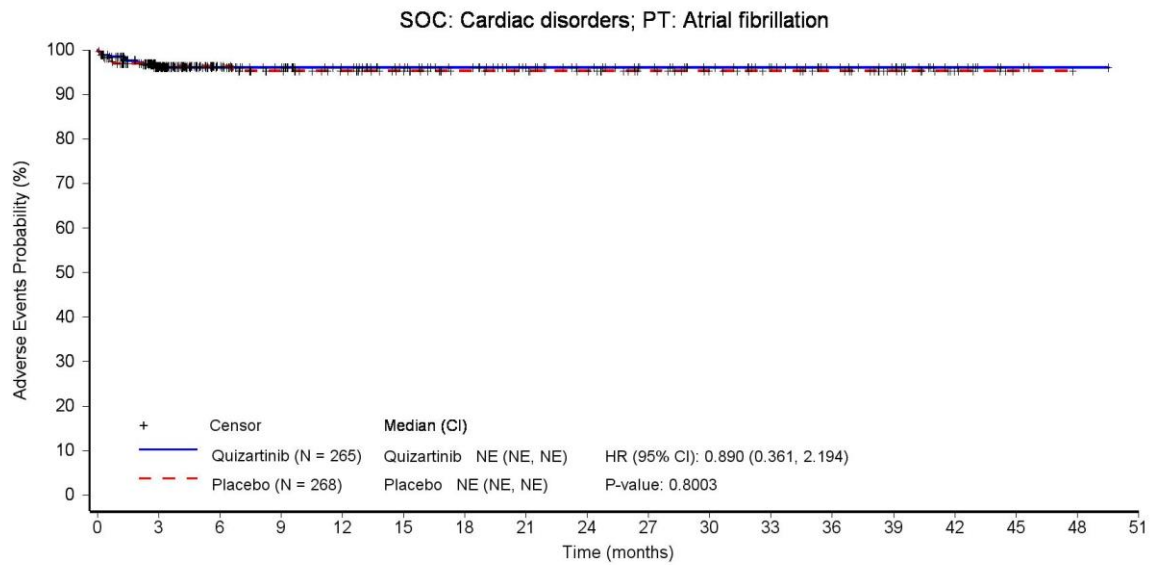
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	122	108	95	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	152	95	82	72	62	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

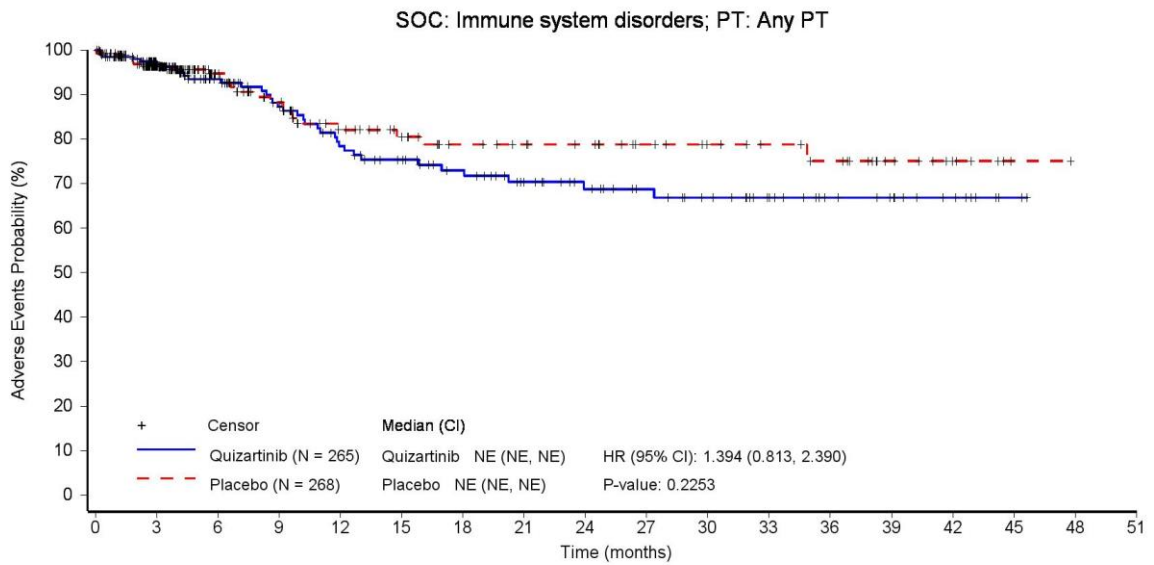
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	116	96	78	68	59	49	42	36	31	24	17	14	9	2	0	0
Placebo (N = 268)	268	151	93	75	59	50	42	39	36	29	25	22	19	11	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

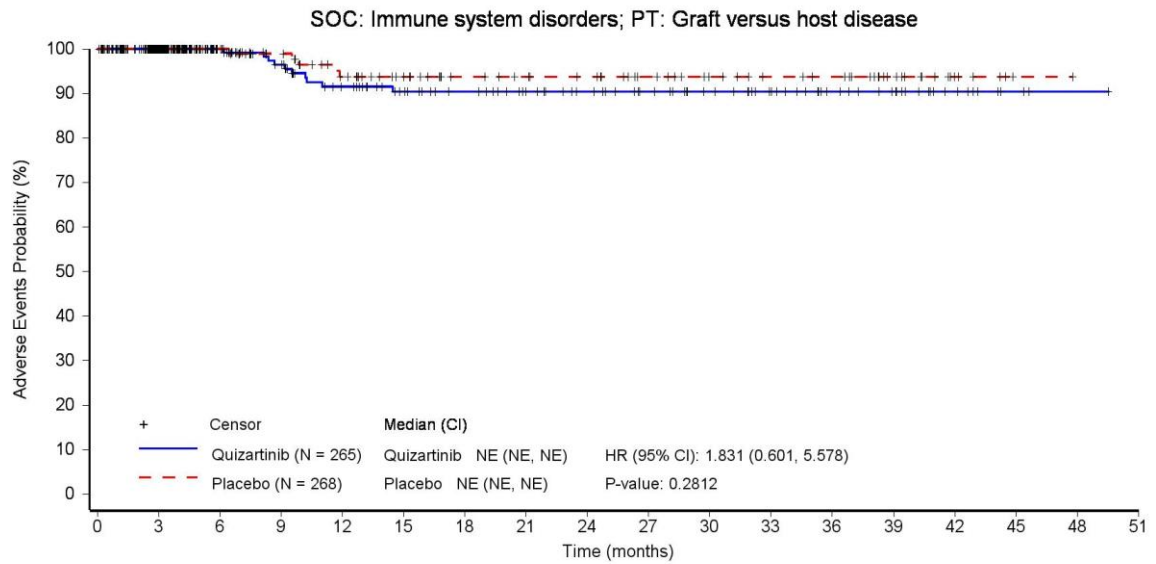
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	166	123	105	88	76	69	61	55	47	40	33	24	19	10	3	1	0
Placebo (N = 268)	268	157	98	83	68	58	50	47	44	36	30	26	24	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

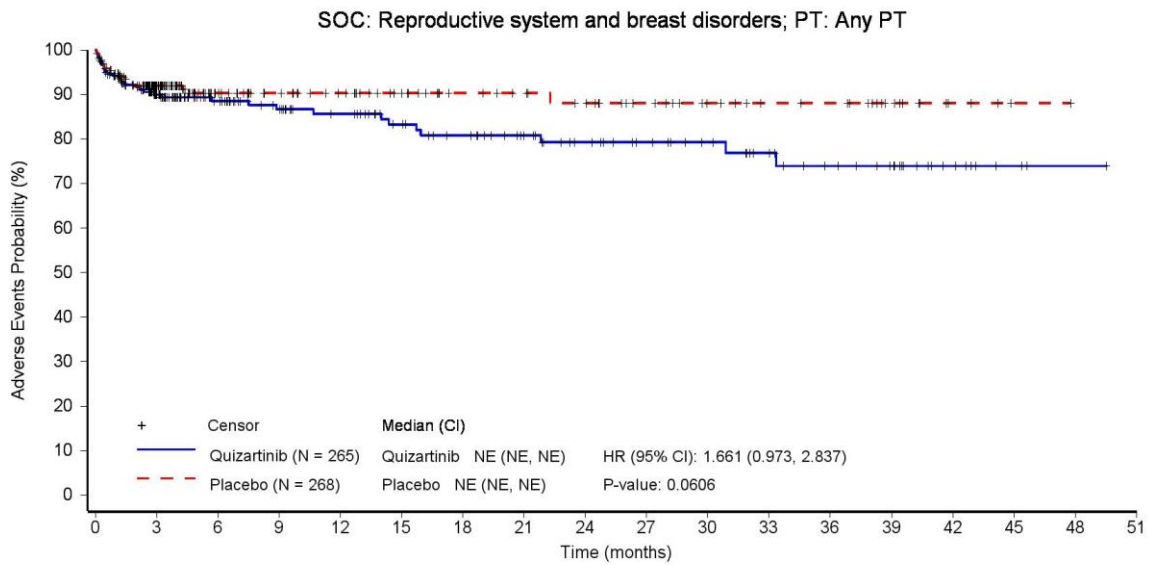
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	147	107	91	81	70	63	54	46	39	34	28	22	18	9	3	1	0
Placebo (N = 268)	268	142	88	74	65	55	45	42	38	30	24	20	19	12	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

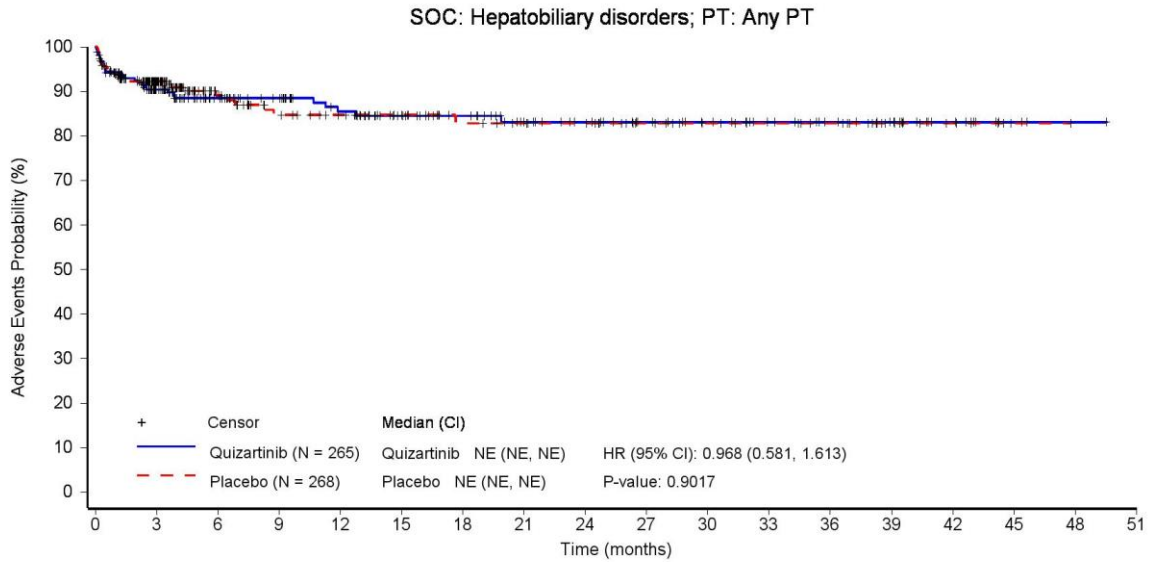
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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	152	114	100	86	74	67	55	49	41	36	29	24	20	11	3	1	0
Placebo (N = 268)	268	147	89	73	64	54	44	41	39	31	26	23	20	11	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

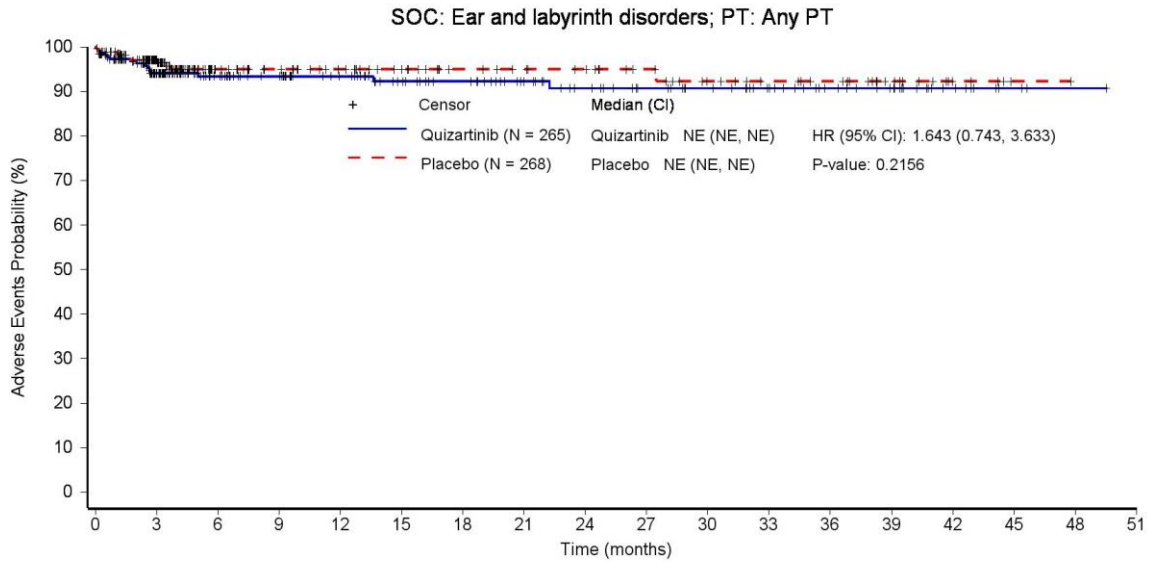
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.1 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	157	118	106	93	79	72	61	53	45	40	33	25	20	10	3	1	0
Placebo (N = 268)	268	151	91	79	68	59	49	46	43	36	29	25	22	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

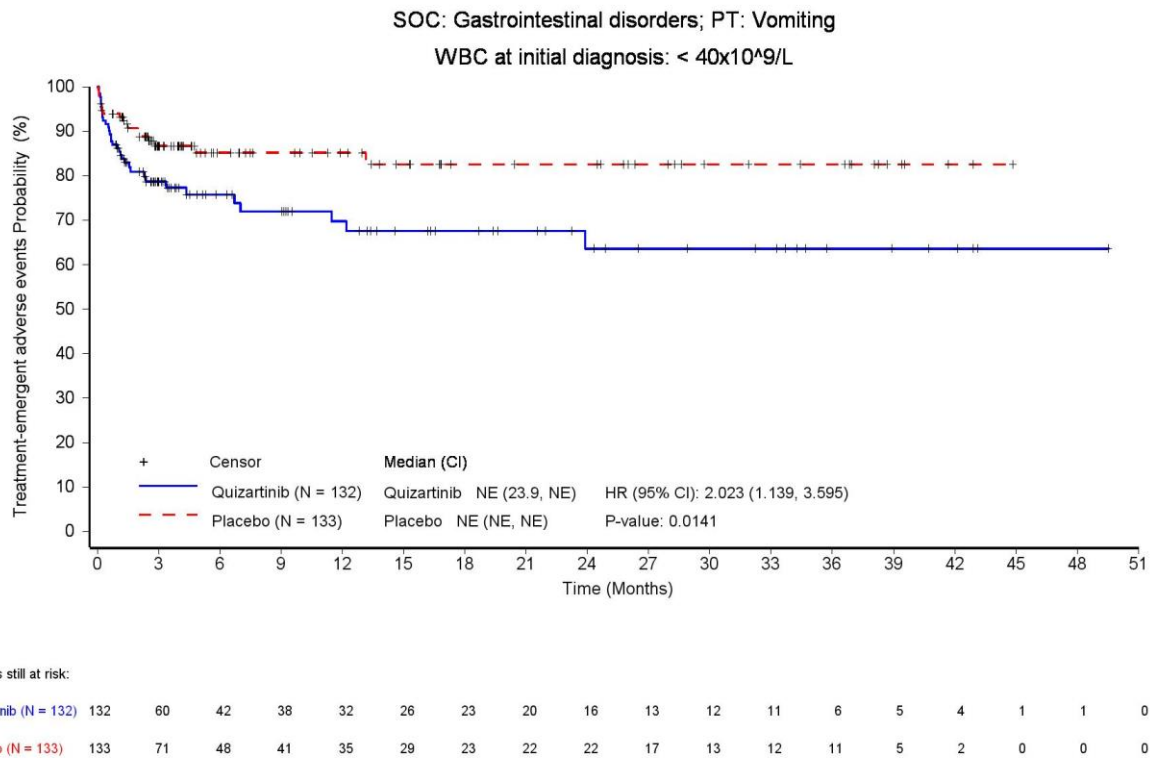
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Run date: 14JUL2023 – 16:26; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_11_1_TEAESOCPT_SAS.rtf

Anhang 4-G2: UE nach SOC und PT – Subgruppenanalysen (alle Schweregrade)

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

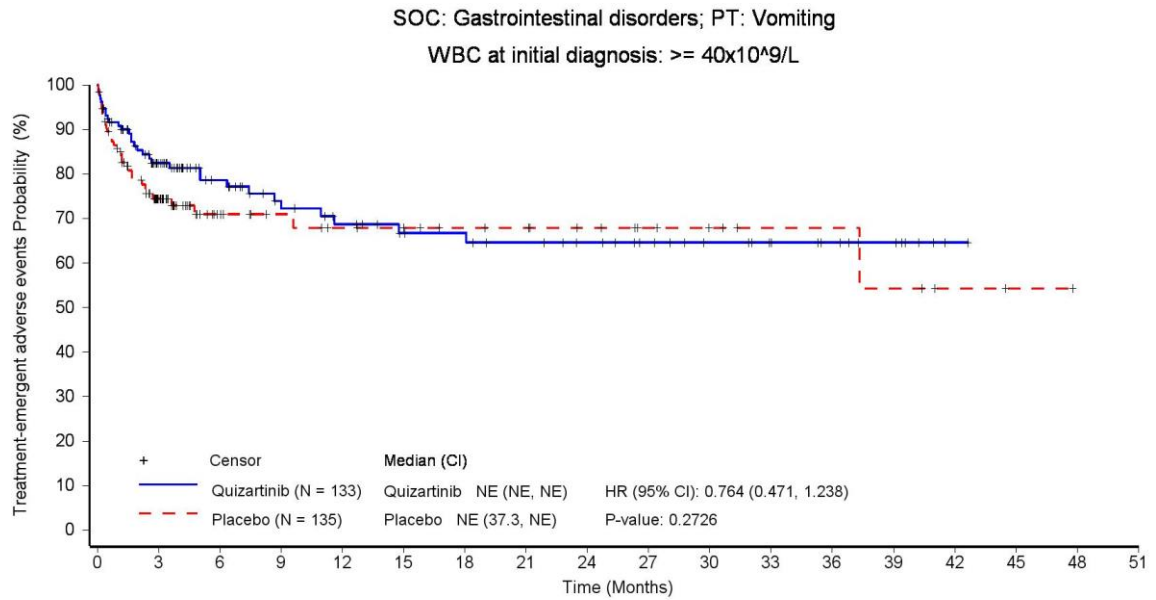
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	77	55	44	38	32	31	28	25	21	17	14	11	8	2	0	0	0
Placebo (N = 135)	135	58	29	23	20	18	16	15	12	9	7	5	5	4	2	1	0	0

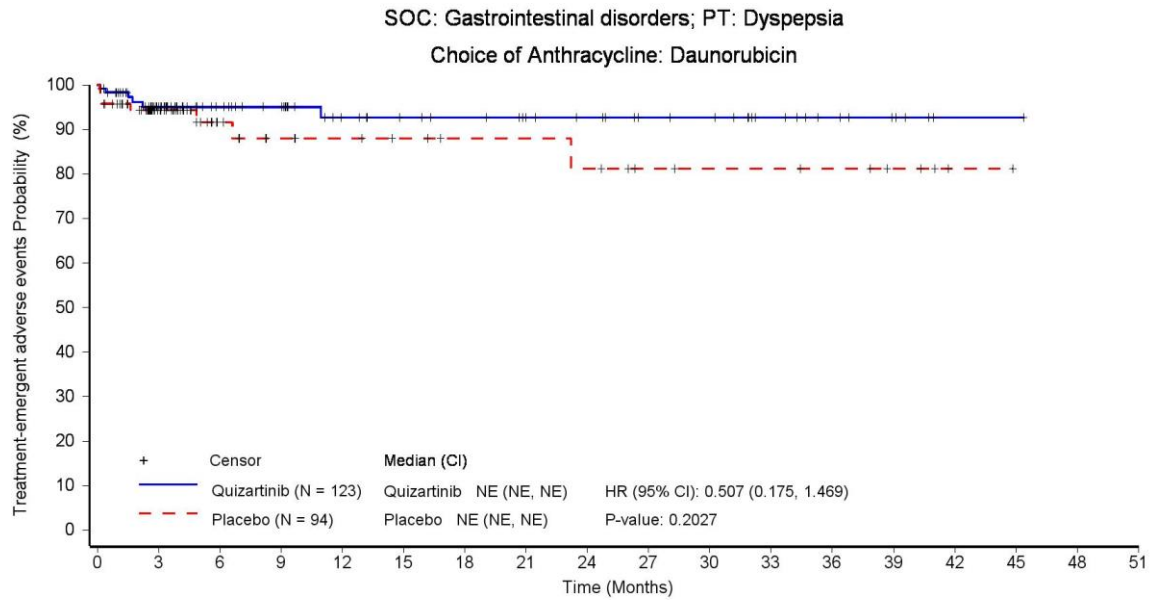
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 123)	123	72	53	47	36	32	30	26	24	19	18	12	8	5	1	1	0	0
Placebo (N = 94)	94	50	27	20	18	16	13	13	12	8	7	7	6	4	1	0	0	0

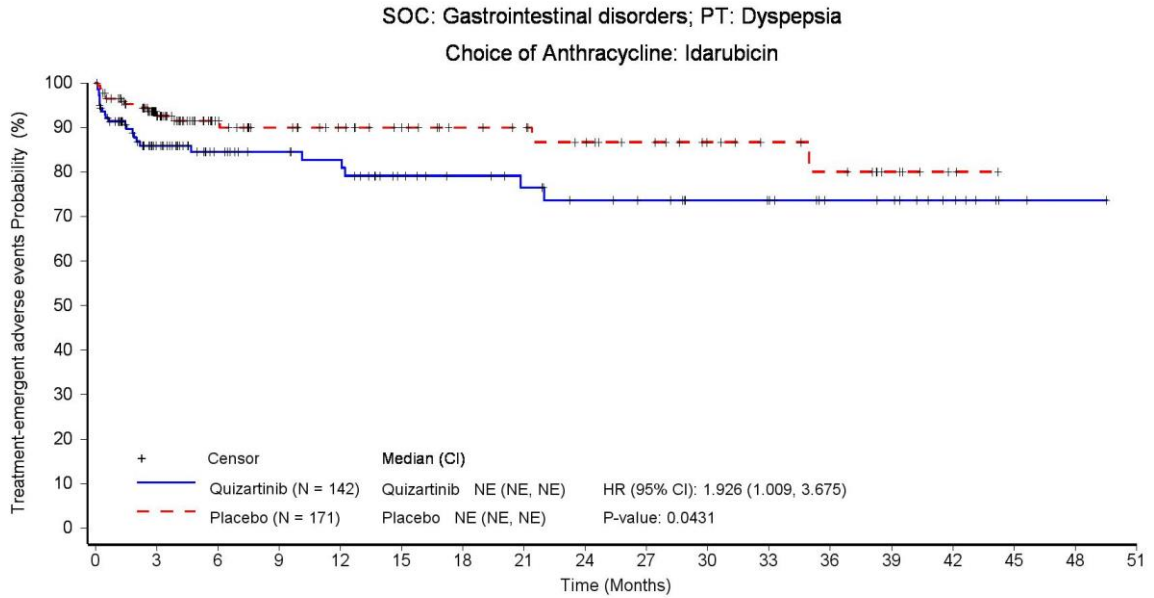
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 142)	142	77	55	49	46	36	32	29	25	23	19	18	13	12	7	2	1	0
Placebo (N = 171)	171	93	60	51	44	38	32	30	26	22	17	14	12	7	2	0	0	0

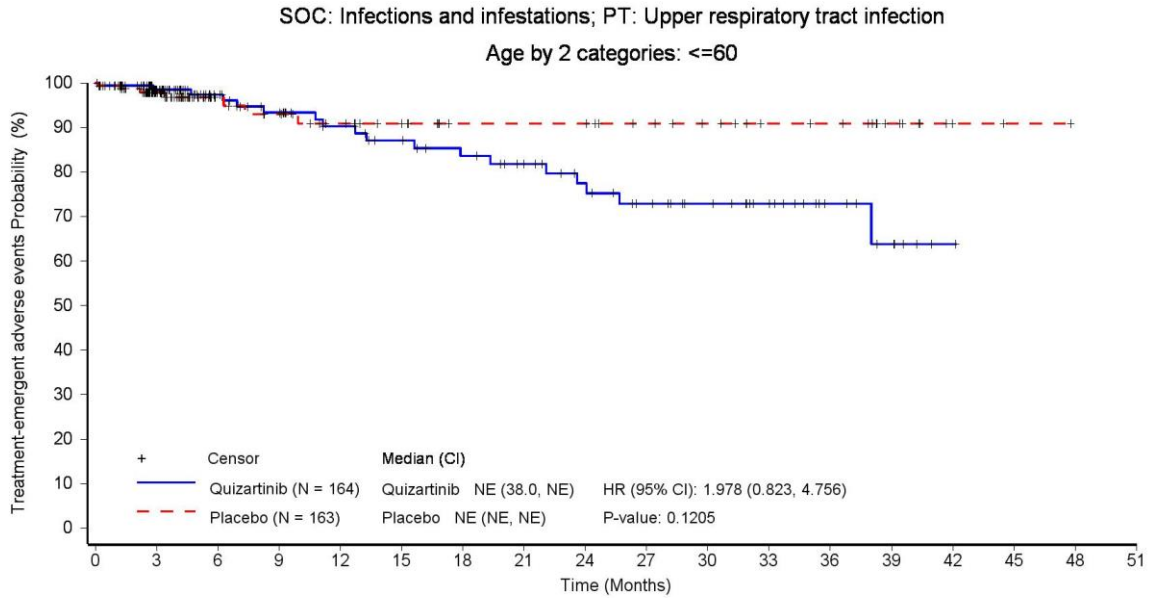
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	105	76	67	58	52	47	41	35	29	24	18	10	6	1	0	0	0
Placebo (N = 163)	163	92	52	46	39	33	27	27	27	22	19	15	14	8	2	1	0	0

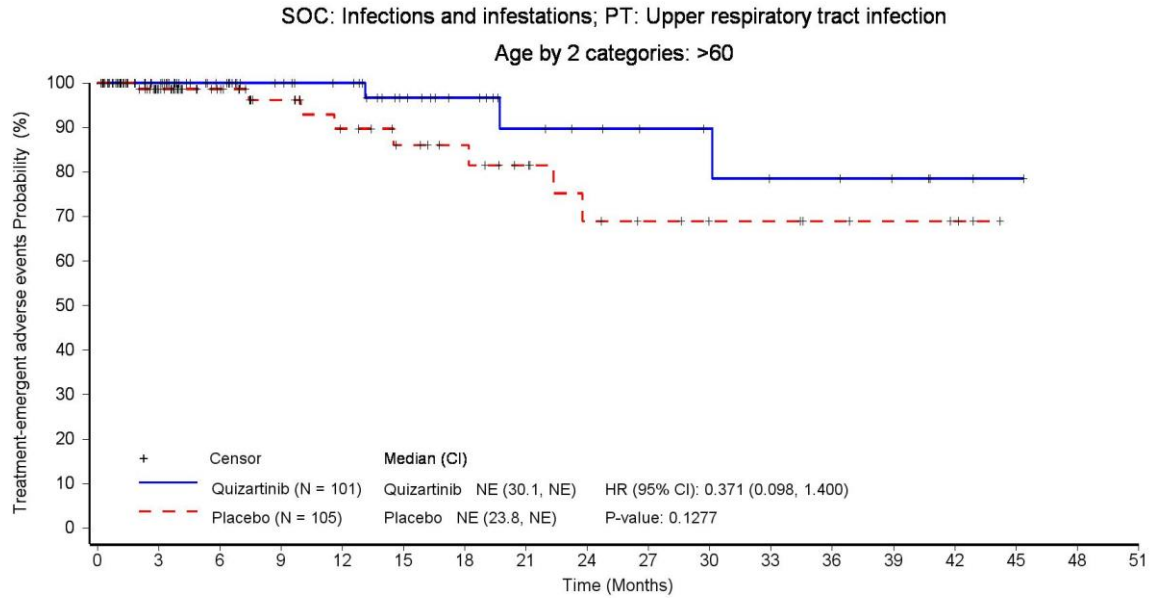
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	60	45	37	33	23	18	13	11	9	8	6	6	4	2	1	0	0
Placebo (N = 105)	105	63	45	34	27	22	19	15	11	9	7	7	5	4	3	0	0	0

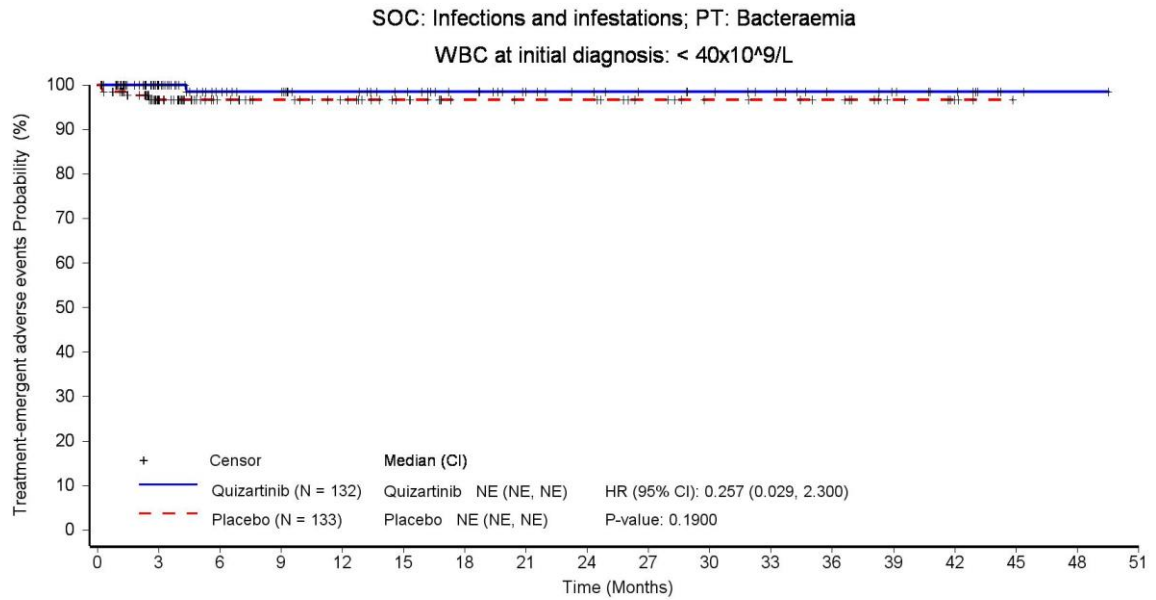
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 132)	132	77	58	54	48	43	37	30	27	23	21	18	13	11	8	2	1	0
Placebo (N = 133)	133	78	54	47	41	33	26	25	25	20	16	15	13	7	3	0	0	0

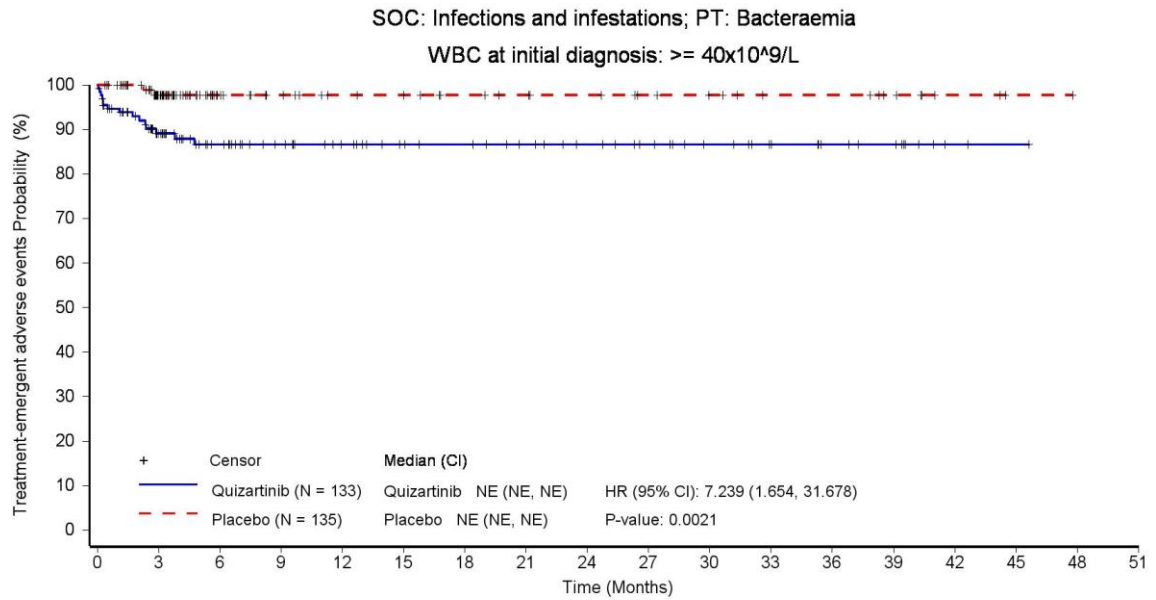
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	82	62	52	45	38	36	32	28	24	19	15	11	9	2	1	0	0
Placebo (N = 135)	135	74	39	32	27	25	22	20	18	15	13	10	10	7	3	1	0	0

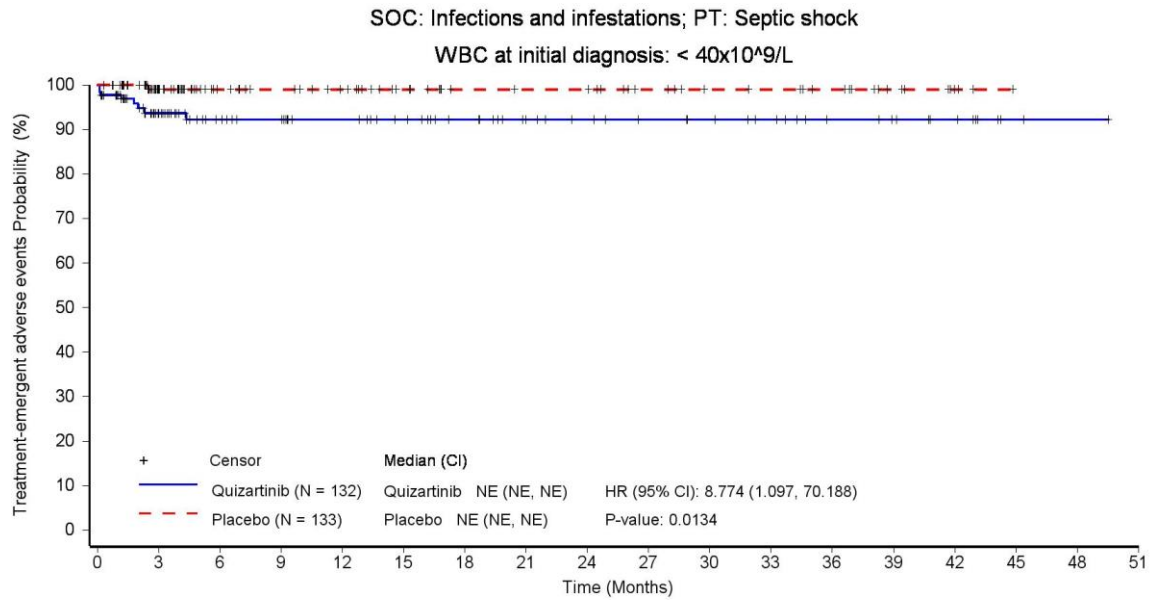
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	75	57	53	47	42	36	29	26	23	21	18	13	11	8	2	1	0
Placebo (N = 133)	133	80	56	50	44	36	29	28	28	22	18	17	14	8	3	0	0	0

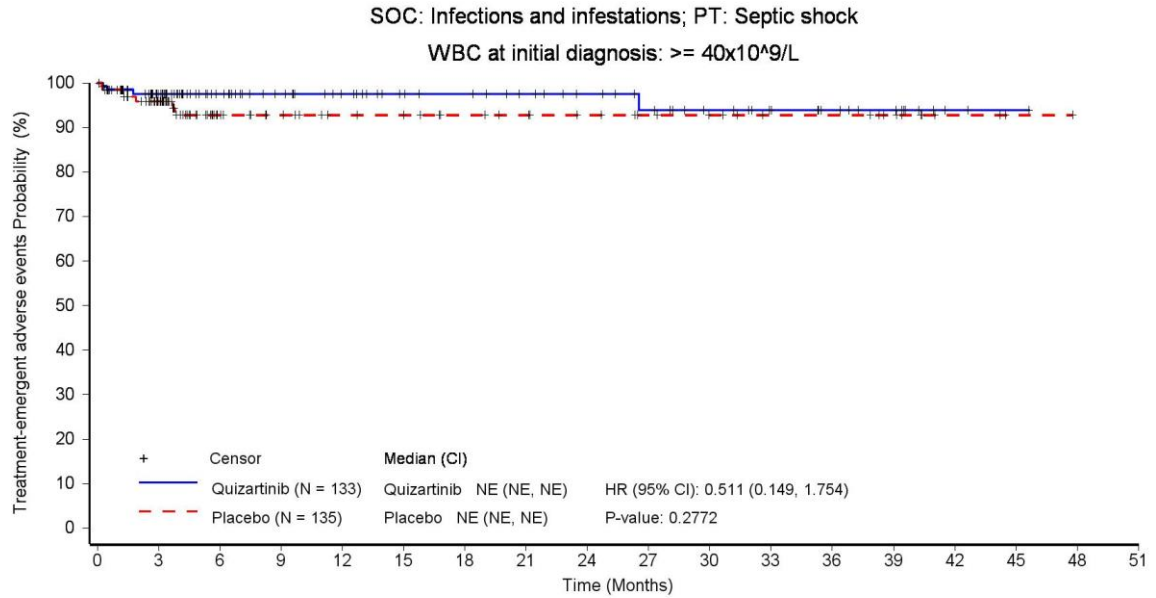
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 133)	133	89	65	55	48	40	38	34	30	26	21	17	13	10	3	1	0	0
Placebo (N = 135)	135	76	41	34	29	27	24	22	19	16	14	11	11	8	3	1	0	0

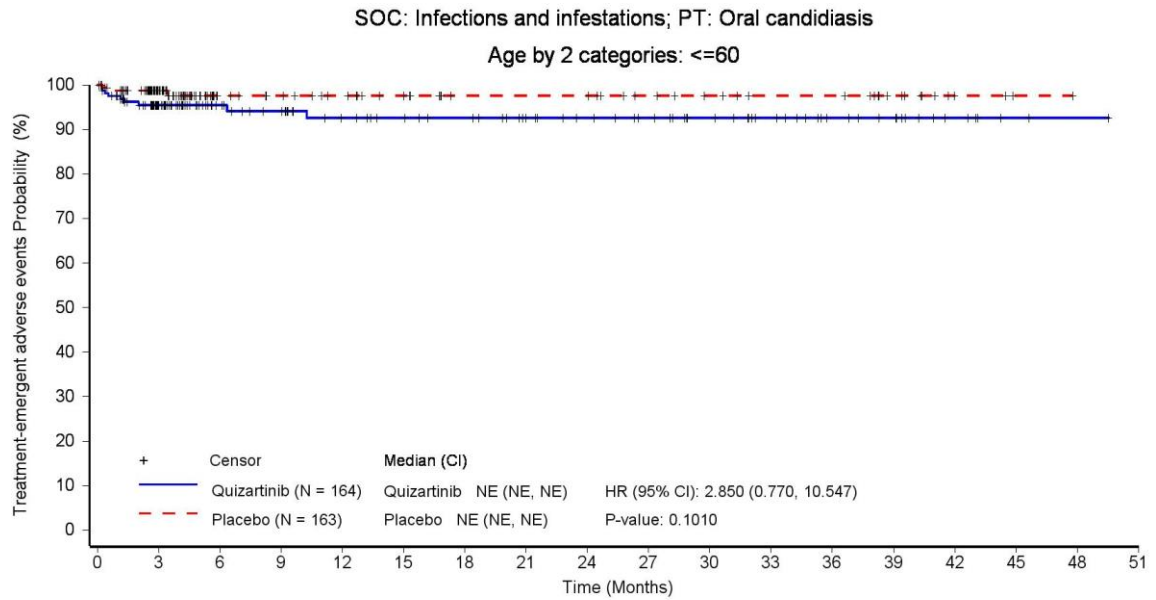
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	103	75	68	58	54	51	44	40	36	30	24	17	14	7	2	1	0
Placebo (N = 163)	163	93	51	47	41	35	28	28	28	22	19	16	16	10	3	1	0	0

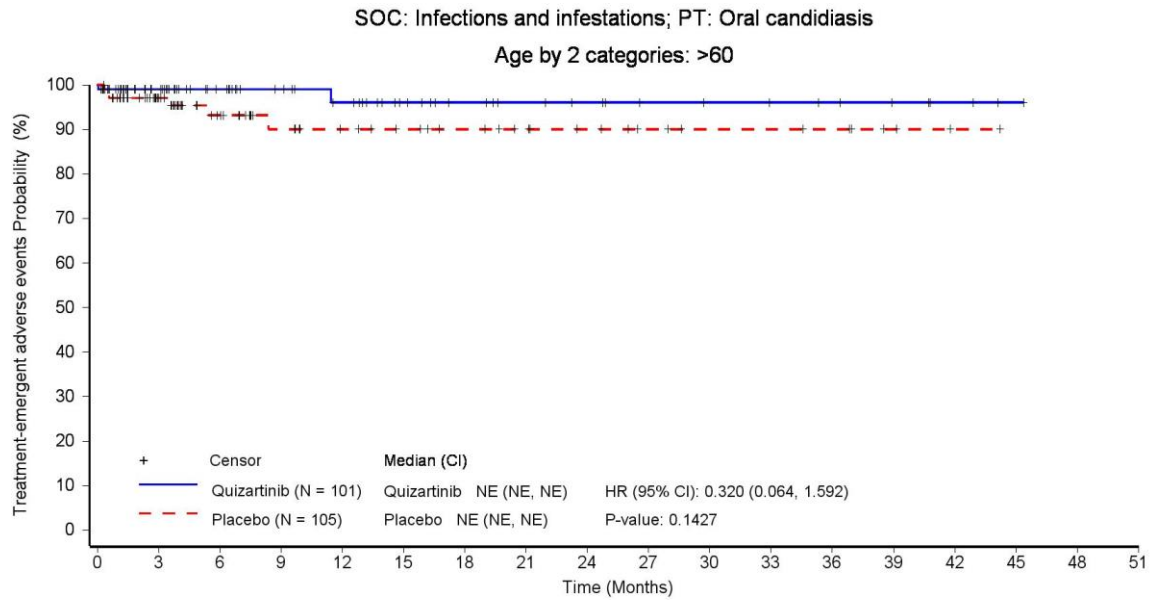
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	60	45	37	32	23	18	15	13	10	9	8	7	5	3	1	0	0
Placebo (N = 105)	105	60	40	29	24	21	18	15	12	9	7	7	6	3	1	0	0	0

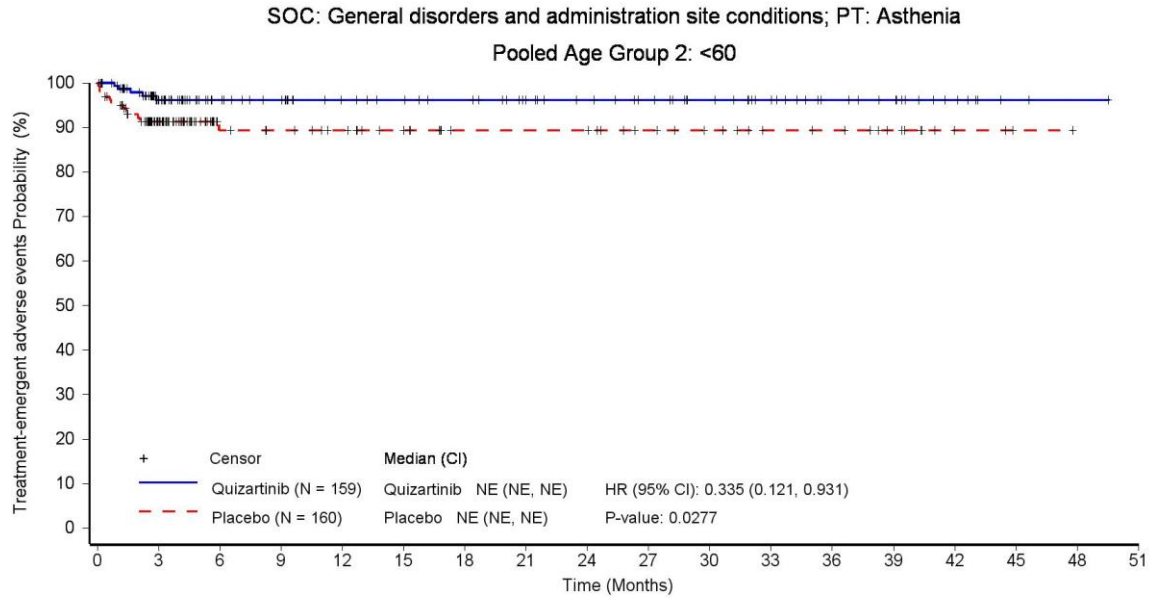
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 159)	159	98	74	68	59	56	53	46	42	37	31	25	18	15	8	2	1	0
Placebo (N = 160)	160	86	46	43	39	33	27	27	27	21	18	14	13	9	3	1	0	0

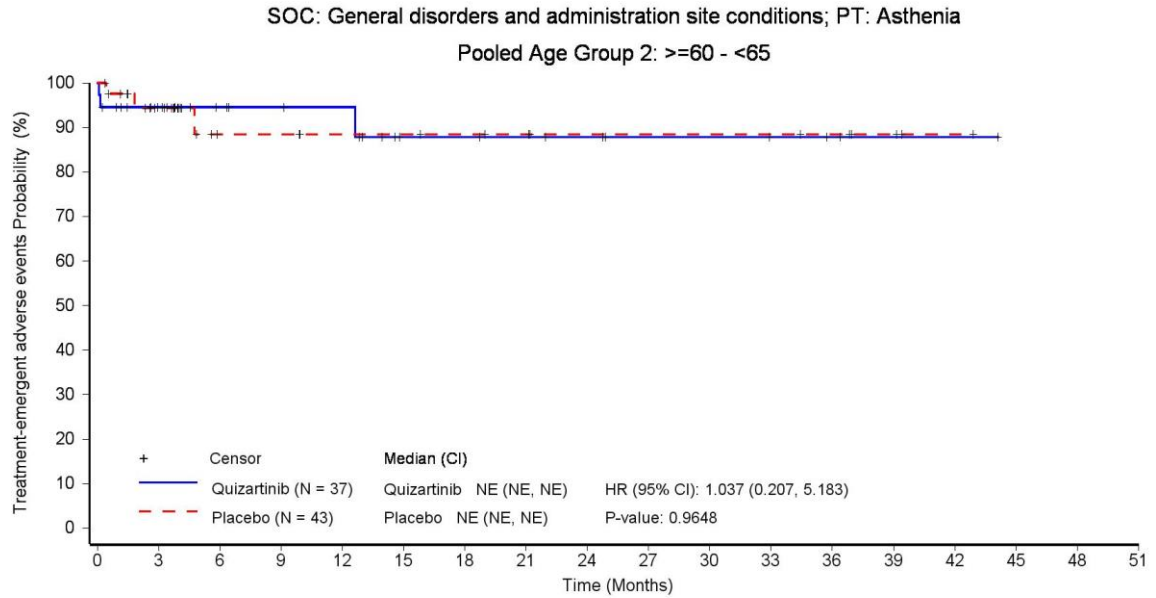
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 37)	37	23	17	15	14	8	8	7	6	4	4	3	2	1	1	0	0	0
Placebo (N = 43)	43	24	12	12	10	10	9	8	6	6	6	6	5	3	1	0	0	0

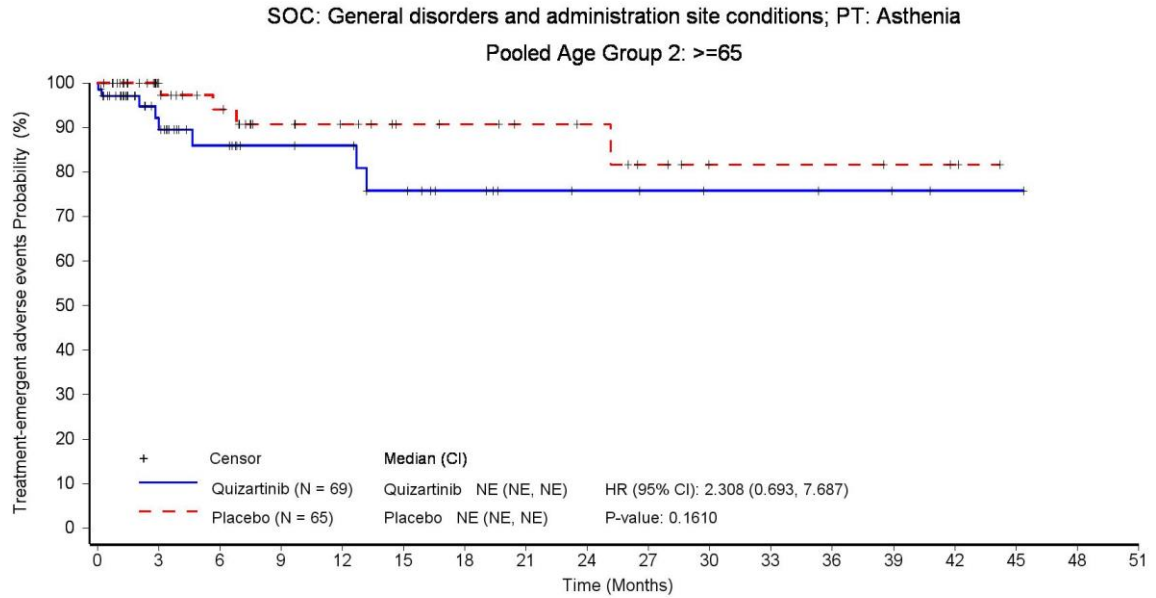
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 69)	69	34	24	19	18	14	10	7	6	5	4	4	3	2	1	1	0	0
Placebo (N = 65)	65	37	29	21	18	14	13	11	10	7	4	4	4	3	2	0	0	0

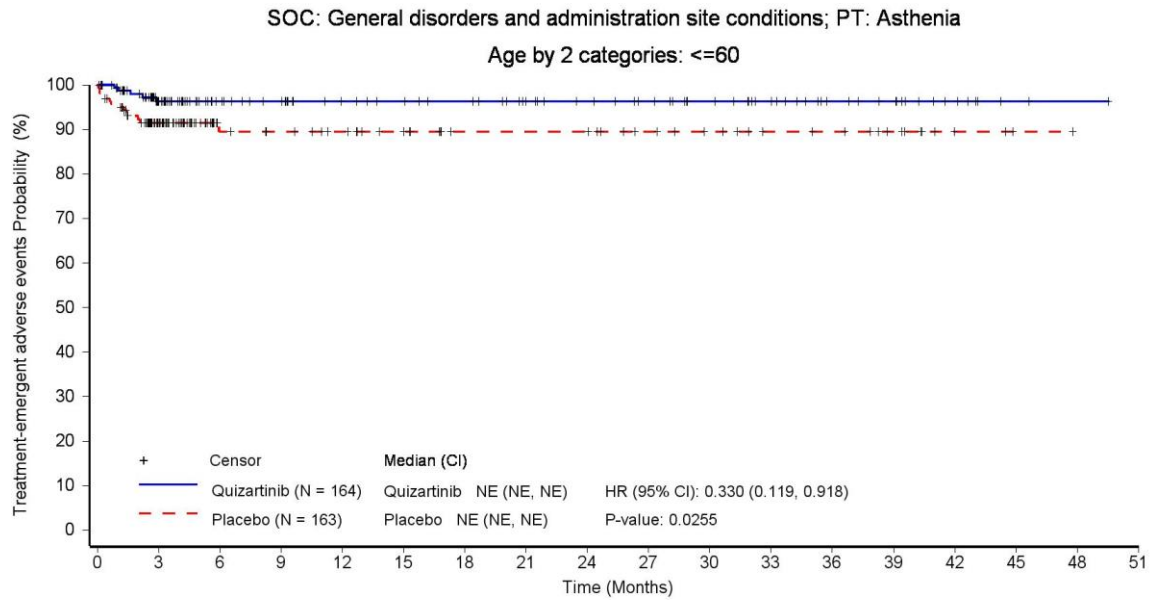
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	101	75	69	60	57	54	47	43	38	32	26	18	15	8	2	1	0
Placebo (N = 163)	163	86	46	43	39	33	27	27	27	21	18	14	13	9	3	1	0	0

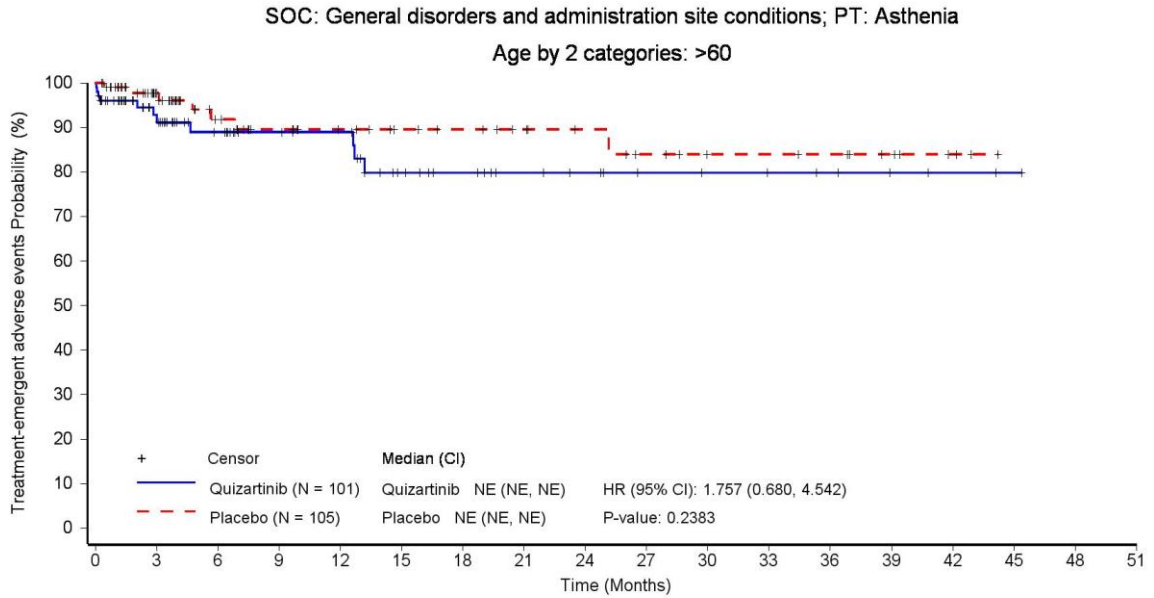
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	54	40	33	31	21	17	13	11	8	7	6	5	3	2	1	0	0
Placebo (N = 105)	105	61	41	33	28	24	22	19	16	13	10	10	9	6	3	0	0	0

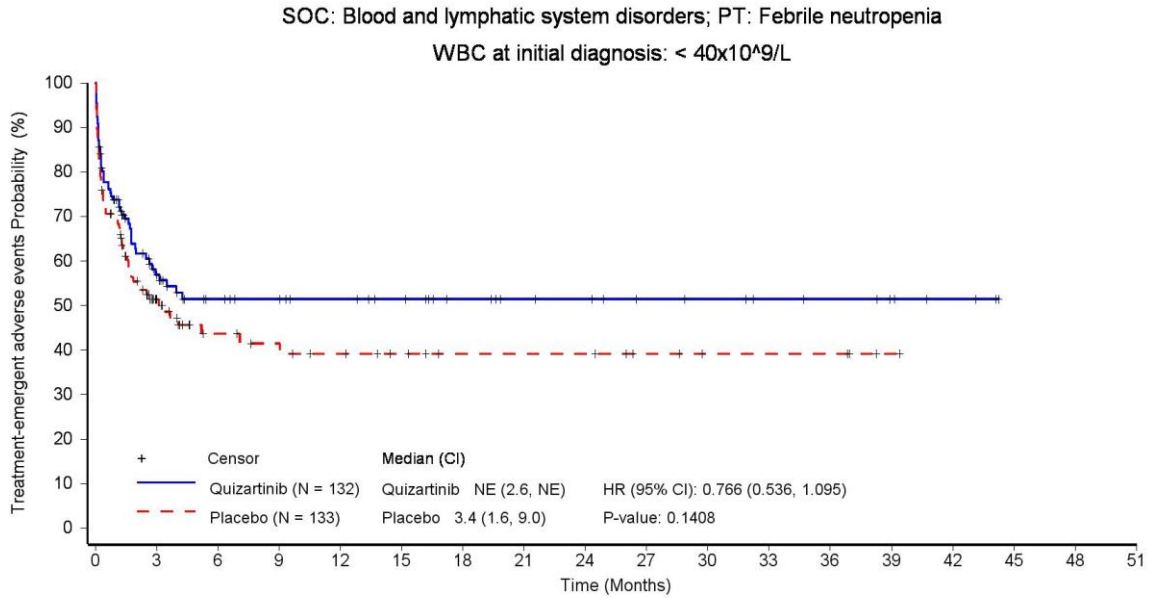
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	45	32	29	26	23	18	15	14	11	10	8	7	5	3	0	0	0
Placebo (N = 133)	133	38	21	18	15	12	9	9	9	6	4	4	4	1	0	0	0	0

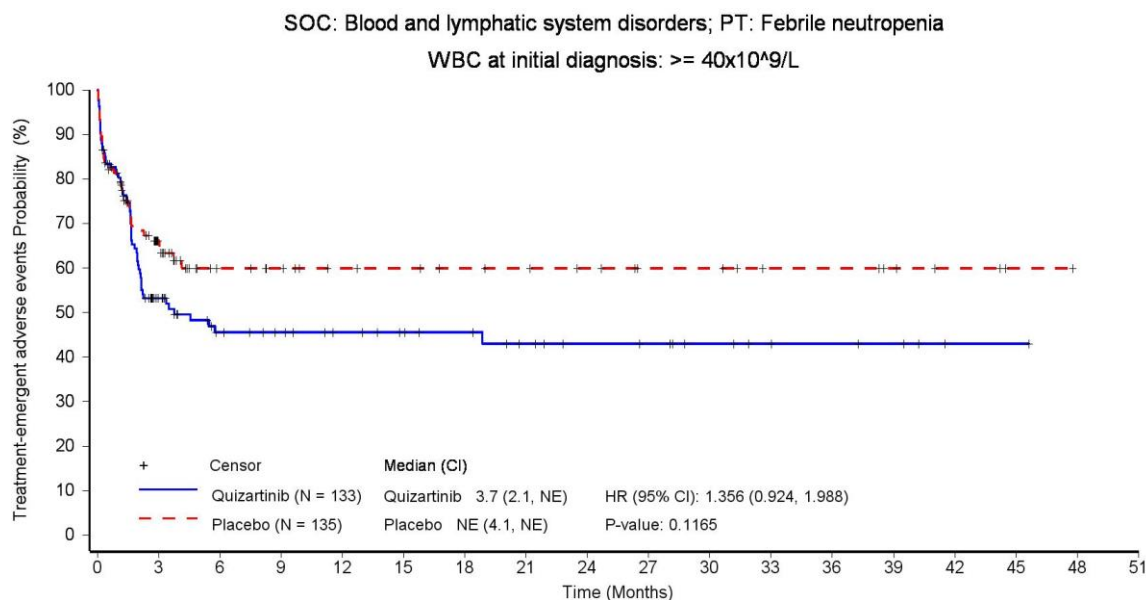
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	48	32	28	24	21	19	15	12	11	8	6	5	4	1	1	0	0
Placebo (N = 135)	135	48	26	23	19	18	16	15	13	10	10	7	7	5	3	1	0	0

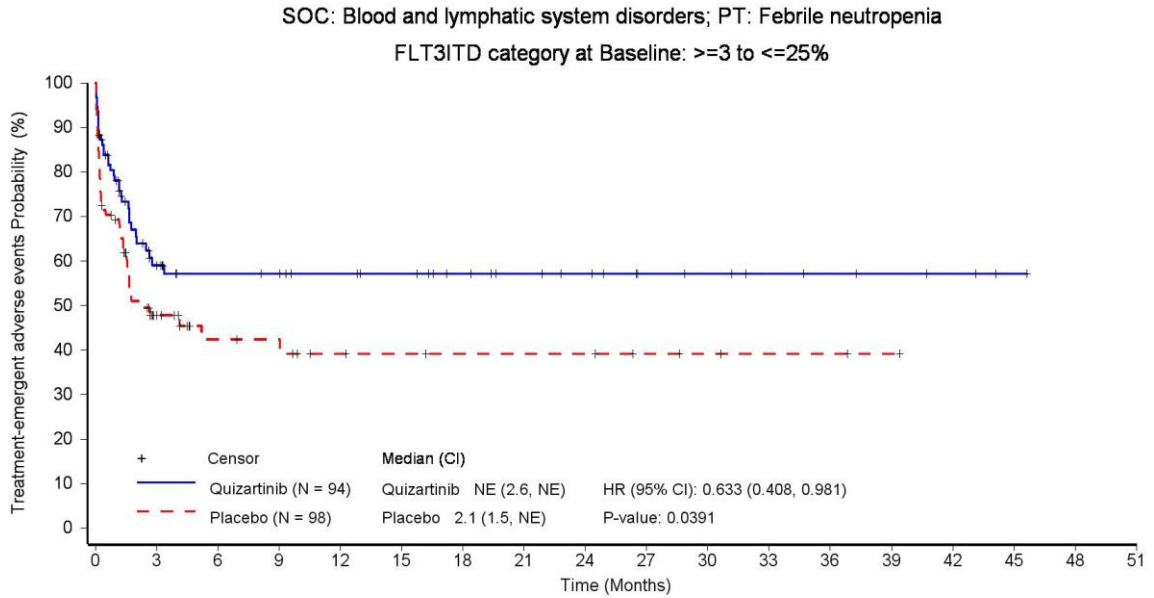
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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 94)	94	34	28	27	24	22	18	15	13	9	8	6	5	4	3	1	0	0
Placebo (N = 98)	98	24	14	13	9	8	7	7	7	4	3	2	2	1	0	0	0	0

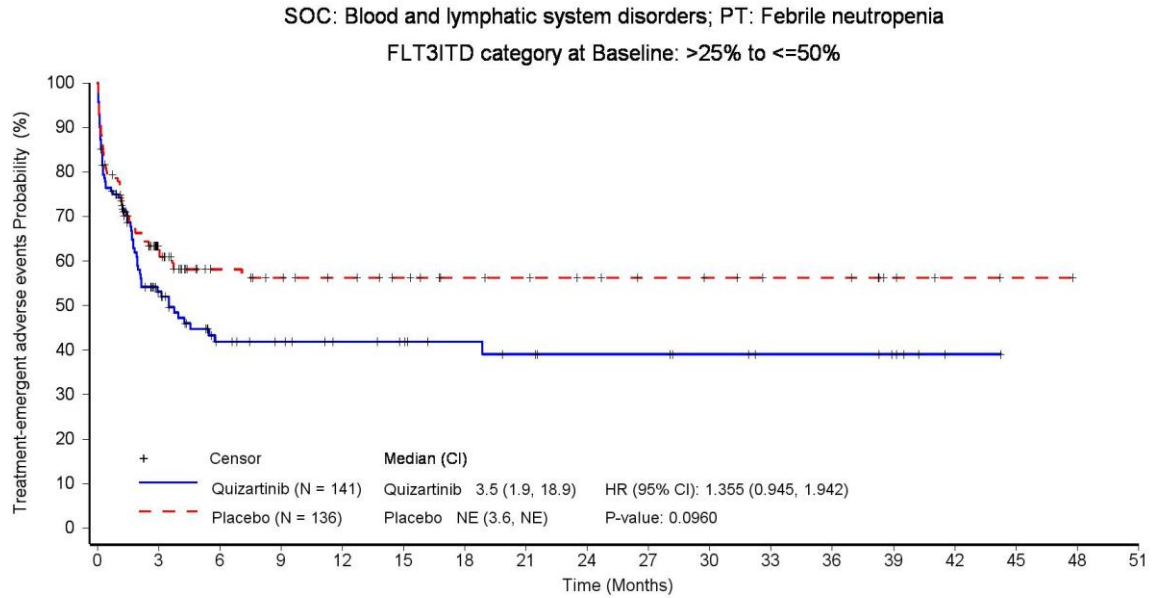
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	48	28	24	20	18	15	13	11	11	9	7	7	5	1	0	0	0
Placebo (N = 136)	136	51	30	26	23	20	16	15	13	11	10	8	8	4	2	1	0	0

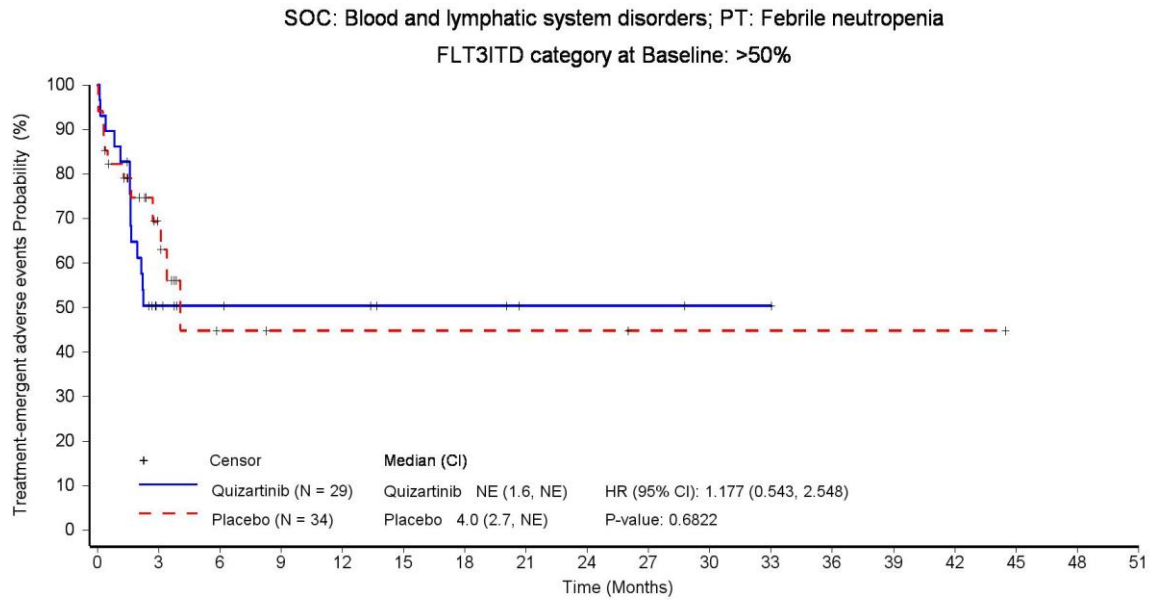
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 29)	29	10	7	6	6	4	4	2	2	2	1	1	0	0	0	0	0	
Placebo (N = 34)	34	11	3	2	2	2	2	2	2	1	1	1	1	1	1	0	0	0

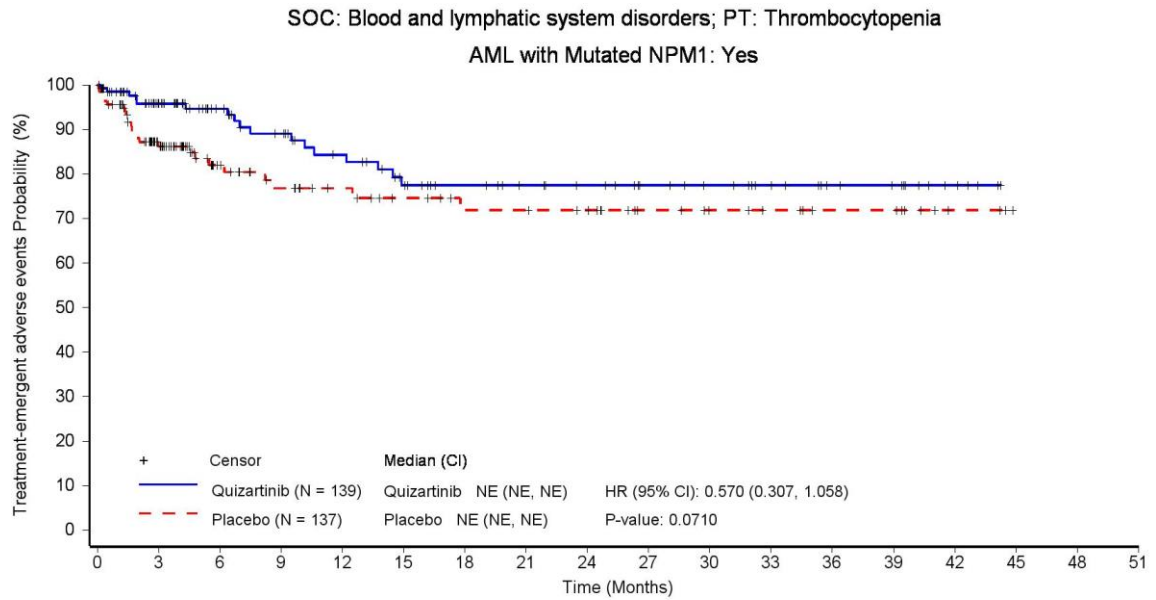
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	
Quizartinib (N = 139)	139	94	71	61	52	43	37	33	30	25	22	18	13	11	5	0	0
Placebo (N = 137)	137	85	52	42	35	30	26	26	24	17	14	12	9	9	3	0	0

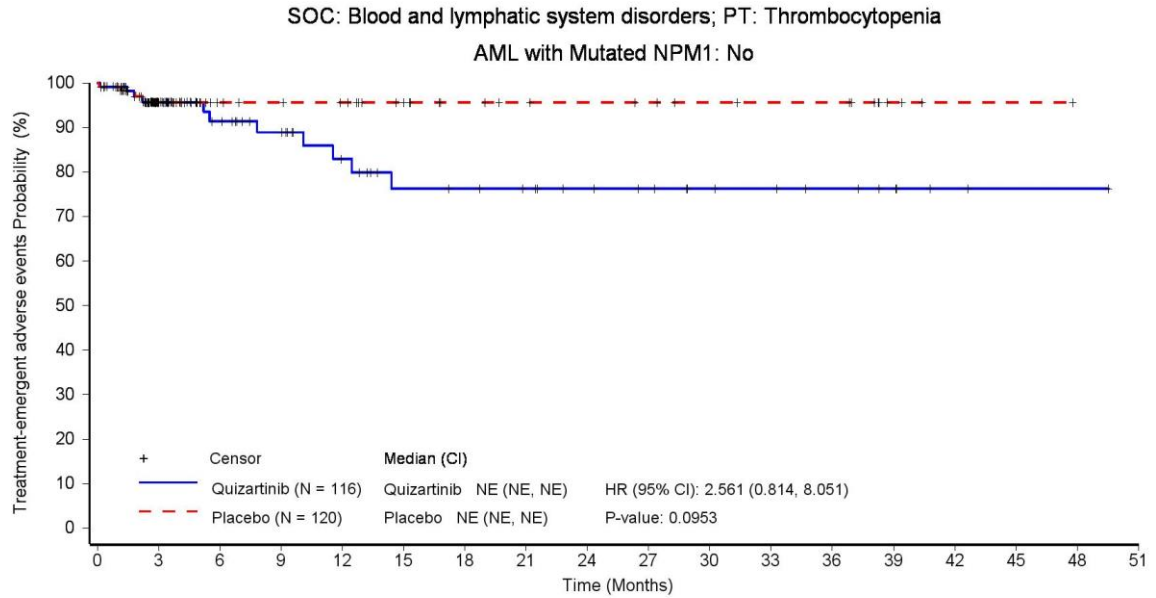
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 116)	116	59	42	35	27	21	20	18	15	13	10	9	7	5	2	1	1	0
Placebo (N = 120)	120	50	31	28	26	20	16	14	13	12	10	9	9	3	1	1	0	0

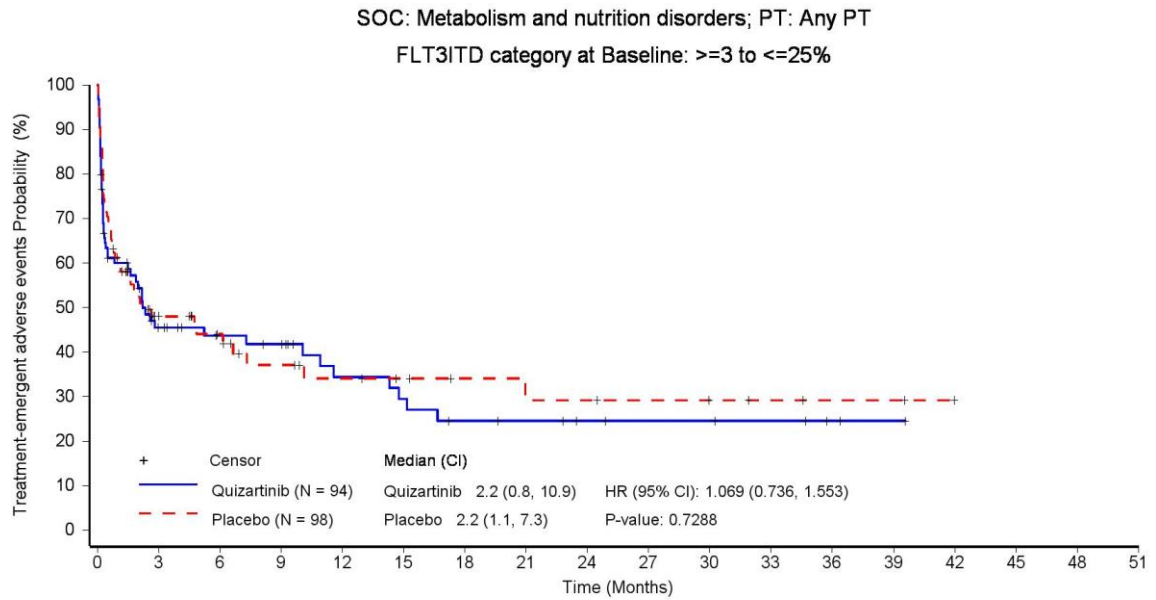
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 94)	94	29	23	21	14	12	9	8	6	5	5	4	2	1	0	0	0	0
Placebo (N = 98)	98	27	21	15	11	9	7	6	6	5	4	3	2	2	0	0	0	0

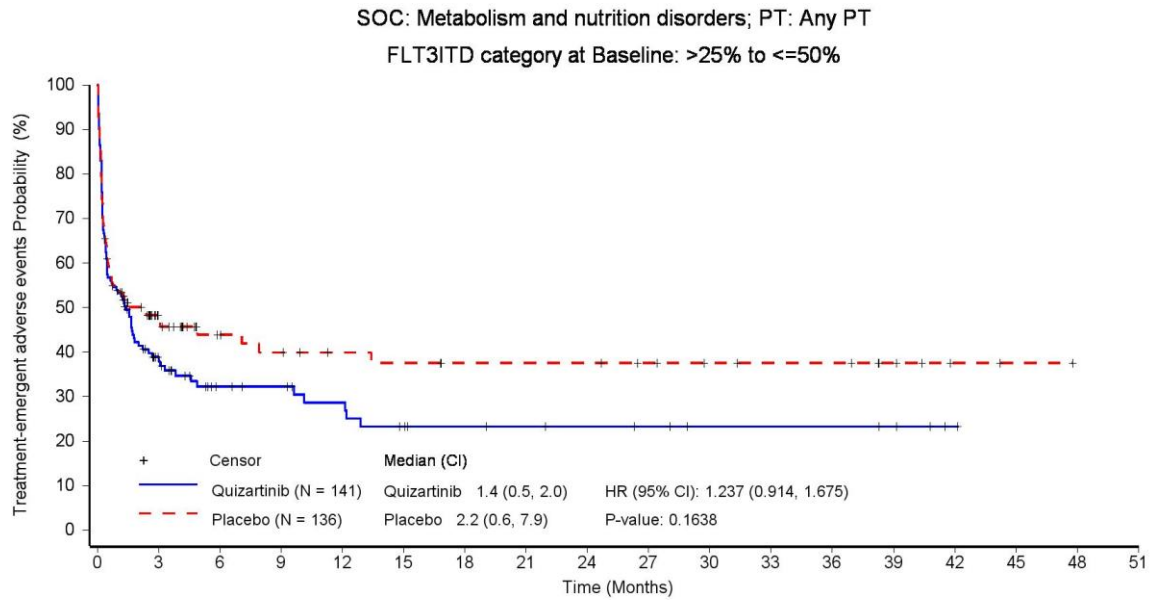
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	38	22	20	16	12	10	9	8	7	5	5	5	4	1	0	0	0
Placebo (N = 136)	136	37	23	20	17	16	13	13	13	11	9	8	8	5	2	1	0	0

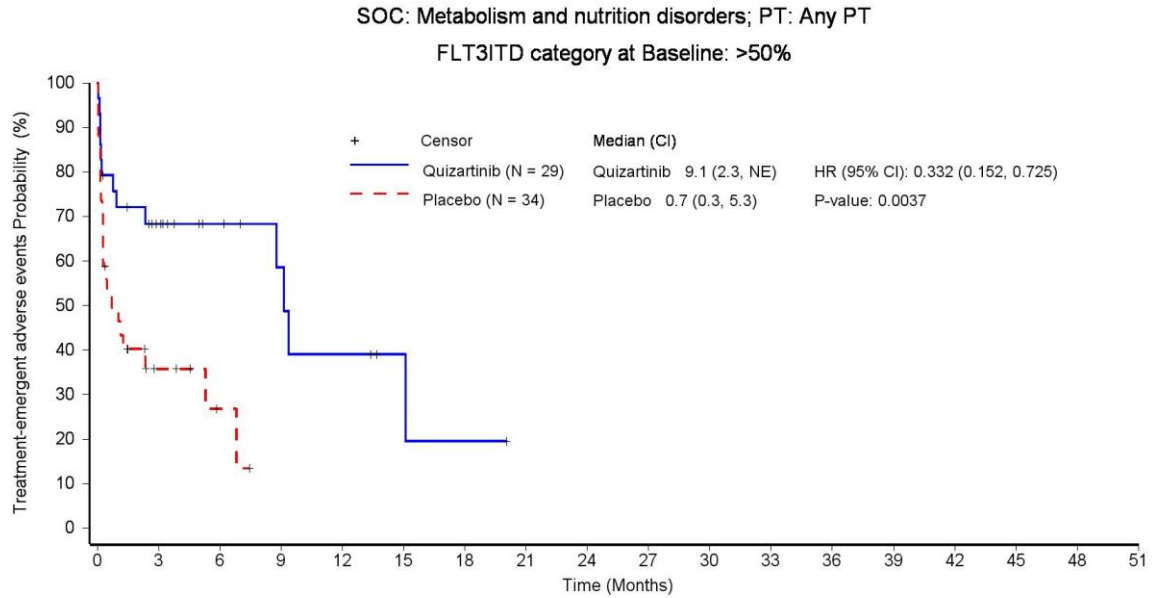
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 29)	29	15	9	6	4	2	1	0	0	0	0	0	0	0	0	0	0	0
Placebo (N = 34)	34	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

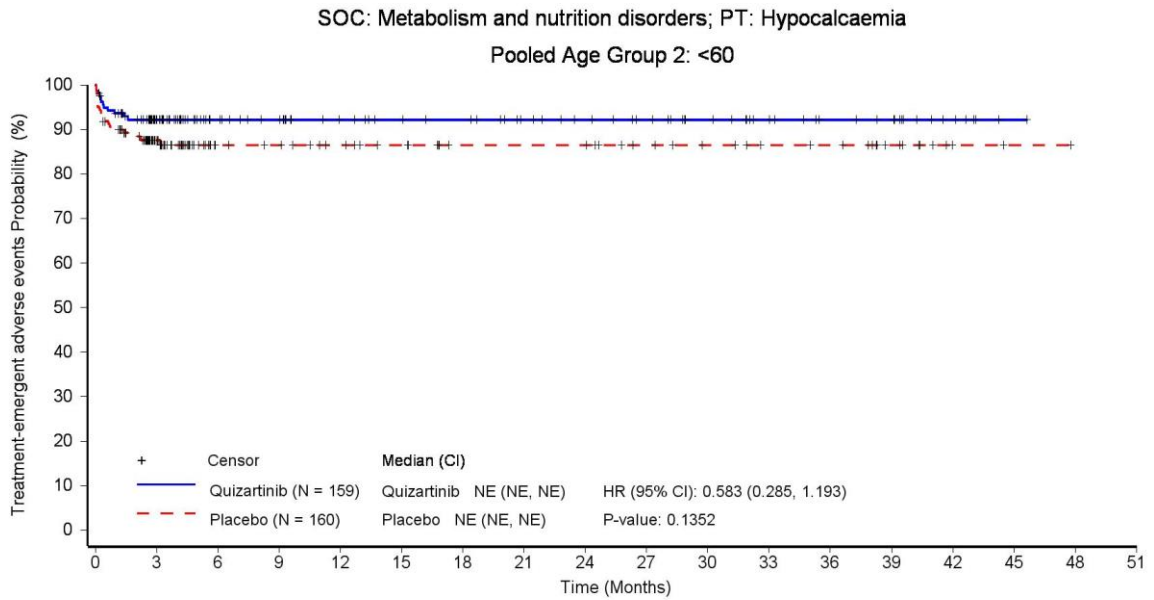
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 159)	159	96	70	64	55	51	49	43	39	34	28	22	17	15	7	1	0	0
Placebo (N = 160)	160	80	47	45	39	35	28	28	28	22	19	16	15	9	2	1	0	0

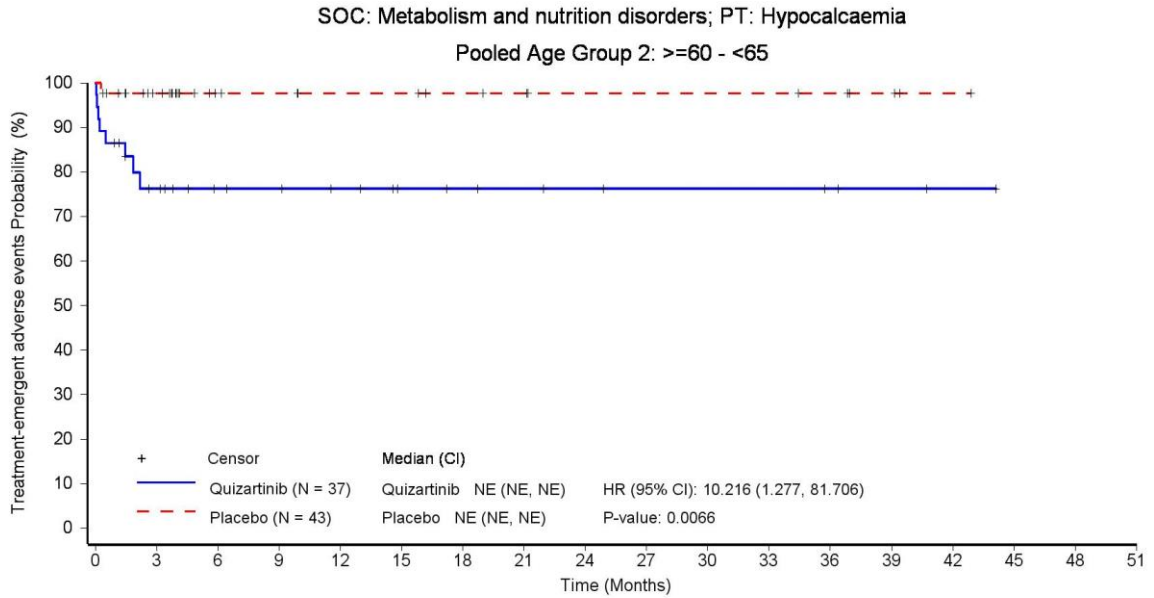
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 37)	37	20	14	13	11	8	7	6	5	4	4	4	3	2	1	0	0	0
Placebo (N = 43)	43	26	14	13	11	11	9	8	6	6	6	6	5	3	1	0	0	0

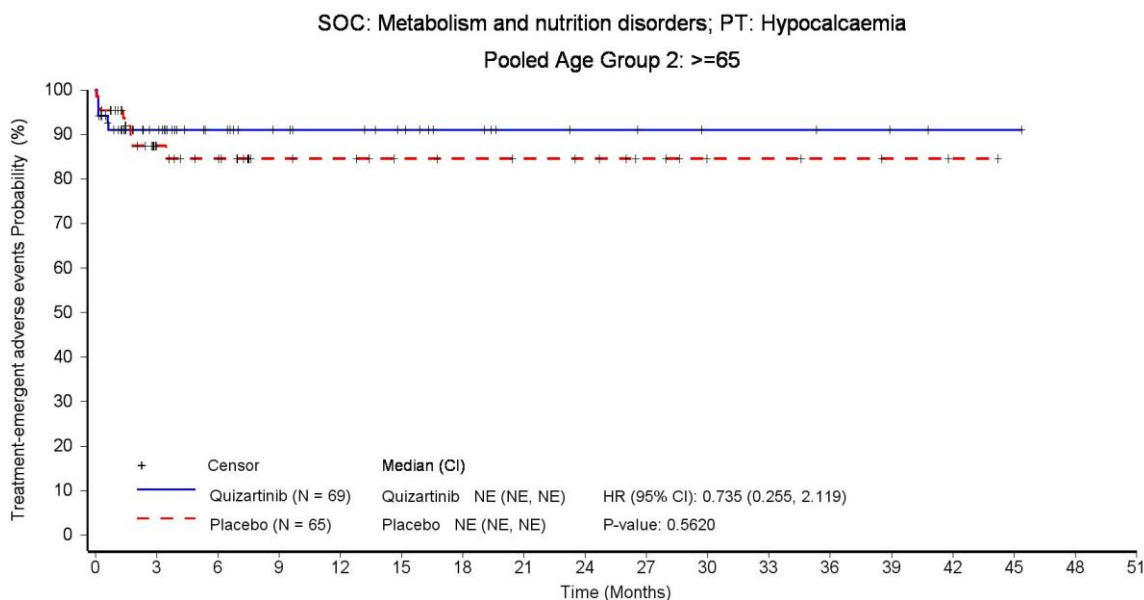
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 69)	69	35	24	19	17	14	10	7	6	5	4	4	3	2	1	1	0	0
Placebo (N = 65)	65	31	26	17	16	13	12	11	10	7	4	4	3	2	1	0	0	0

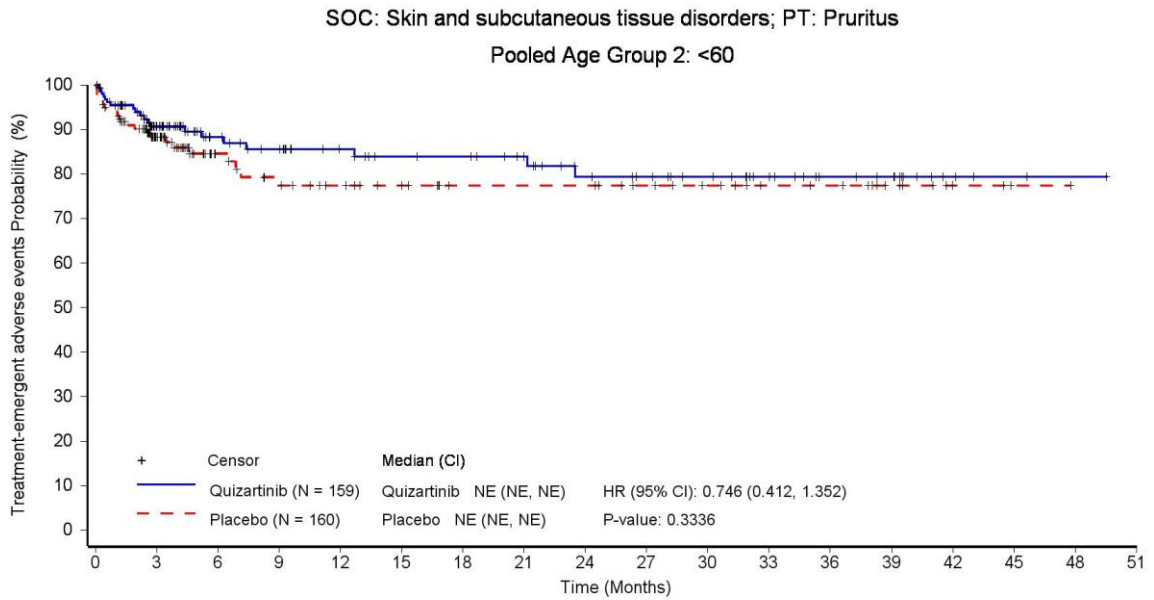
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 159)	159	95	67	60	51	46	45	40	33	30	26	20	14	12	4	2	1	0
Placebo (N = 160)	160	84	49	41	36	31	26	26	26	21	18	14	13	8	3	1	0	0

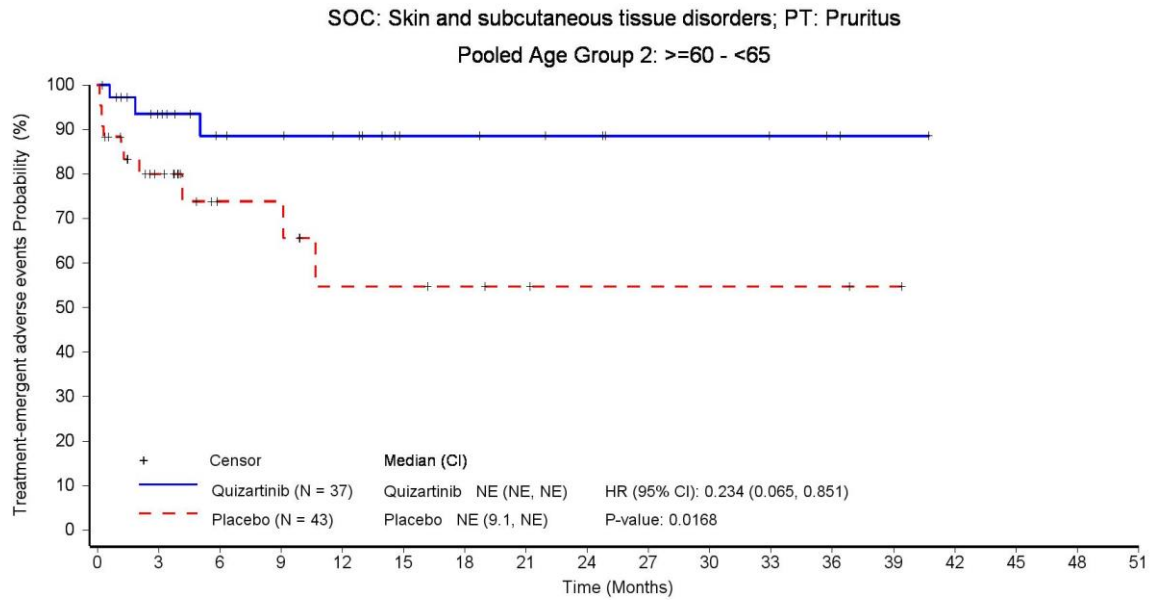
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 37)	37	23	16	15	13	8	8	7	6	4	4	3	2	1	0	0	0	0
Placebo (N = 43)	43	20	9	9	5	5	4	3	2	2	2	2	2	1	0	0	0	0

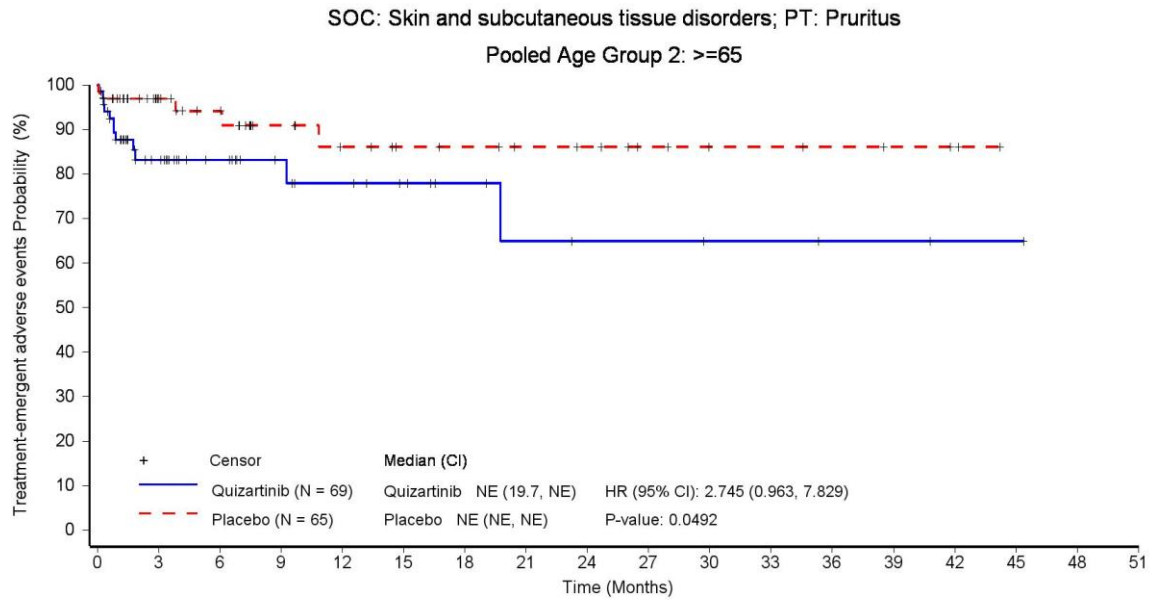
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45		
Quizartinib (N = 69)	69	32	22	16	13	10	7	5	4	4	3	3	2	2	1	1	0	0
Placebo (N = 65)	65	37	30	21	17	14	13	11	10	7	5	5	4	3	2	0	0	0

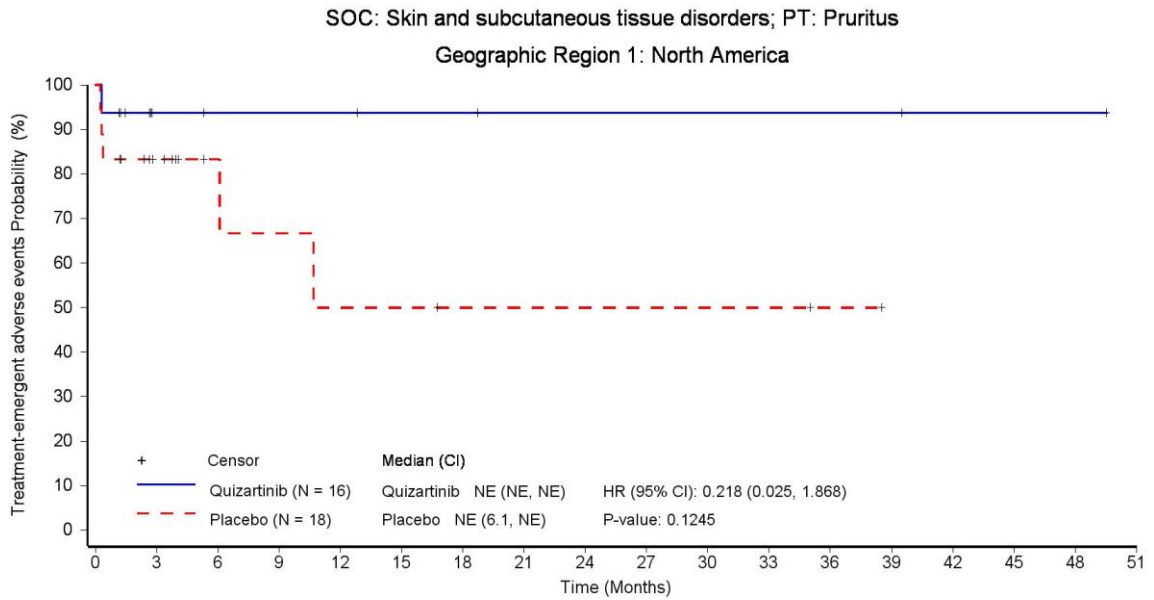
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 16)	16	5	4	4	4	3	3	2	2	2	2	2	2	1	1	1	0
Placebo (N = 18)	18	10	5	4	3	3	2	2	2	2	2	2	1	0	0	0	0

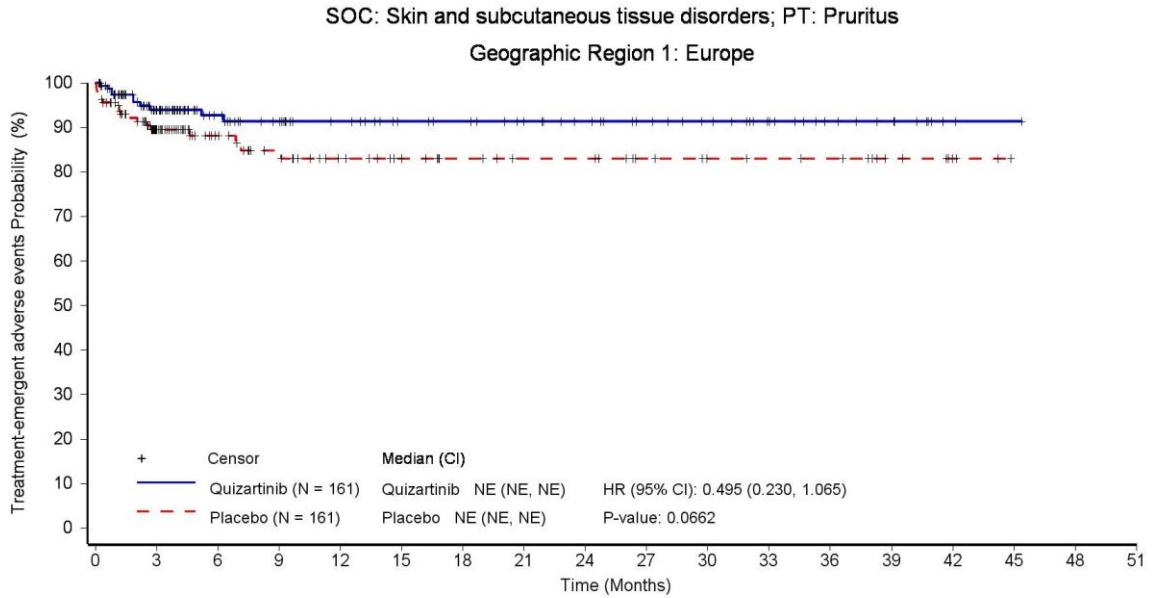
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45		
Quizartinib (N = 161)	161	98	69	59	51	44	42	37	33	28	24	18	12	9	2	1	0	0
Placebo (N = 161)	161	83	56	46	36	30	26	23	23	17	14	13	12	7	3	0	0	0

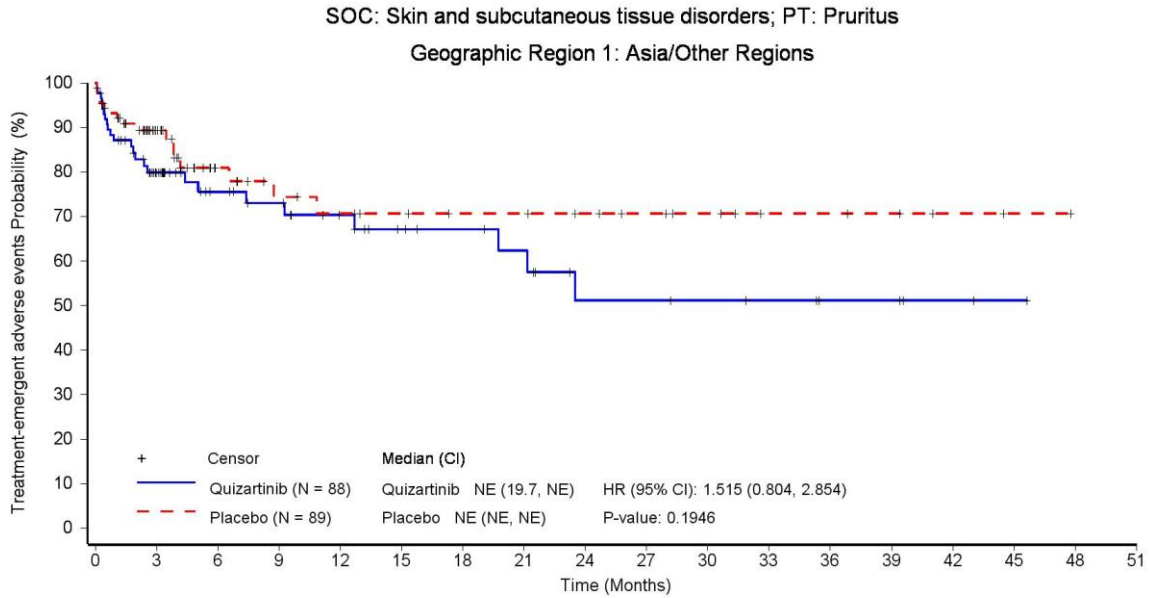
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 88)	88	47	32	28	22	17	15	13	8	8	7	6	4	4	2	1	0	0
Placebo (N = 89)	89	48	27	21	19	17	15	15	13	11	9	6	6	5	2	1	0	0

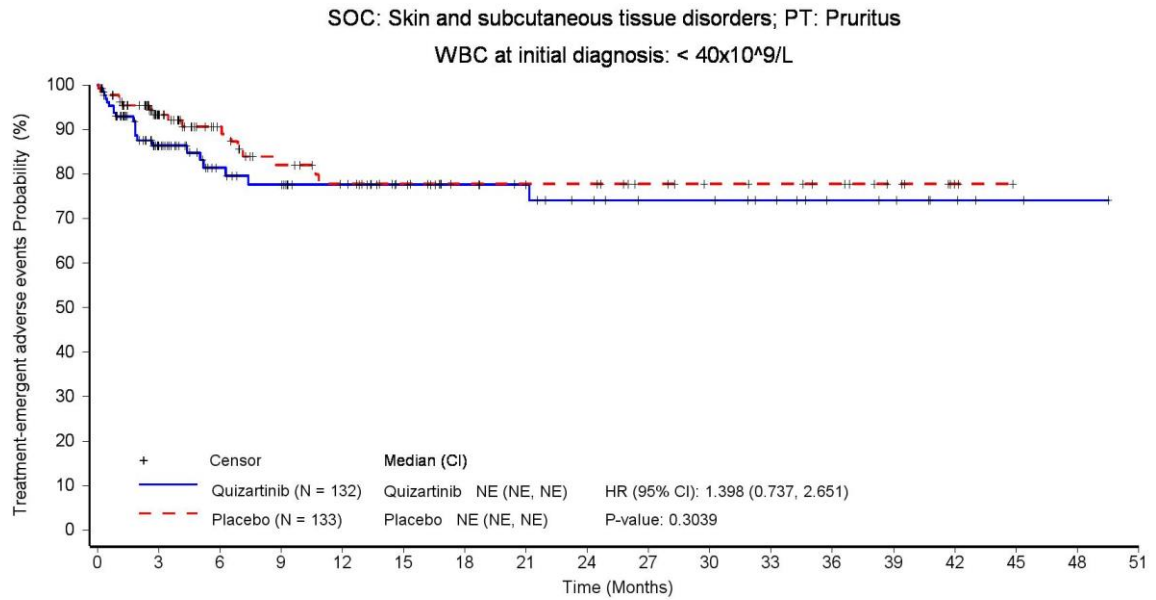
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	66	44	39	33	28	25	22	18	15	15	12	8	7	4	2	1	0
Placebo (N = 133)	133	77	55	43	36	29	23	22	22	17	14	13	11	7	2	0	0	0

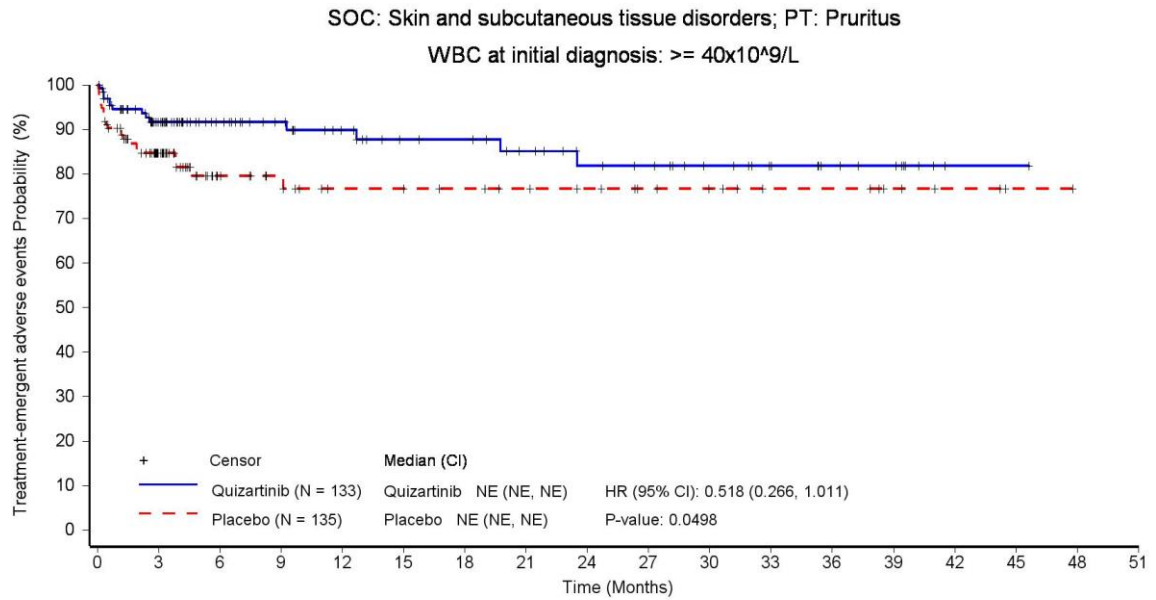
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	84	61	52	44	36	35	30	25	23	18	14	10	8	1	1	0	0
Placebo (N = 135)	135	64	33	28	22	21	20	18	16	13	11	8	8	5	3	1	0	0

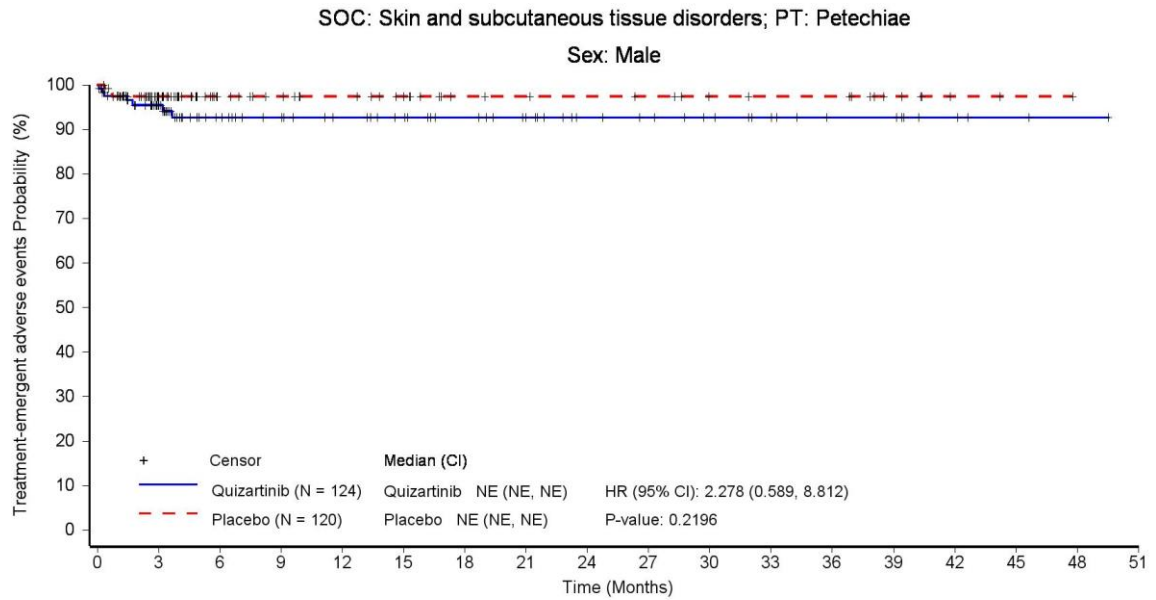
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 124)	124	72	52	46	41	37	32	27	21	19	16	13	9	9	5	2	1	0
Placebo (N = 120)	120	64	39	34	30	25	19	18	17	16	13	12	12	7	2	1	0	0

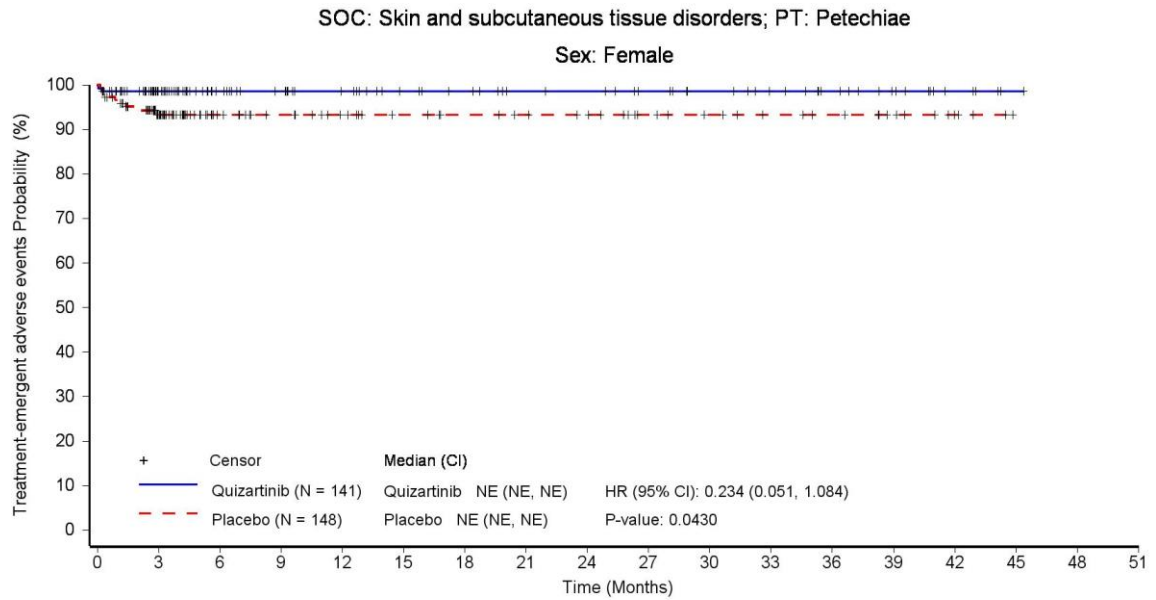
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 141)	141	88	65	58	51	43	40	35	34	29	25	21	16	11	5	1	0	0
Placebo (N = 148)	148	87	55	47	40	35	31	29	27	21	18	15	13	9	4	0	0	0

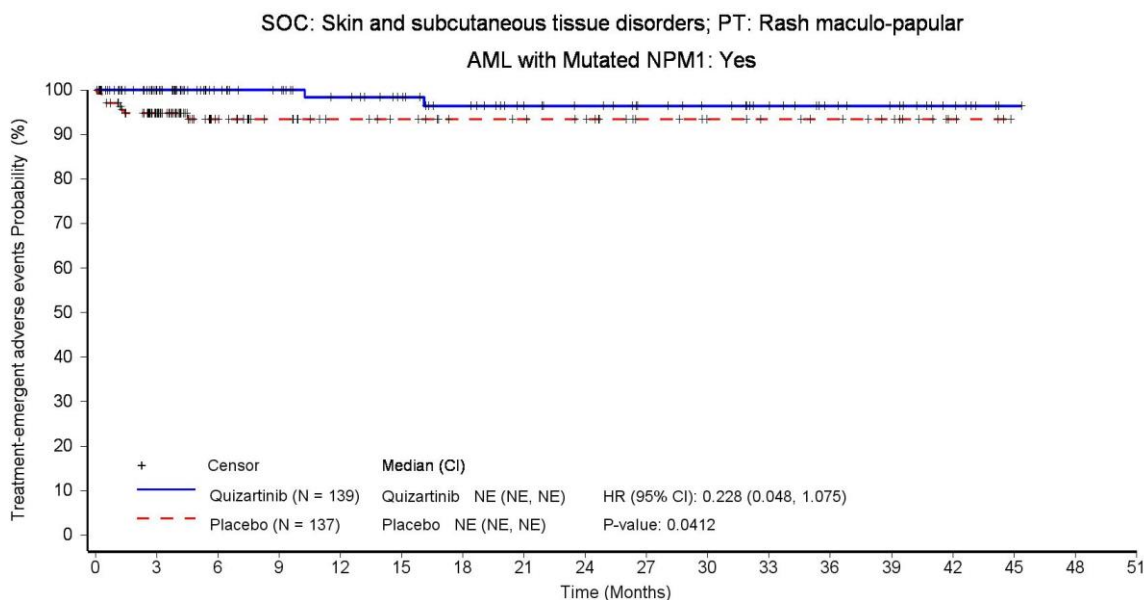
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 139)	139	98	73	67	60	53	46	38	35	30	27	22	16	13	7	1	0	0
Placebo (N = 137)	137	91	58	48	39	36	31	30	28	21	18	16	14	11	4	0	0	0

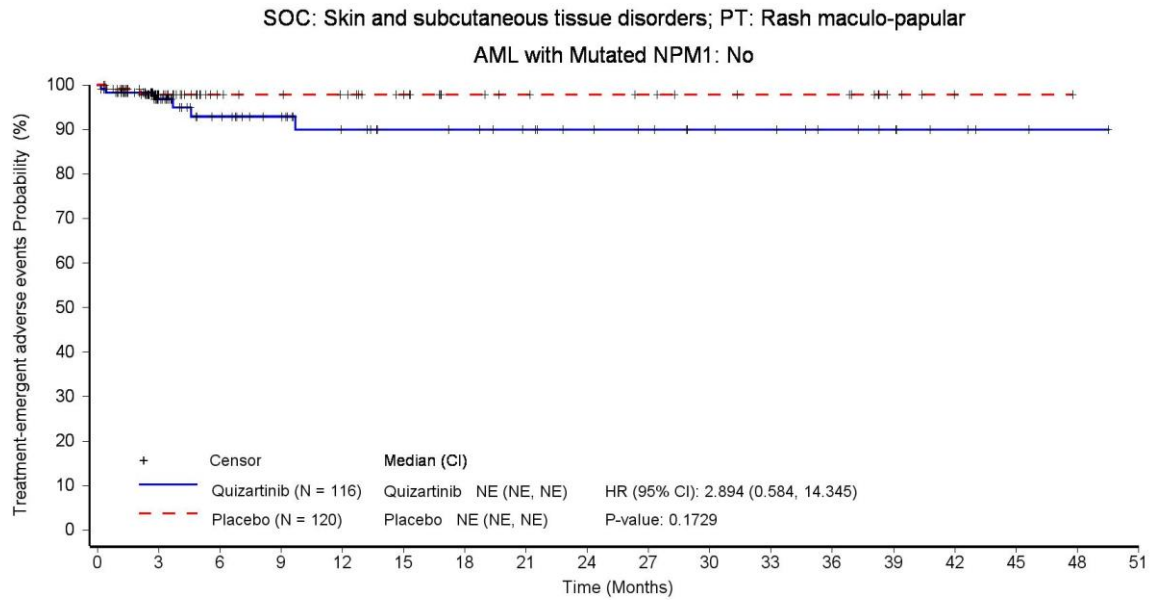
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 116)	116	60	43	36	29	25	24	21	18	16	13	12	9	7	4	2	1	0
Placebo (N = 120)	120	52	33	30	28	22	17	15	14	13	11	10	10	4	1	1	0	0

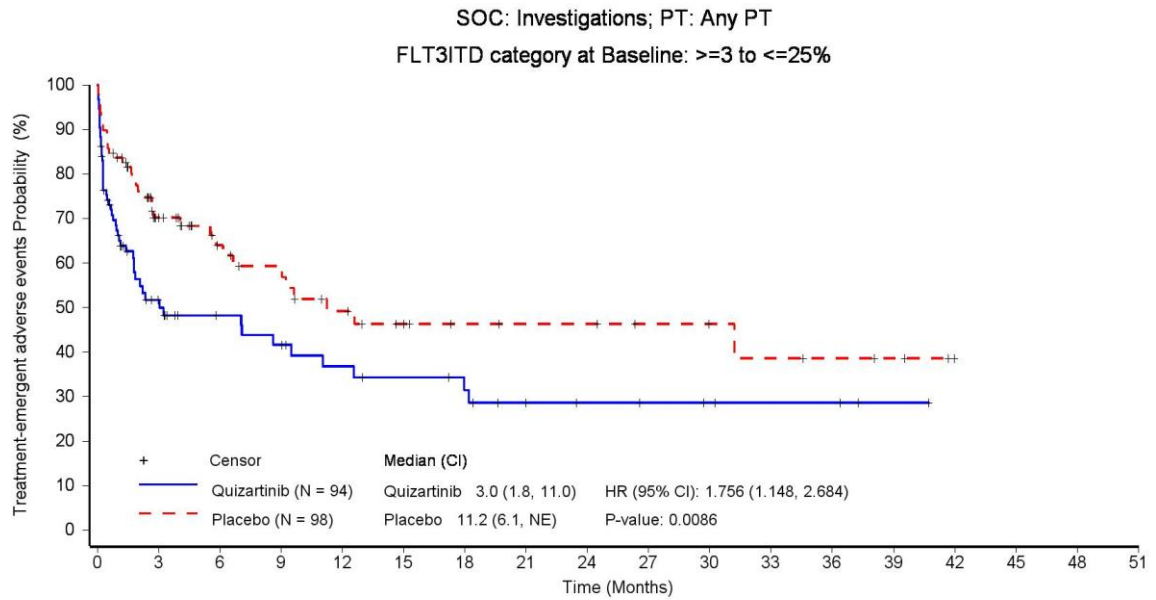
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42
Quizartinib (N = 94)	94	30	22	19	15	13	11	7	6	5	4	3	3	1	0
Placebo (N = 98)	98	41	28	24	18	13	11	10	10	7	6	5	4	3	0

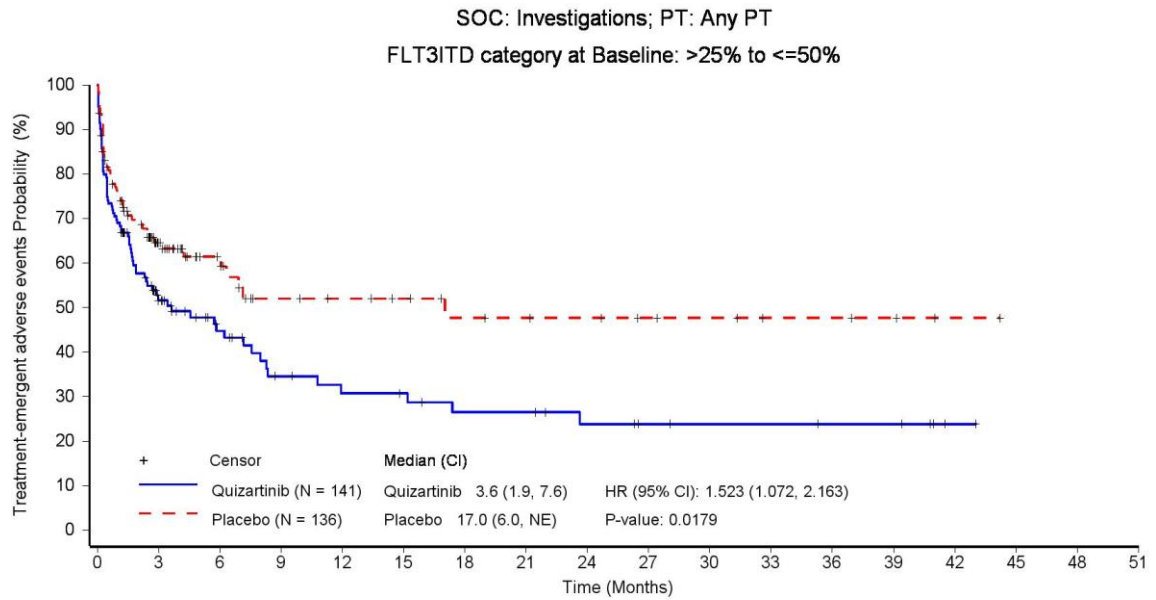
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	
Quizartinib (N = 141)	141	45	29	19	16	15	12	12	9	7	6	6	5	5	1	0	0
Placebo (N = 136)	136	48	28	18	16	14	11	10	9	7	6	4	4	3	1	0	0

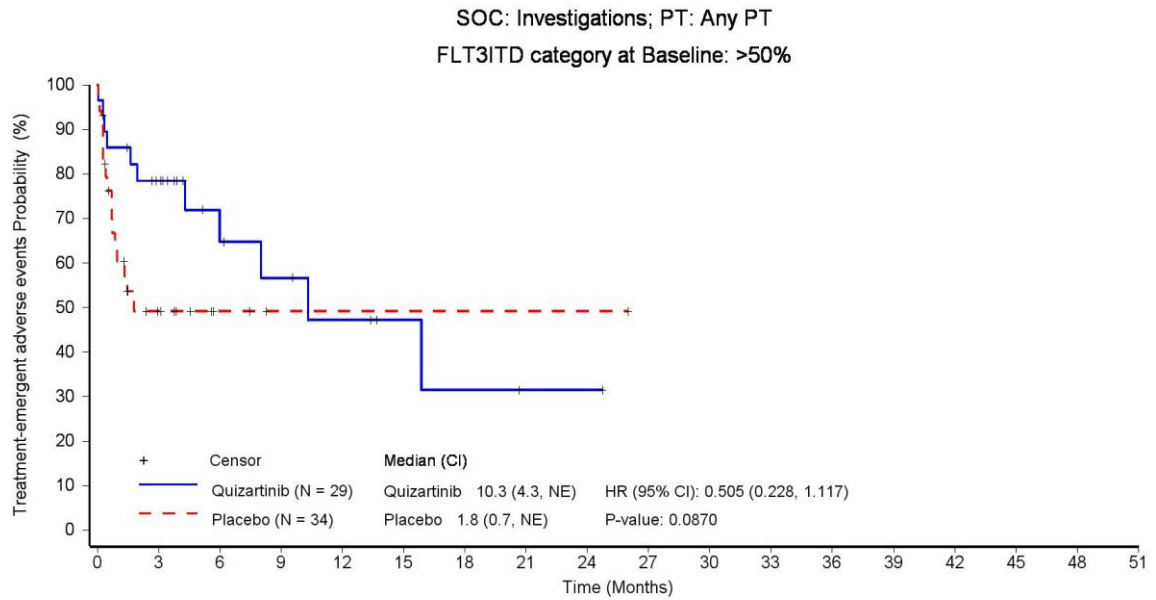
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 29)	29	18	9	7	5	3	2	1	1	0	0	0	0	0	0	0	0	0
Placebo (N = 34)	34	9	3	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0

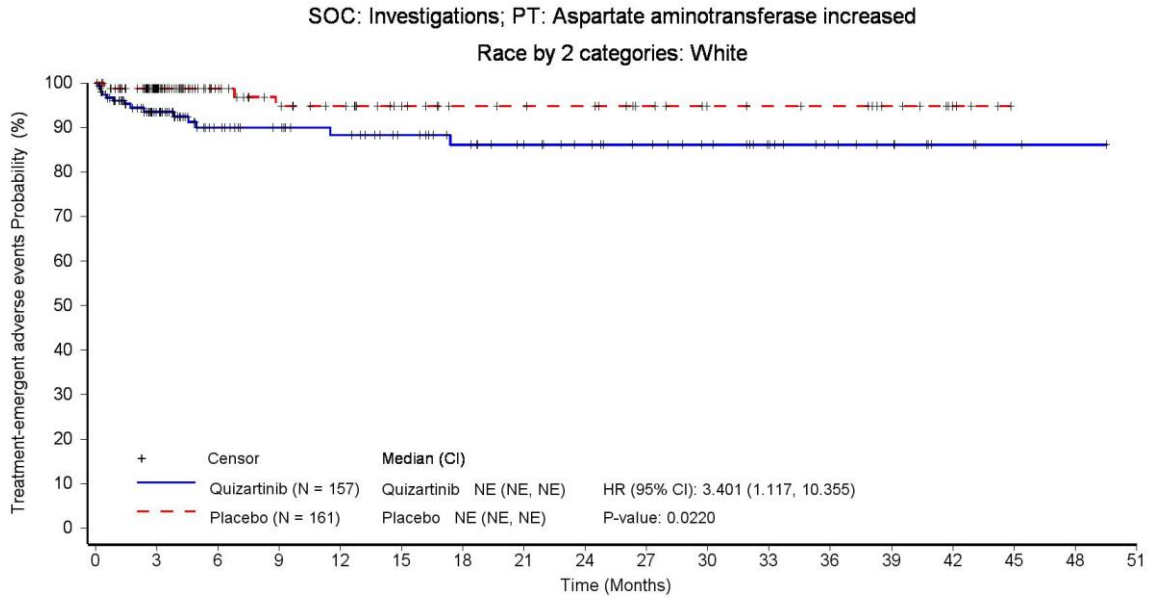
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 157)	157	94	65	58	53	46	40	34	30	26	22	17	12	9	4	2	1	0
Placebo (N = 161)	161	91	56	46	40	32	26	25	24	19	15	14	13	9	4	0	0	0

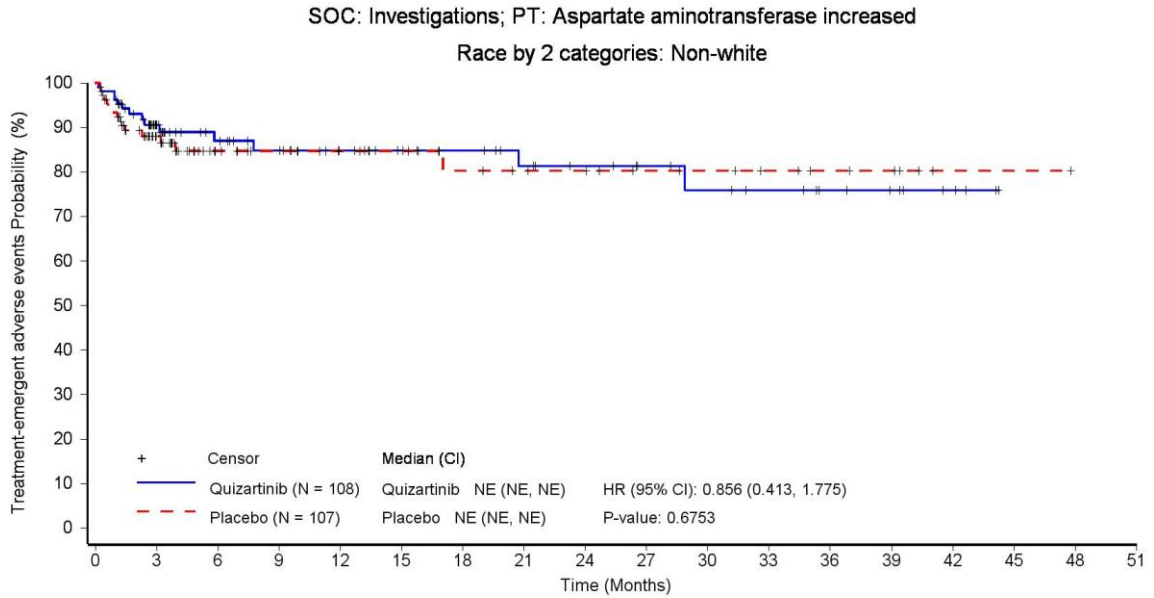
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	58	45	39	34	29	27	23	20	16	14	12	9	7	4	0	0	0
Placebo (N = 107)	107	57	35	30	25	23	18	16	15	12	11	9	7	6	1	1	0	0

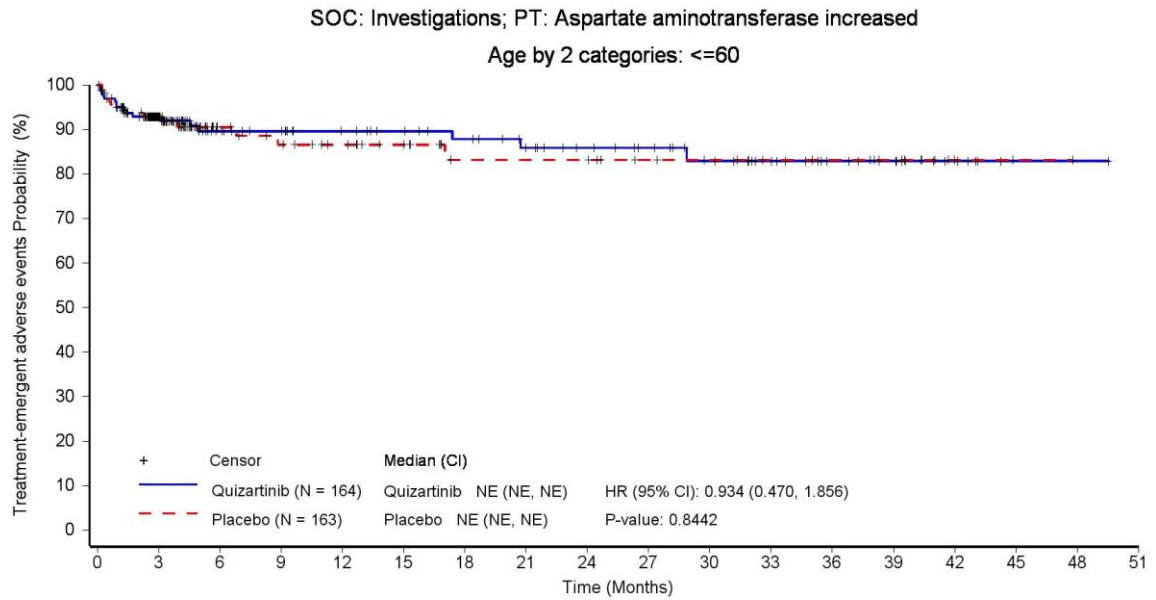
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	98	69	64	57	53	49	43	38	33	28	22	15	12	6	1	1	0
Placebo (N = 163)	163	87	48	43	37	31	23	23	23	18	16	13	12	9	2	1	0	0

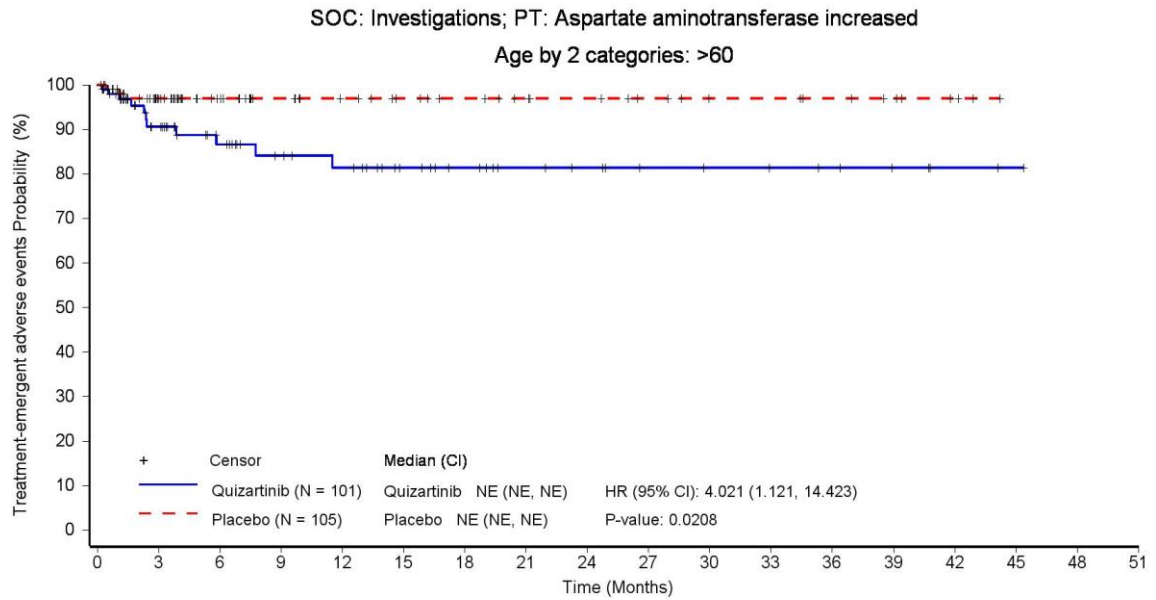
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	54	41	33	30	22	18	14	12	9	8	7	6	4	2	1	0	0
Placebo (N = 105)	105	61	43	33	28	24	21	18	16	13	10	10	8	6	3	0	0	0

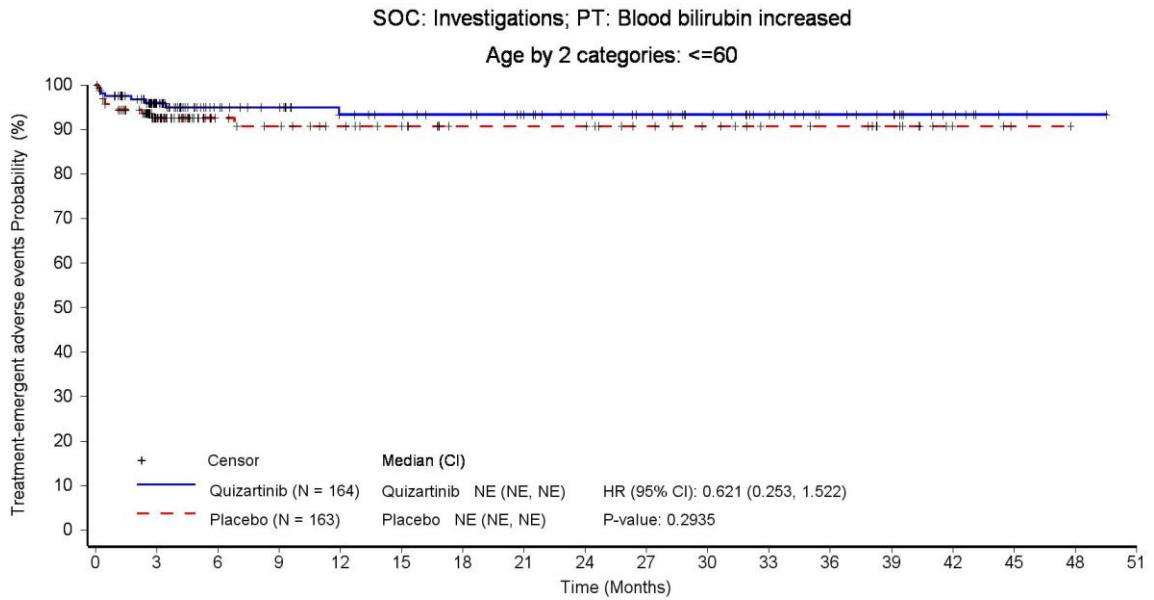
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	101	73	67	59	56	53	47	42	37	31	25	18	15	8	2	1	0
Placebo (N = 163)	163	85	50	46	40	35	28	28	28	22	19	15	14	10	3	1	0	0

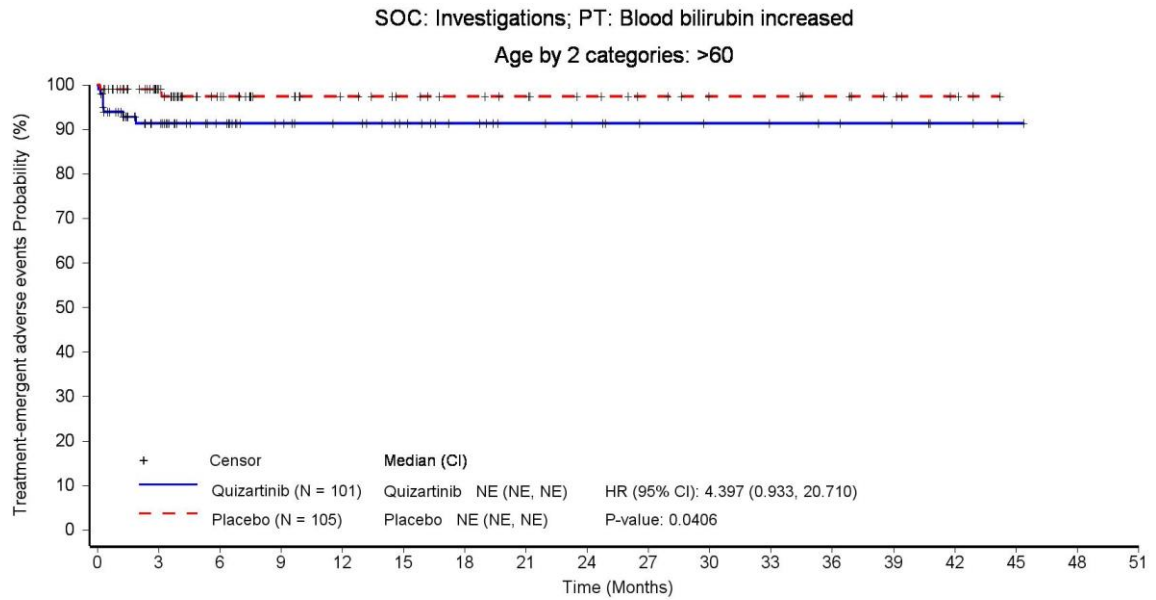
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	56	42	34	30	24	19	15	13	10	9	8	7	5	3	1	0	0
Placebo (N = 105)	105	63	44	34	29	25	22	20	17	14	11	11	9	6	3	0	0	0

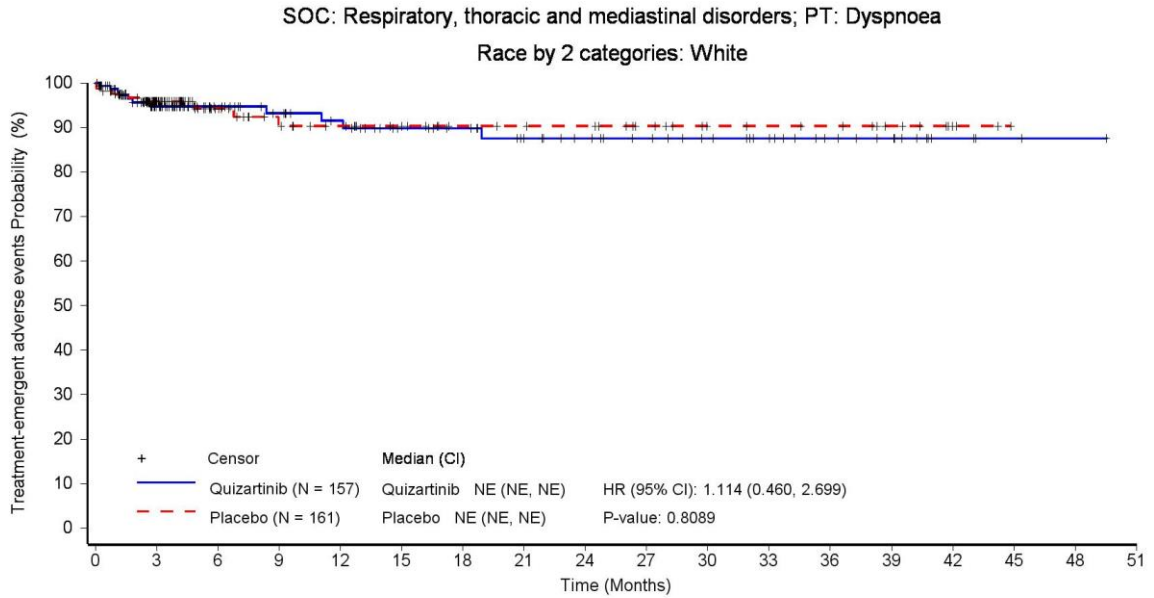
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 157)	157	97	69	60	54	46	43	36	32	28	24	20	14	11	4	2	1	0
Placebo (N = 161)	161	89	53	43	37	31	26	25	24	19	14	13	12	8	3	0	0	0

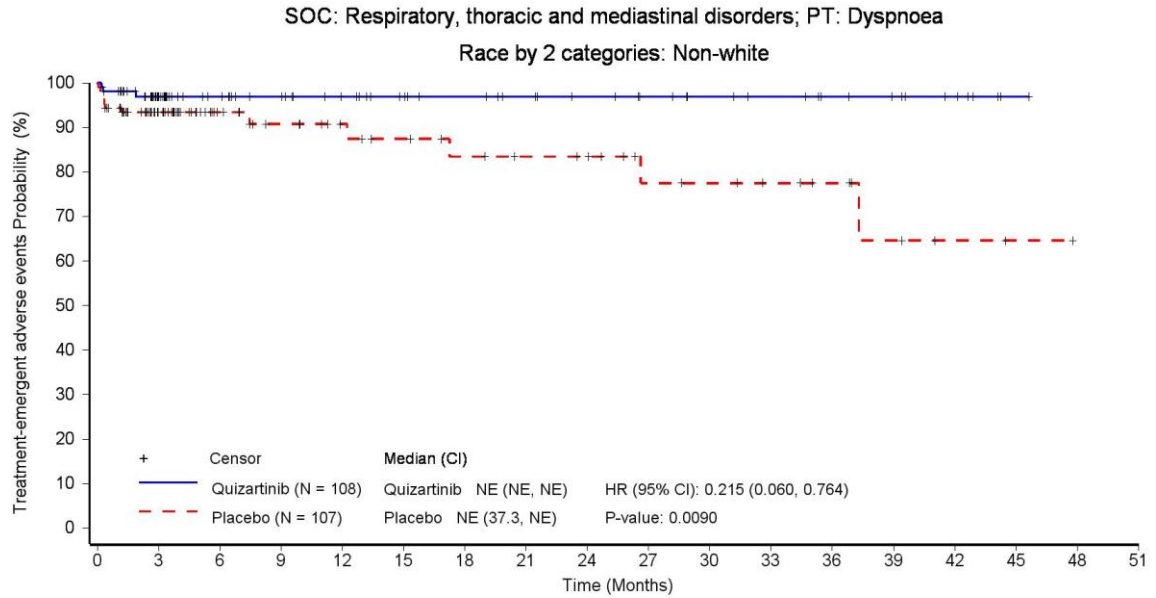
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	63	50	44	38	33	30	27	24	20	17	15	12	10	7	1	0	0
Placebo (N = 107)	107	61	39	32	27	24	21	19	18	13	12	10	8	5	2	1	0	0

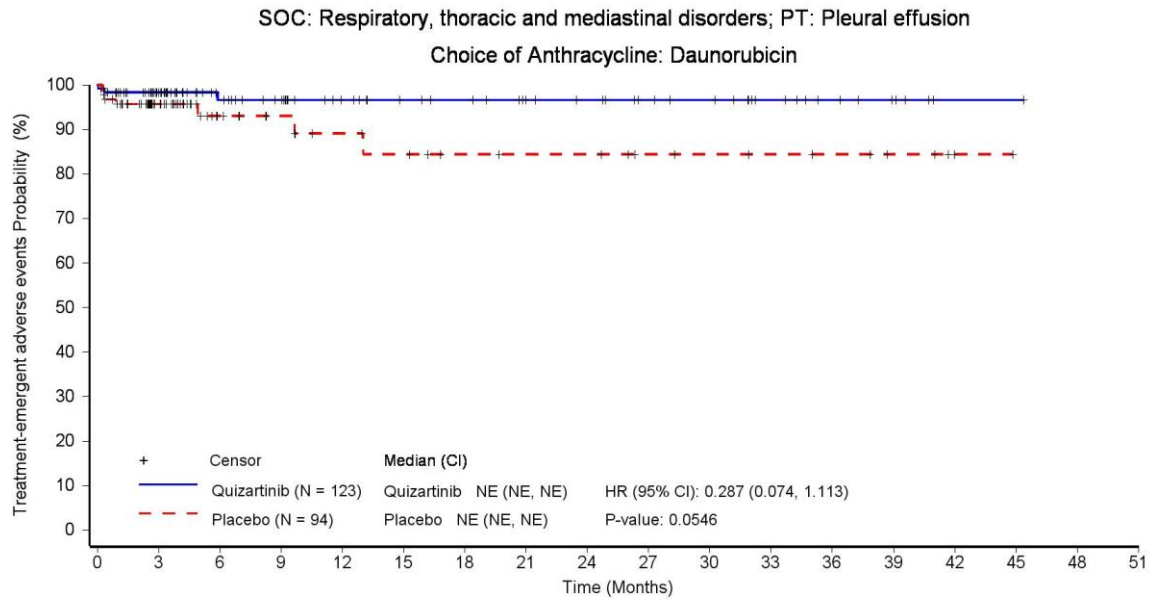
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 123)	123	76	56	49	39	34	32	27	25	20	18	12	8	5	1	1	0	0
Placebo (N = 94)	94	52	30	24	20	18	14	13	13	9	8	7	6	4	1	0	0	0

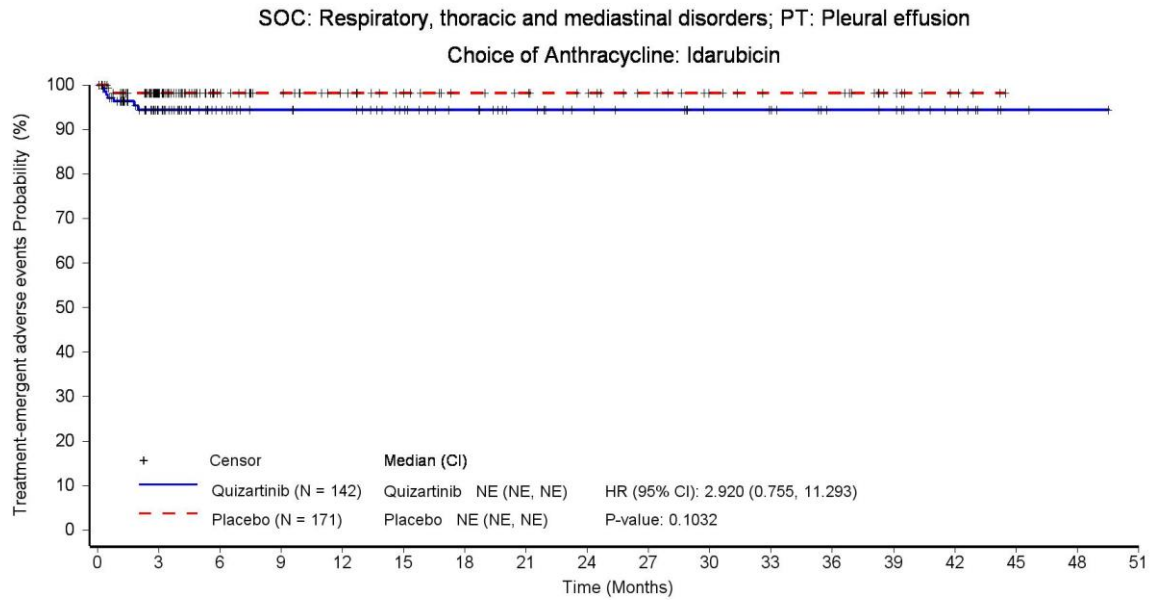
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Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 142)	142	84	61	54	52	45	39	33	28	26	22	21	16	15	9	2	1	0
Placebo (N = 171)	171	101	85	57	49	42	36	34	31	26	21	18	17	10	4	0	0	0

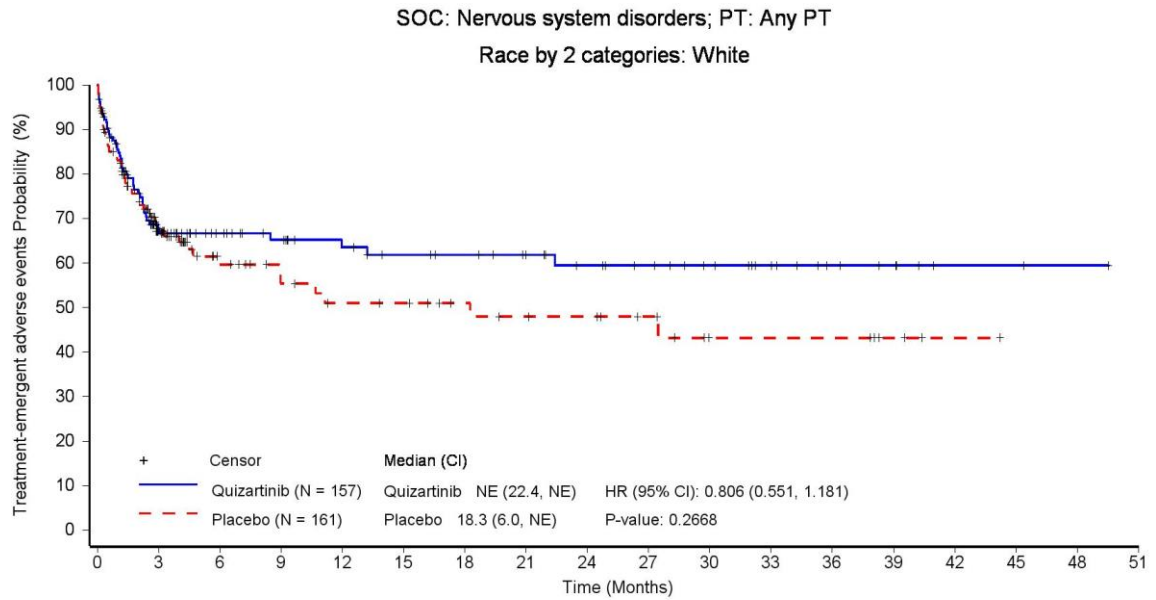
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 157)	157	68	51	44	38	34	32	28	24	21	17	13	8	6	2	2	1	0
Placebo (N = 161)	161	60	33	26	22	21	17	15	14	11	6	6	6	3	1	0	0	0

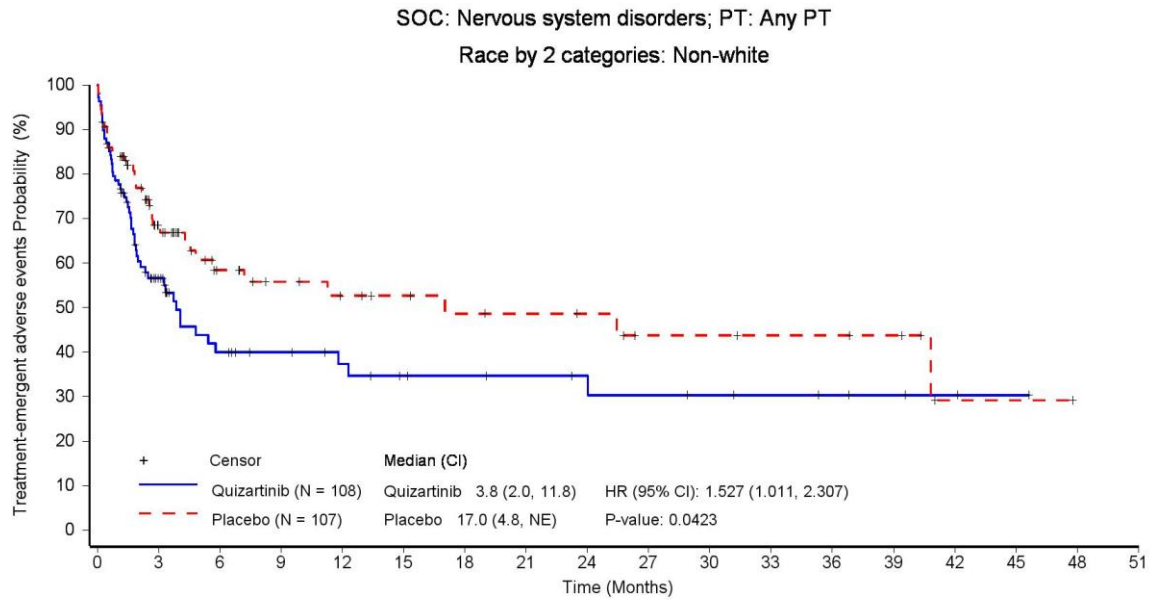
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	37	21	17	14	11	10	9	8	7	6	5	4	3	2	1	0	0
Placebo (N = 107)	107	42	24	19	16	14	12	11	10	7	7	6	6	5	1	1	0	0

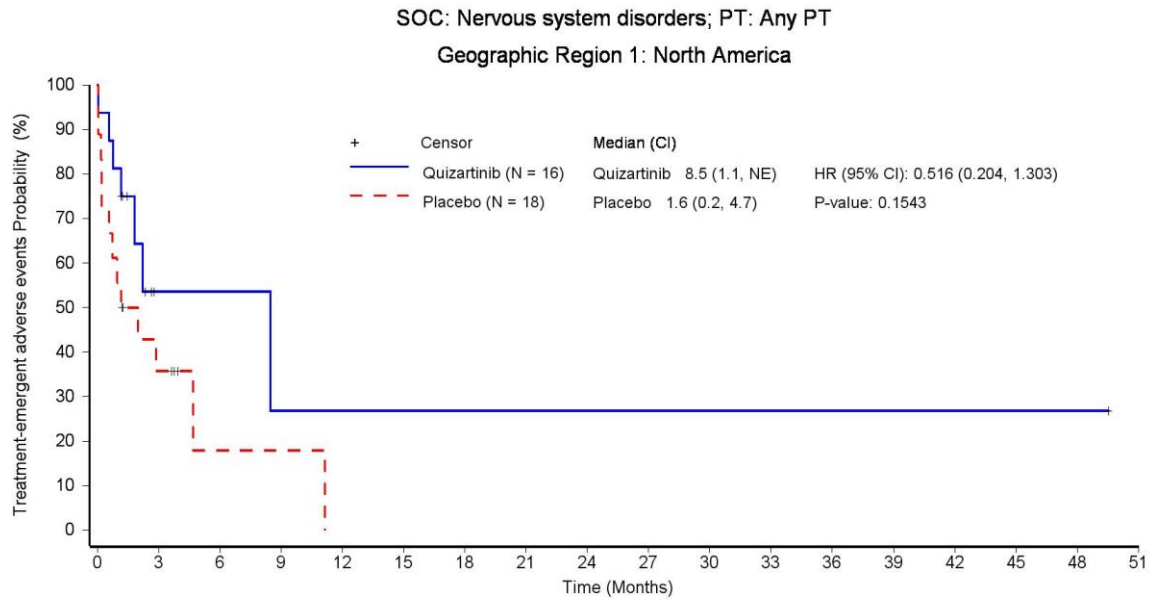
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 16)	16	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Placebo (N = 18)	18	5	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0

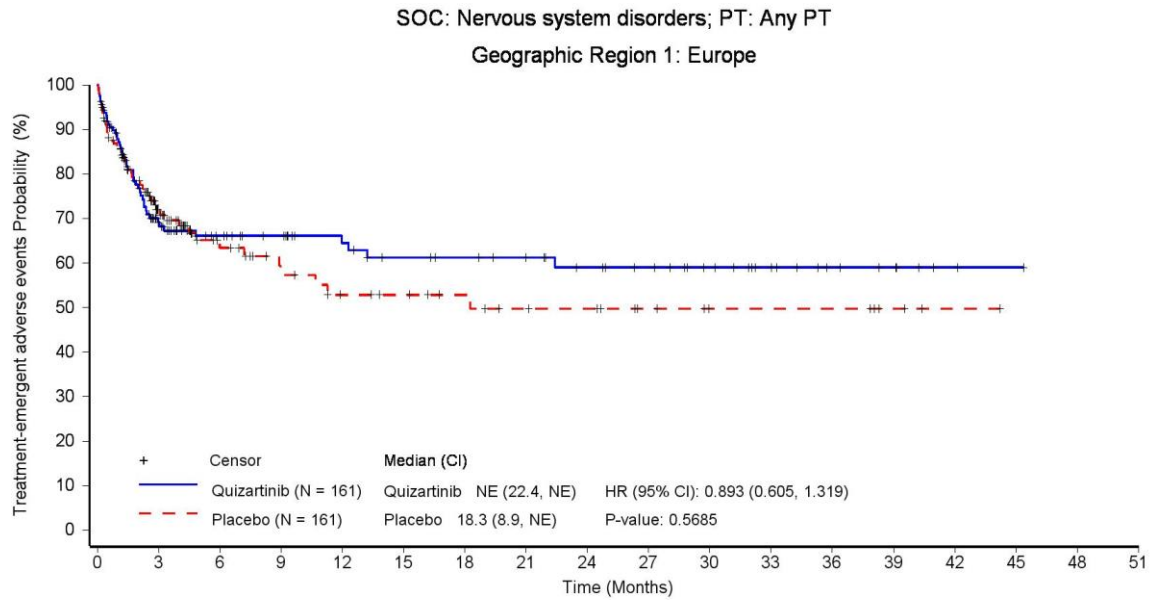
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 161)	161	73	53	47	40	35	33	30	26	23	18	13	8	6	2	1	0	0
Placebo (N = 161)	161	64	36	27	22	20	17	14	13	9	6	6	6	3	1	0	0	0

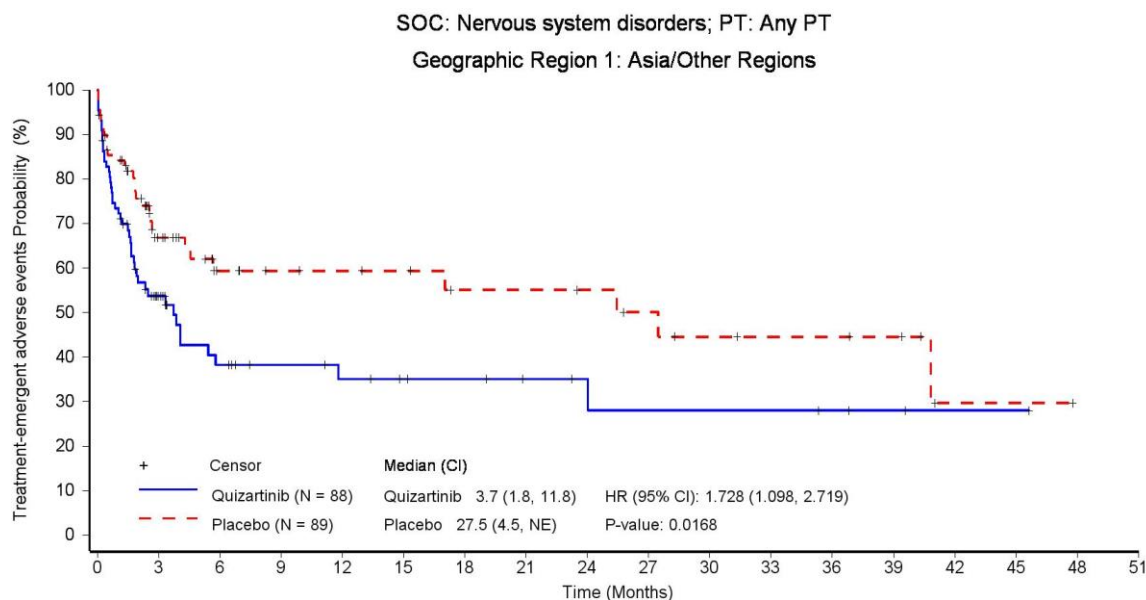
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Quizartinib (N = 88)	88	30	17	13	11	9	8	6	5	4	4	4	3	2	1	1	0	0
Placebo (N = 89)	89	33	20	17	16	15	12	12	11	9	7	6	6	5	1	1	0	0

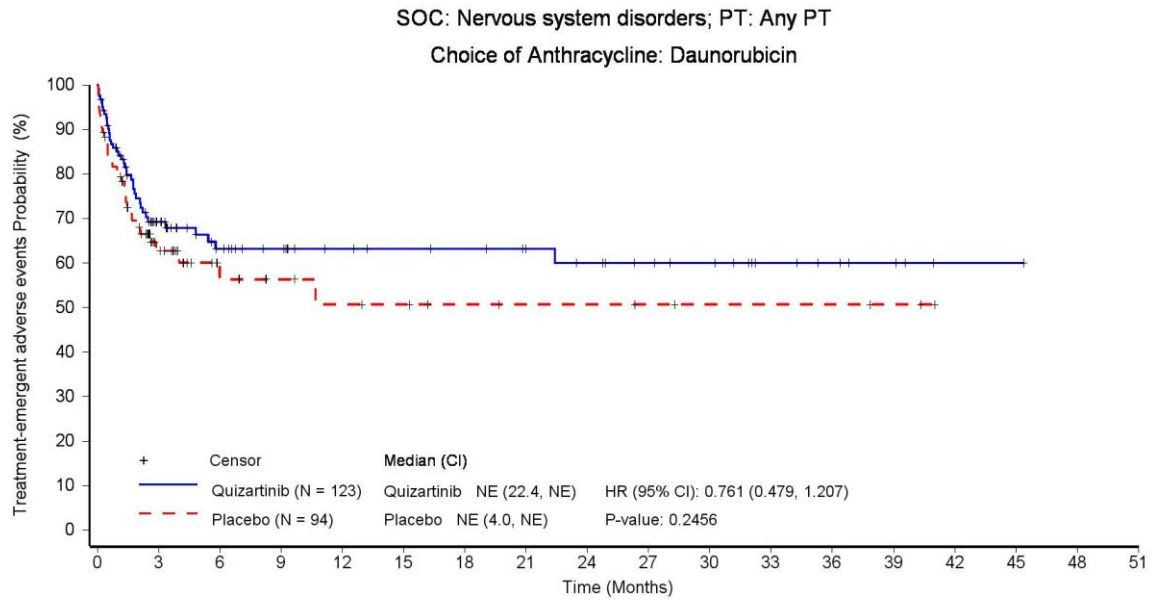
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 123)	123	55	38	32	26	24	23	20	18	15	13	8	6	4	1	1	0	0
Placebo (N = 94)	94	31	15	11	9	8	6	5	5	4	3	3	3	2	0	0	0	0

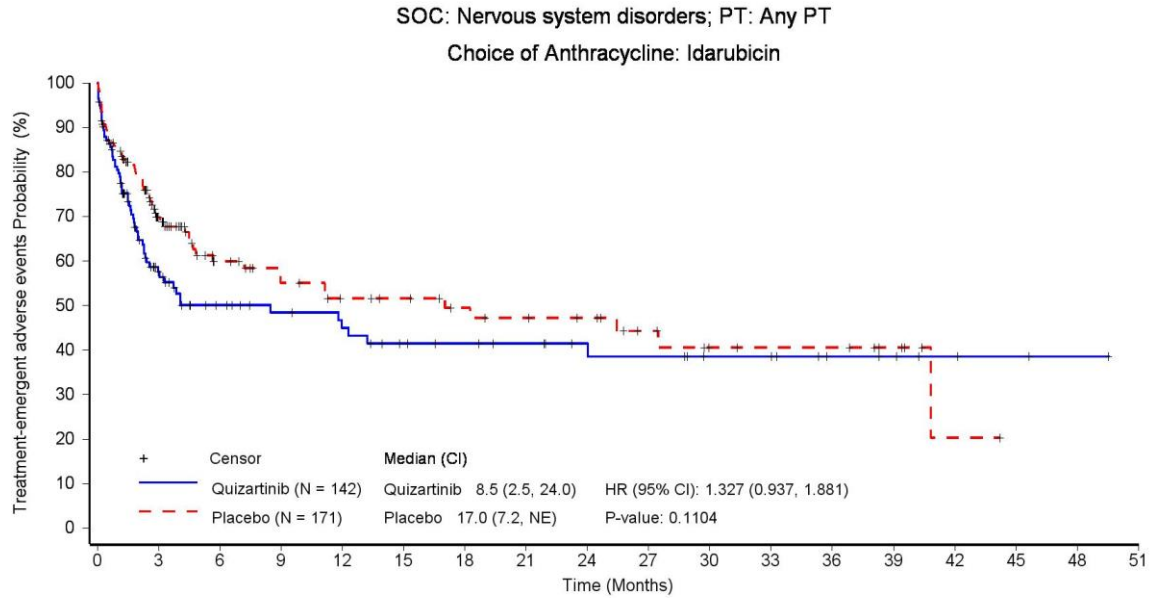
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 142)	142	50	34	29	26	21	19	17	14	13	10	10	6	5	3	2	1	0
Placebo (N = 171)	171	69	41	33	28	26	22	20	18	13	9	8	8	5	1	0	0	0

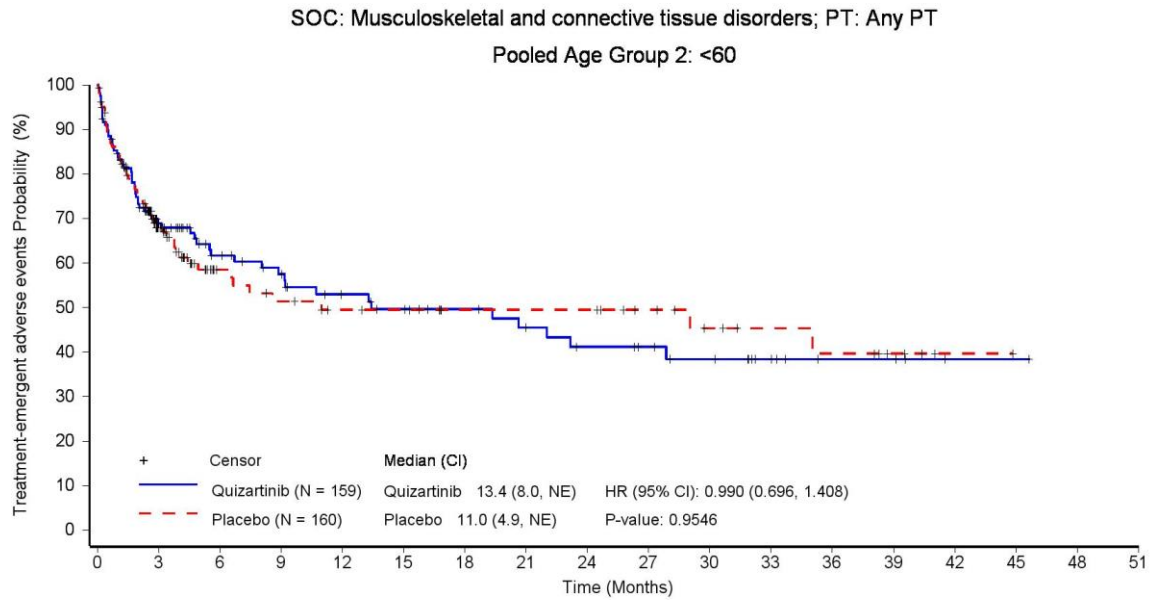
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Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 159)	159	69	47	40	32	28	25	21	18	16	13	8	4	4	1	1	0	0
Placebo (N = 160)	160	66	33	28	24	23	19	19	19	14	10	8	7	4	1	0	0	0

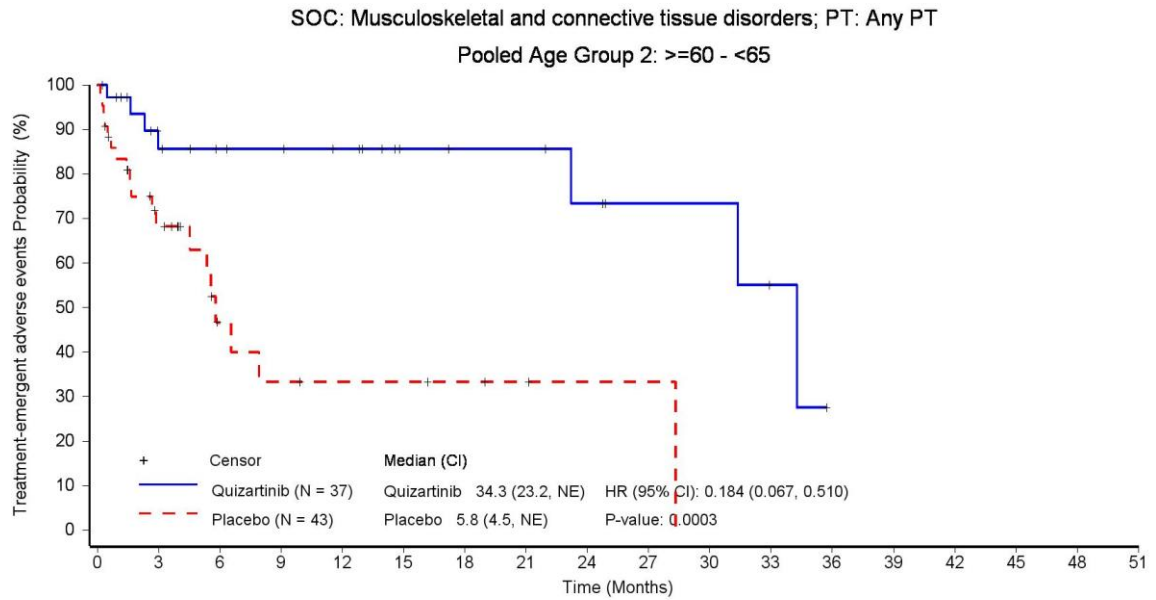
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 37)	37	21	17	16	14	9	8	8	6	4	4	2	0	0	0	0	0	0
Placebo (N = 43)	43	19	7	5	4	4	3	2	1	1	0	0	0	0	0	0	0	0

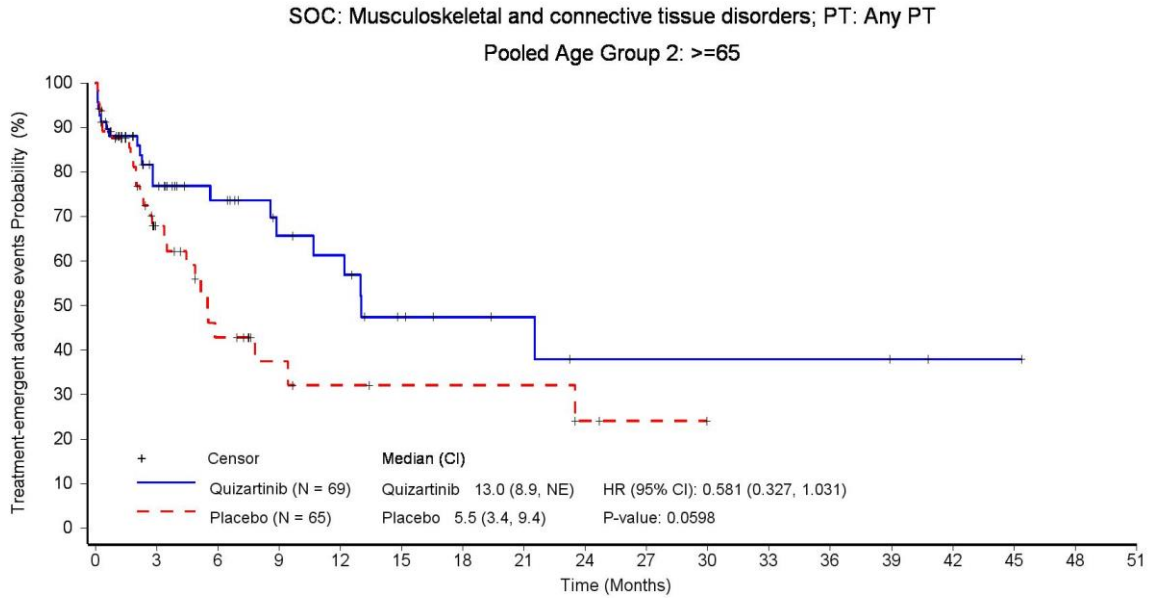
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 69)	69	32	23	16	14	8	6	5	3	3	3	3	3	2	1	1	0	0
Placebo (N = 65)	65	24	13	7	5	4	4	4	2	1	0	0	0	0	0	0	0	0

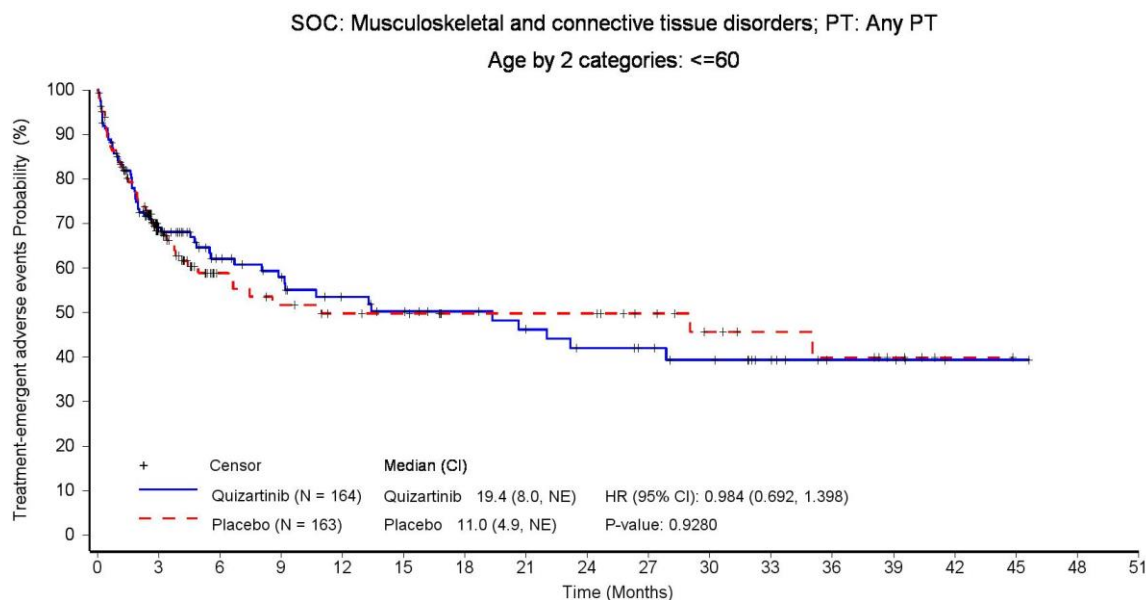
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	71	48	41	33	29	26	22	19	17	14	9	4	4	1	1	0	0
Placebo (N = 163)	163	66	33	28	24	23	19	19	19	14	10	8	7	4	1	0	0	0

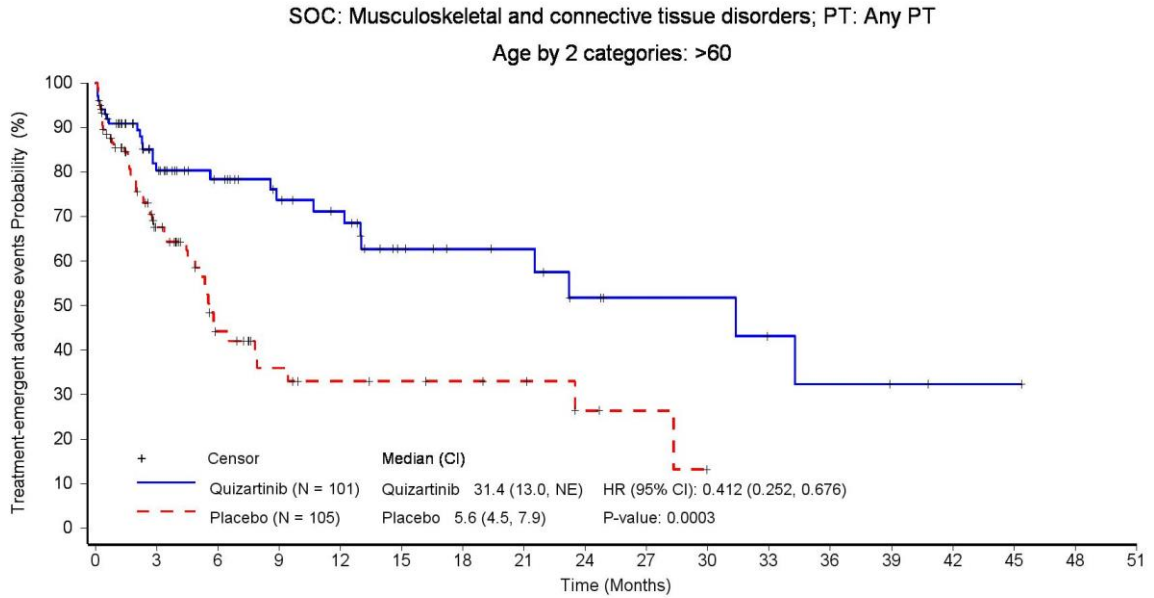
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 101)	101	51	39	31	27	16	13	12	8	6	6	4	3	2	1	1	0	0
Placebo (N = 105)	105	43	20	12	9	8	7	6	3	2	0	0	0	0	0	0	0	0

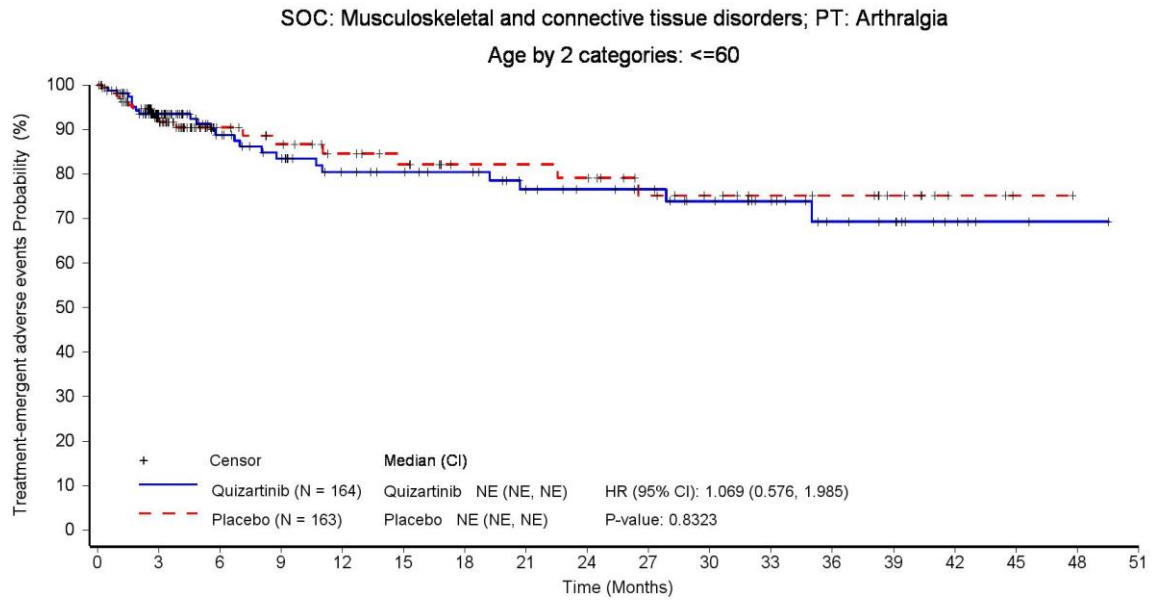
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	100	71	61	51	48	45	37	34	30	25	20	13	11	5	2	1	0
Placebo (N = 163)	163	88	51	45	38	34	27	27	26	19	16	13	12	8	3	1	0	0

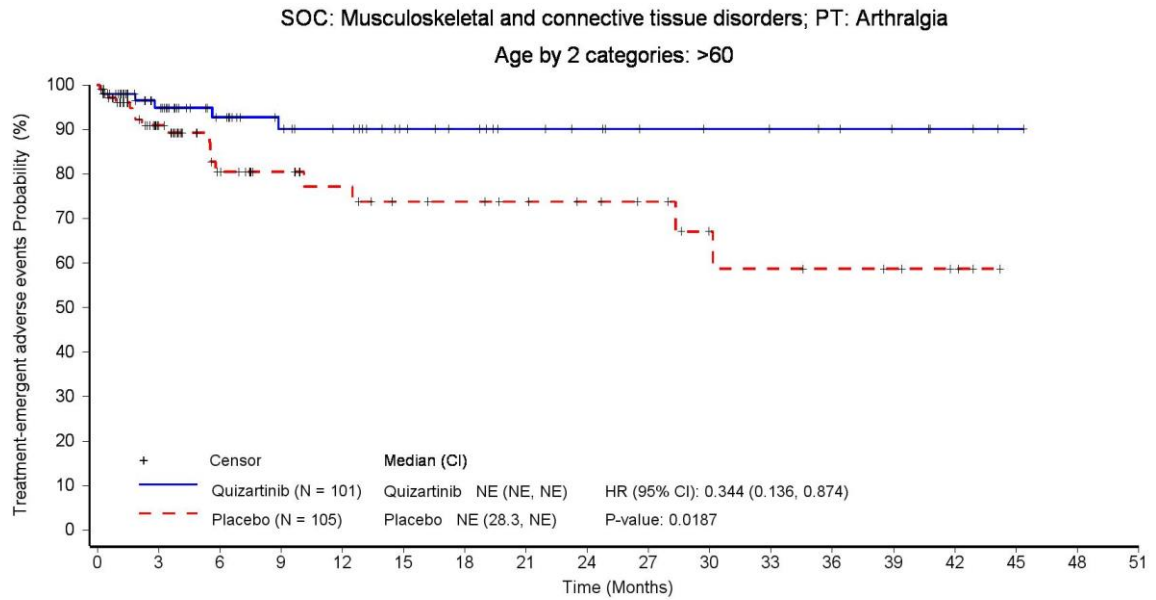
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 101)	101	58	42	34	30	22	19	15	13	10	9	8	7	5	3	1	0	0
Placebo (N = 105)	105	57	35	28	23	19	18	16	14	12	8	7	6	5	3	0	0	0

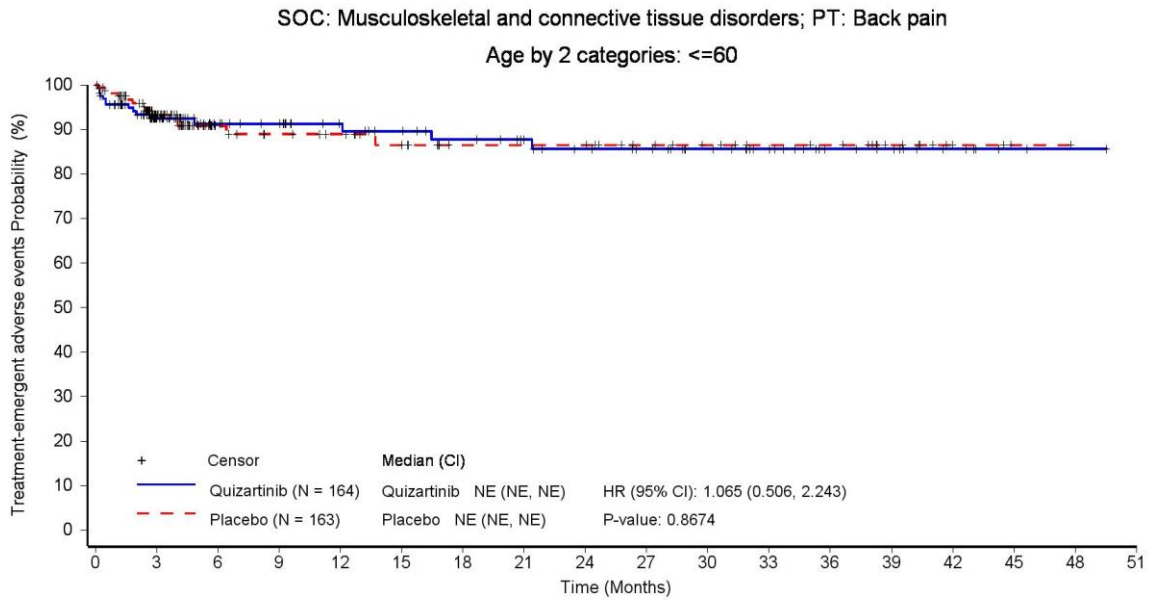
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	95	69	64	55	51	47	42	38	34	28	22	14	12	7	2	1	0
Placebo (N = 163)	163	89	49	44	40	34	28	28	28	22	19	16	15	9	3	1	0	0

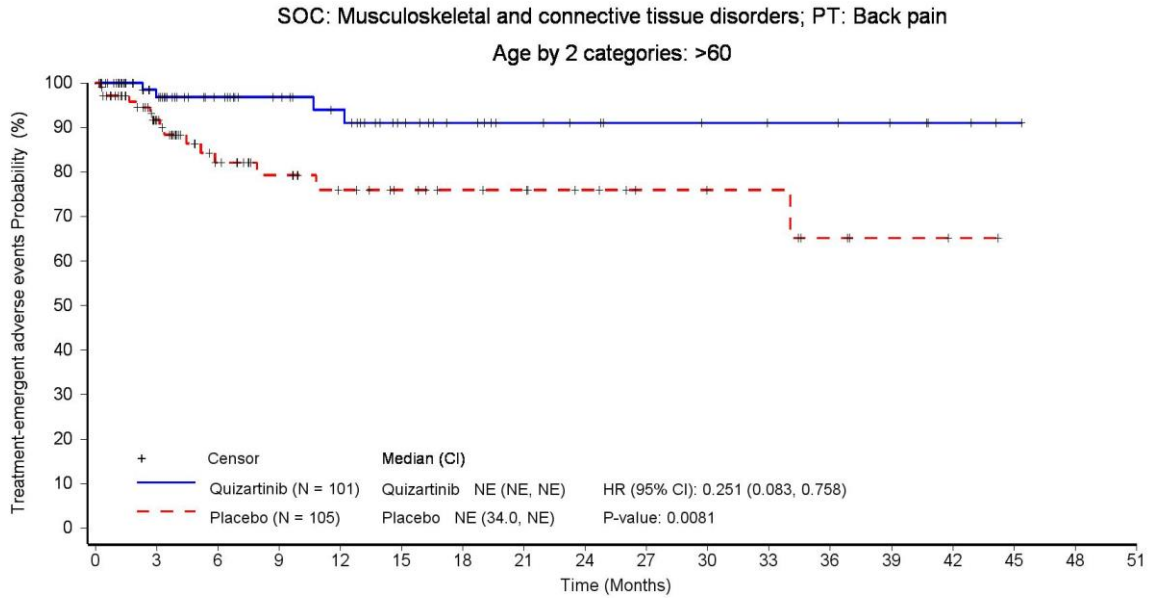
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	58	44	37	32	22	17	13	11	9	8	7	7	5	3	1	0	0
Placebo (N = 105)	105	57	37	28	22	18	15	14	11	8	7	7	4	2	1	0	0	0

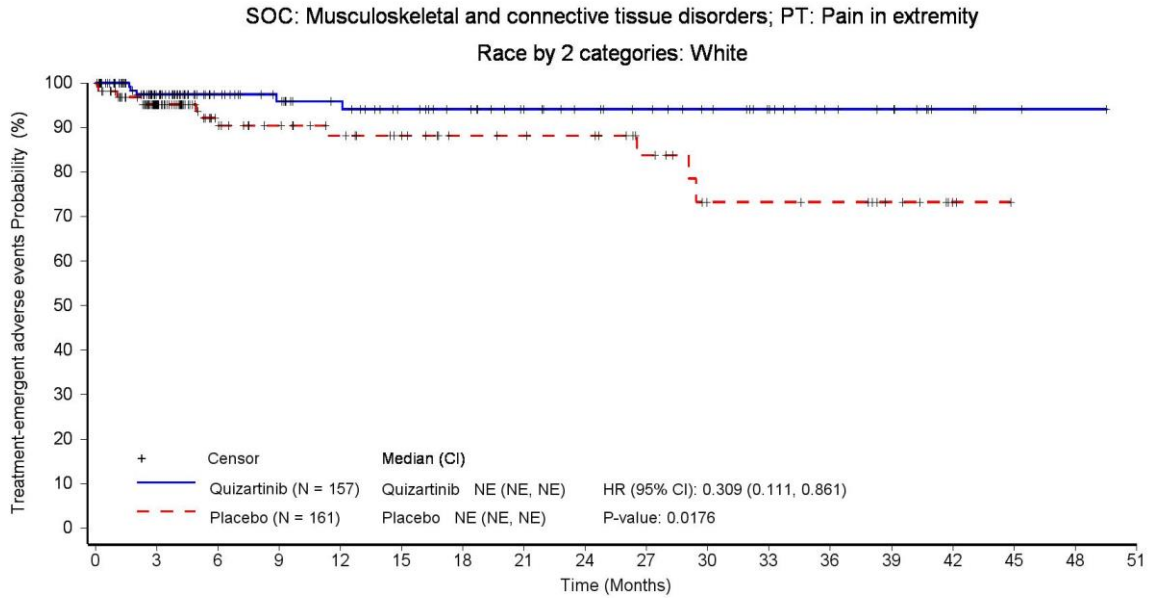
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 157)	157	99	70	61	54	46	41	34	30	27	23	18	12	10	4	2	1	0
Placebo (N = 161)	161	89	54	46	39	33	27	26	25	19	12	12	11	7	2	0	0	0

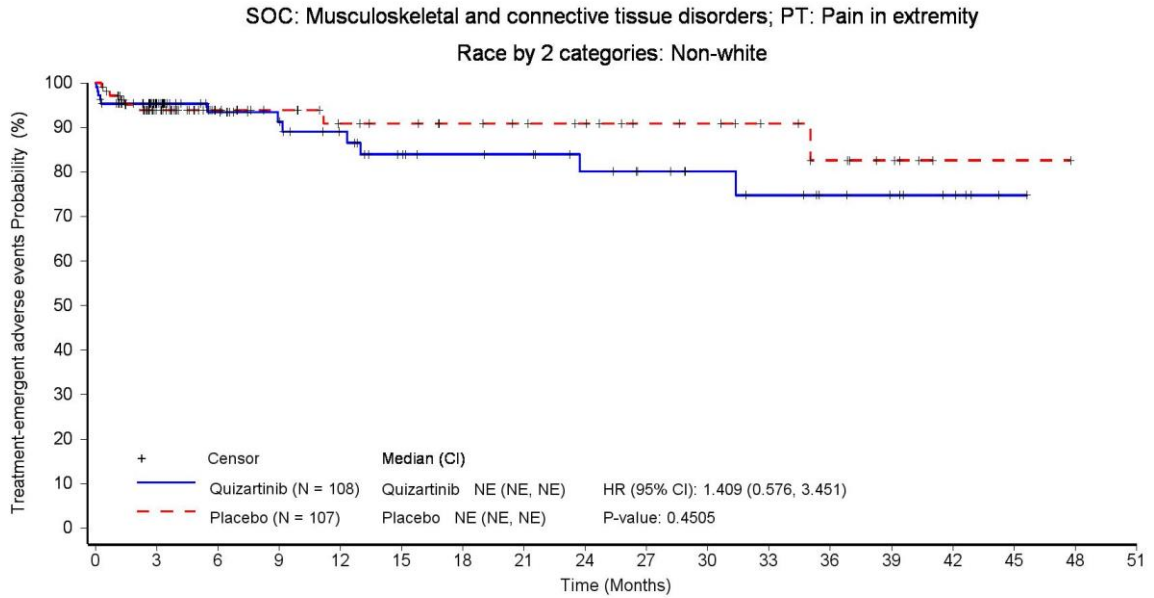
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	63	49	42	36	29	26	25	21	18	15	13	10	8	5	1	0	0
Placebo (N = 107)	107	62	40	34	29	27	24	22	20	16	15	12	9	6	1	1	0	0

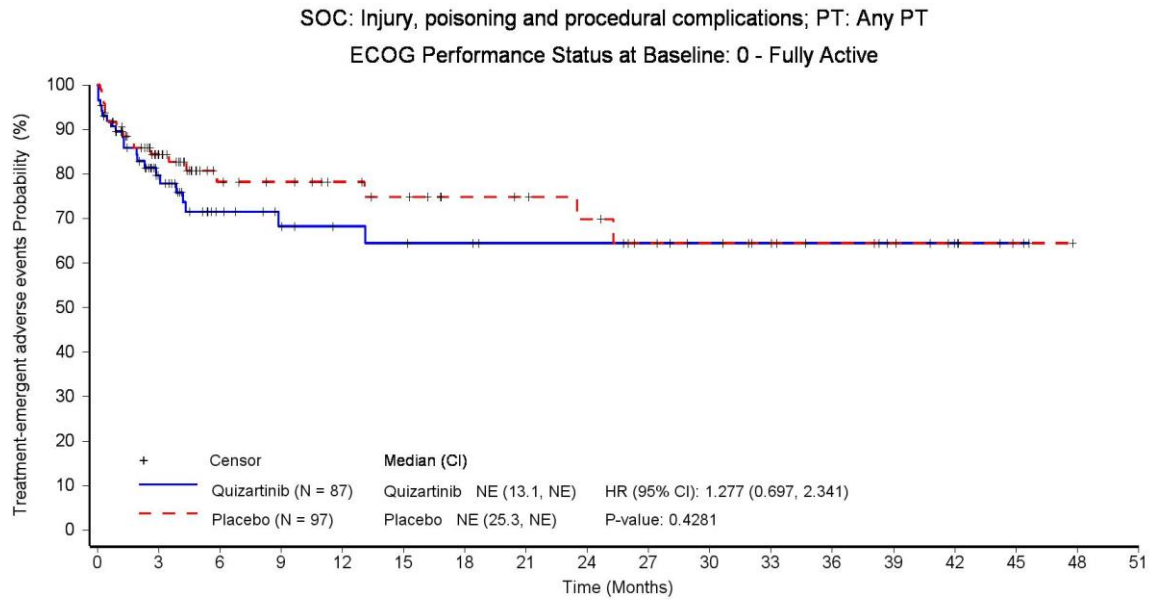
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 87)	87	44	26	21	18	17	16	14	14	13	11	9	6	5	3	2	0	0
Placebo (N = 97)	97	52	31	28	24	21	17	16	14	10	9	8	8	6	4	1	0	0

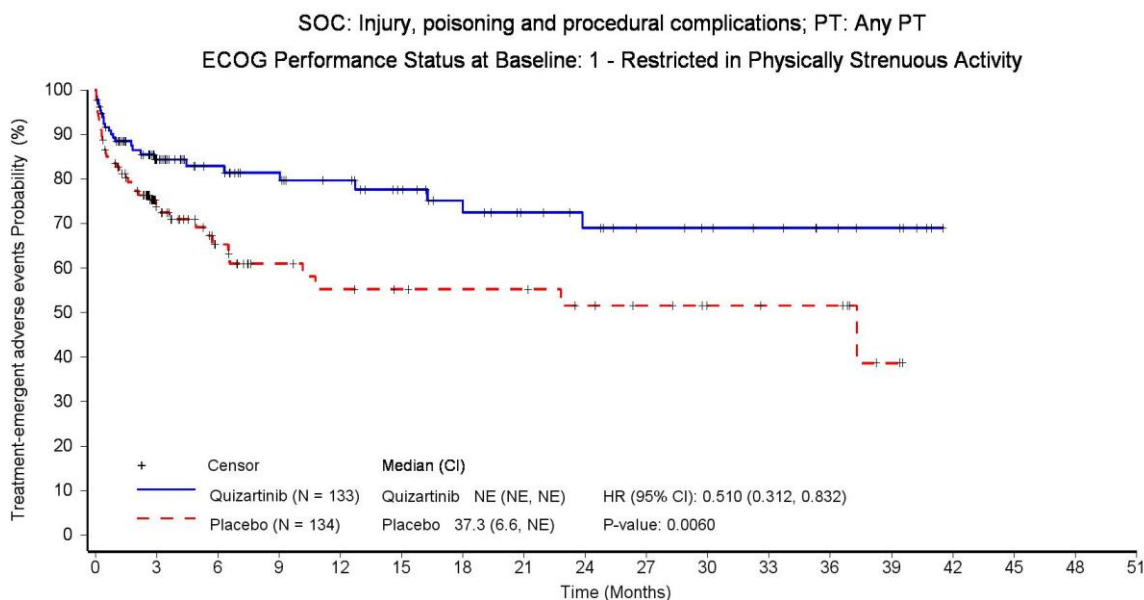
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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	71	54	47	42	34	28	23	20	15	13	11	8	6	0	0	0	0
Placebo (N = 134)	134	53	31	22	19	17	16	16	13	11	8	7	7	2	0	0	0	0

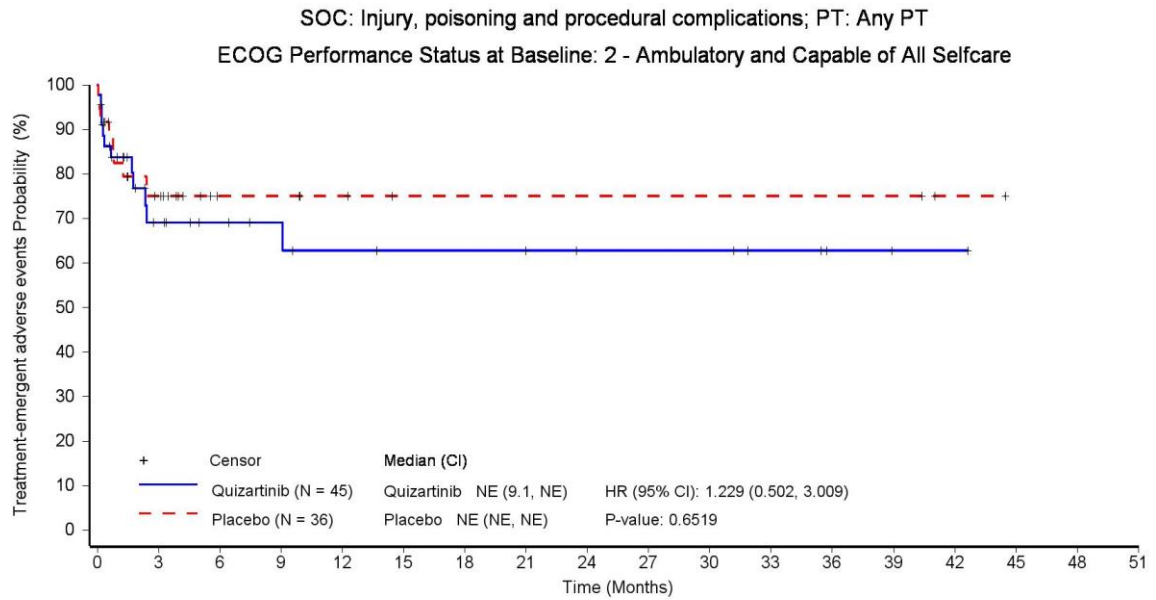
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 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 45)	45	17	13	11	9	8	8	7	6	6	6	4	2	1	1	0	0	0
Placebo (N = 36)	36	16	7	7	5	3	3	3	3	3	3	3	3	3	1	0	0	0

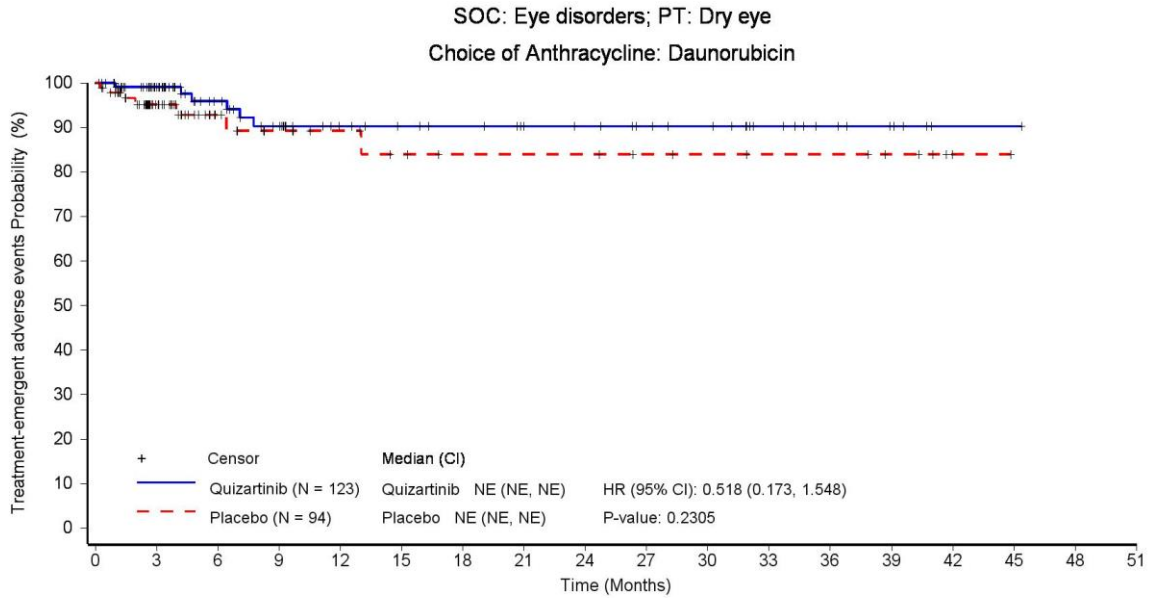
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 123)	123	75	54	44	34	31	29	25	24	20	18	12	8	5	1	1	0	0
Placebo (N = 94)	94	49	27	21	18	15	12	12	12	9	8	7	7	5	1	0	0	0

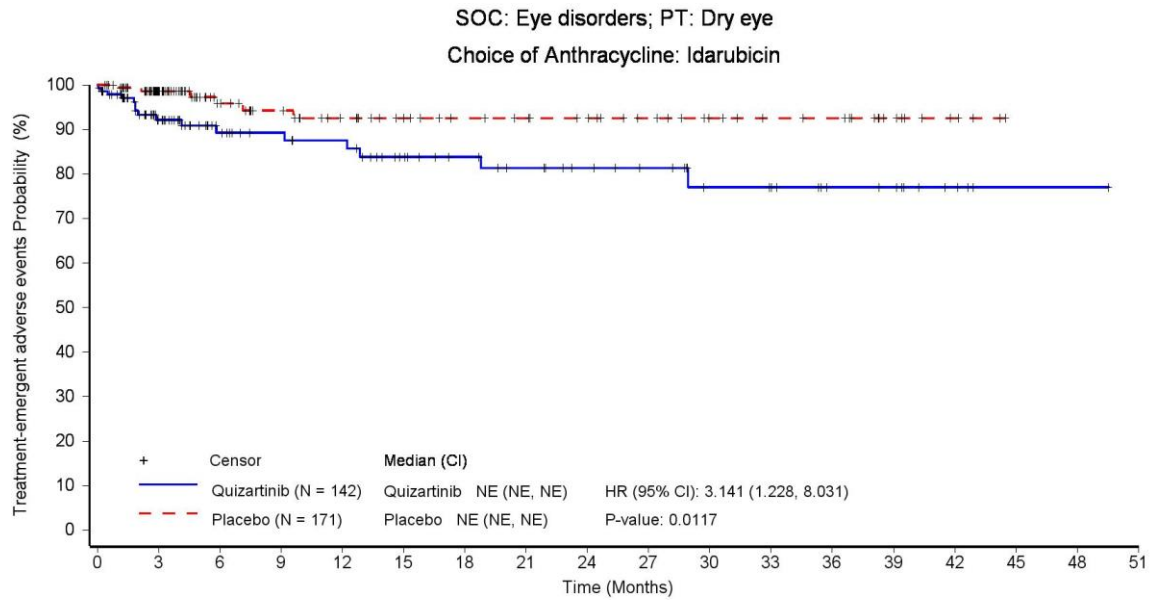
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 142)	142	81	57	51	48	39	34	30	26	23	17	16	11	10	5	1	1	0
Placebo (N = 171)	171	100	64	55	47	40	36	34	31	26	21	18	17	10	4	0	0	0

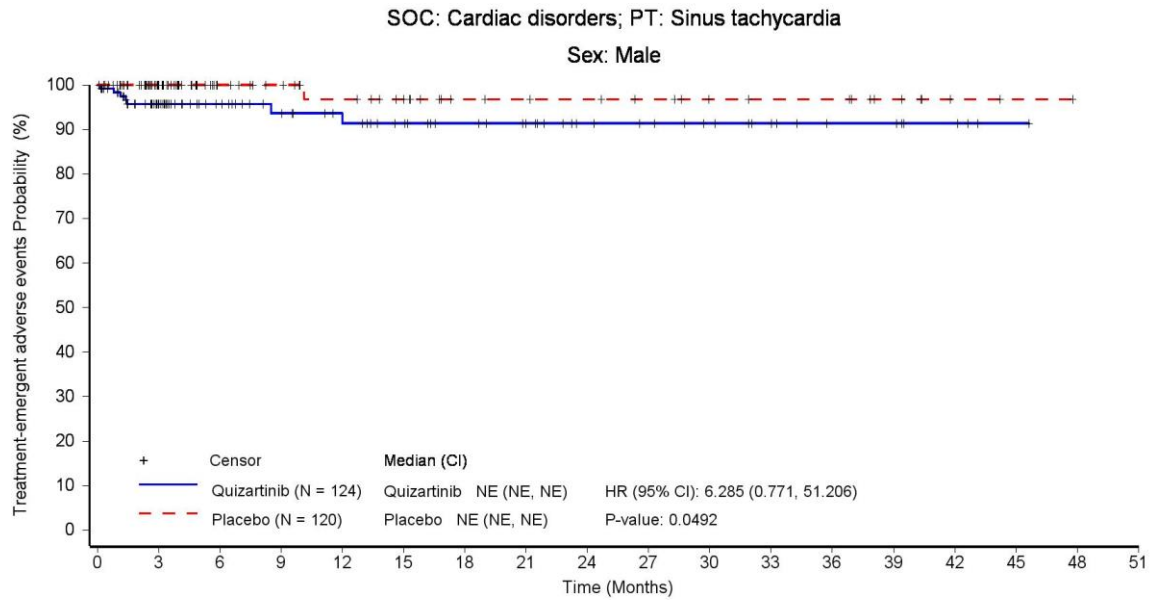
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

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Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 124)	124	71	54	46	40	35	30	26	20	18	15	12	8	8	5	1	0	0
Placebo (N = 120)	120	65	40	35	30	25	19	18	17	15	12	11	11	7	2	1	0	0

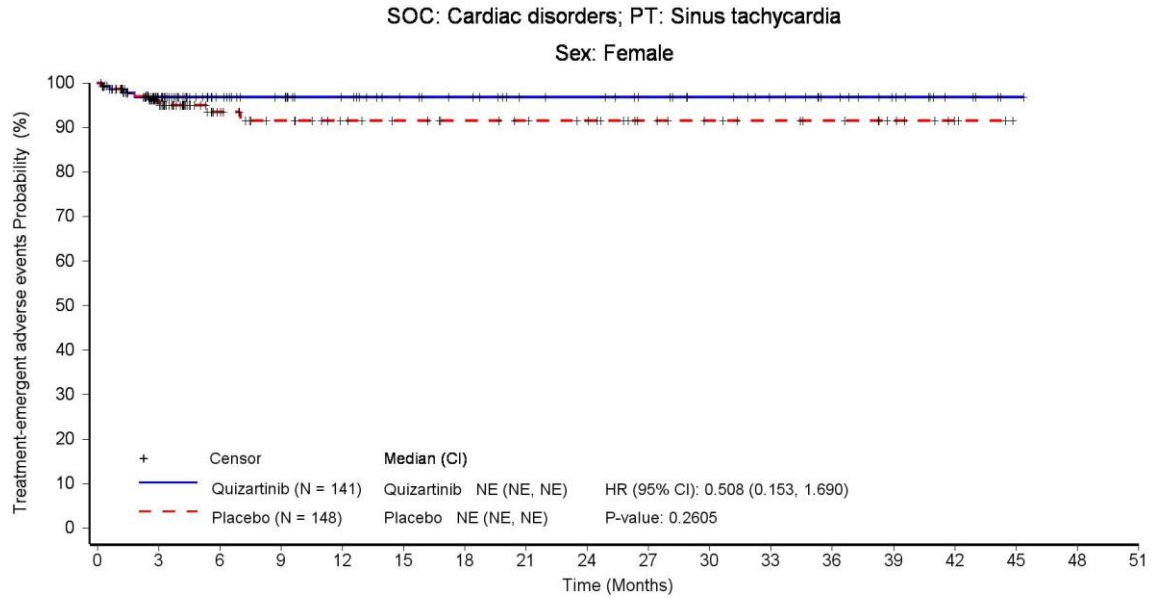
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	88	64	57	50	43	40	34	33	29	25	21	16	11	5	1	0	0
Placebo (N = 148)	148	88	54	44	37	34	30	28	26	19	16	14	12	8	3	0	0	0

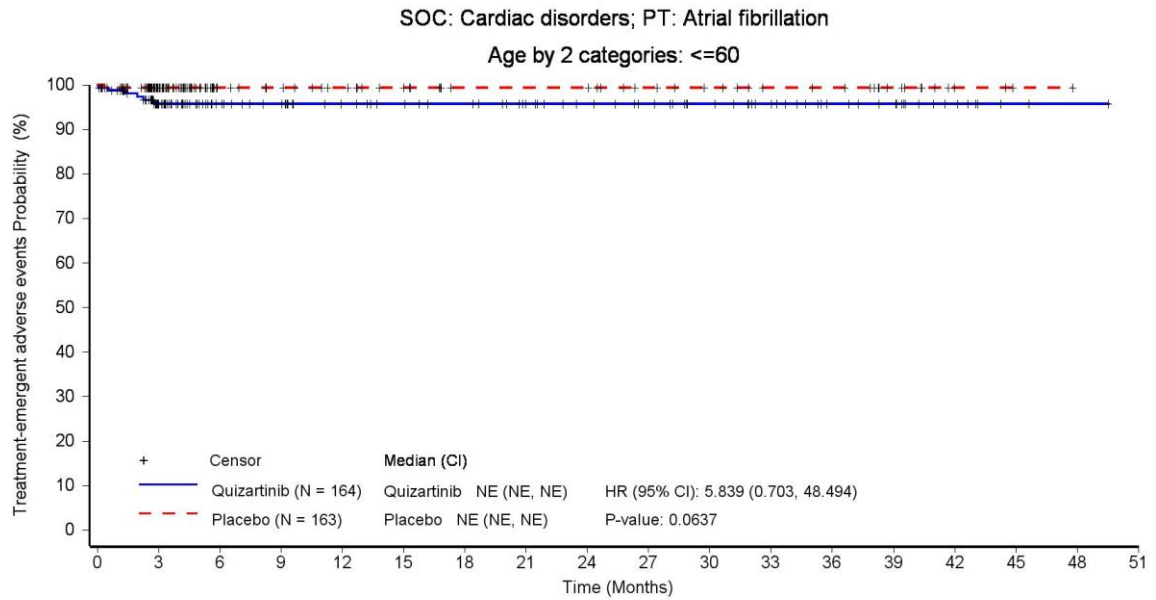
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 164)	164	105	78	72	63	59	56	49	44	39	33	27	19	16	8	2	1	0
Placebo (N = 163)	163	94	53	49	43	37	30	30	30	24	21	17	16	10	3	1	0	0

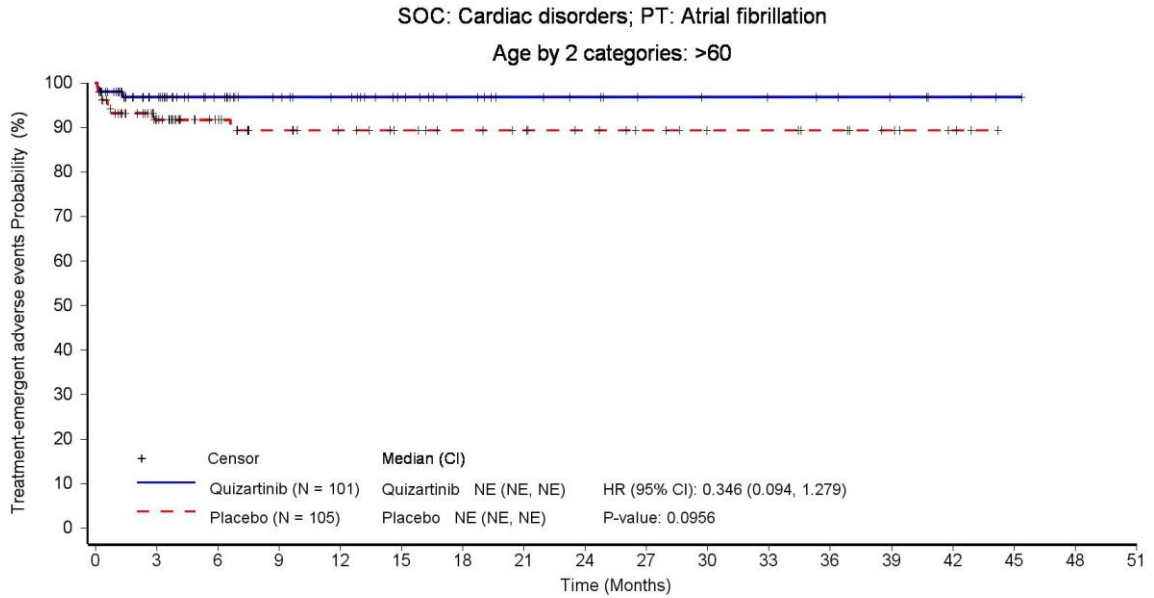
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.11.2 Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 101)	101	58	44	36	32	24	19	15	13	10	9	8	7	5	3	1	0	0
Placebo (N = 105)	105	58	42	33	29	25	22	20	17	14	11	11	9	6	3	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

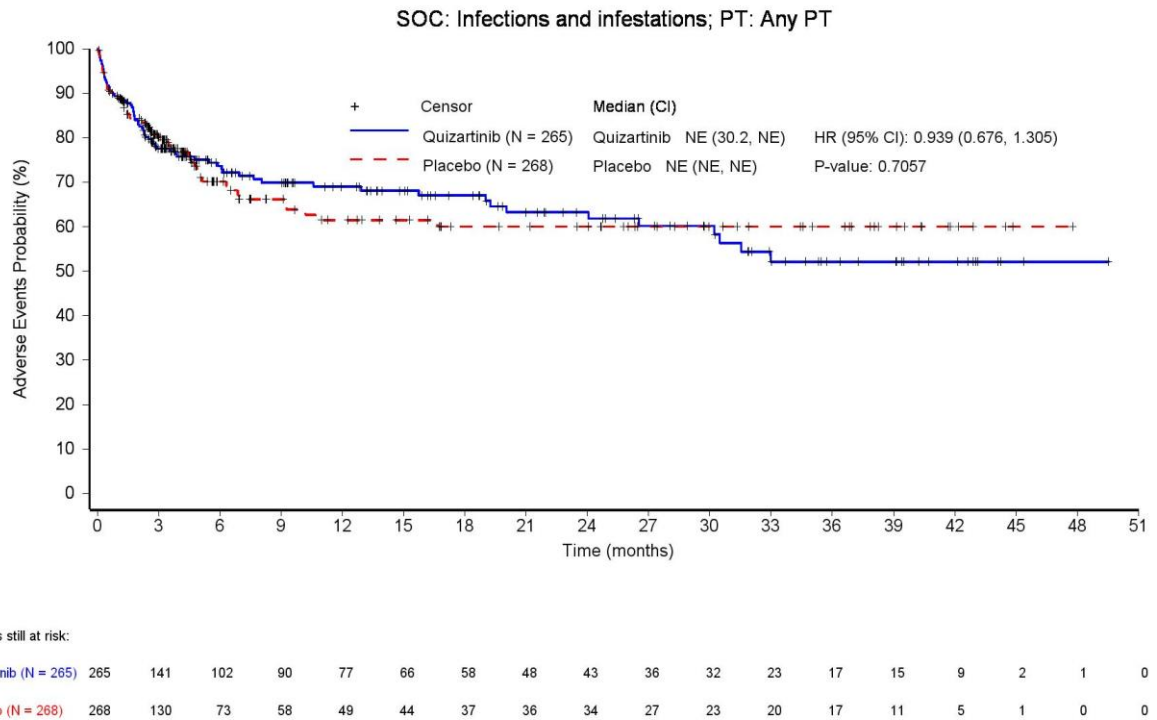
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:11; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_11_2_TEAESOCPT_SUB_SAS.rtf

Anhang 4-G3: SUE nach SOC und PT

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Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

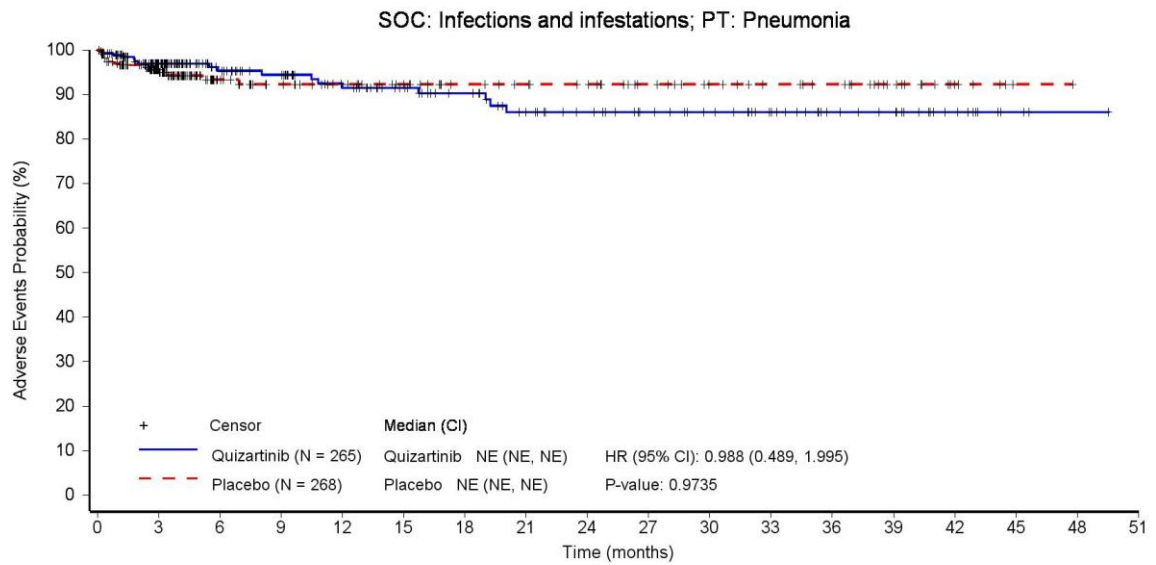
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	117	106	90	78	69	58	52	44	39	32	23	20	11	3	1	0
Placebo (N = 268)	268	151	92	78	69	61	51	48	45	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

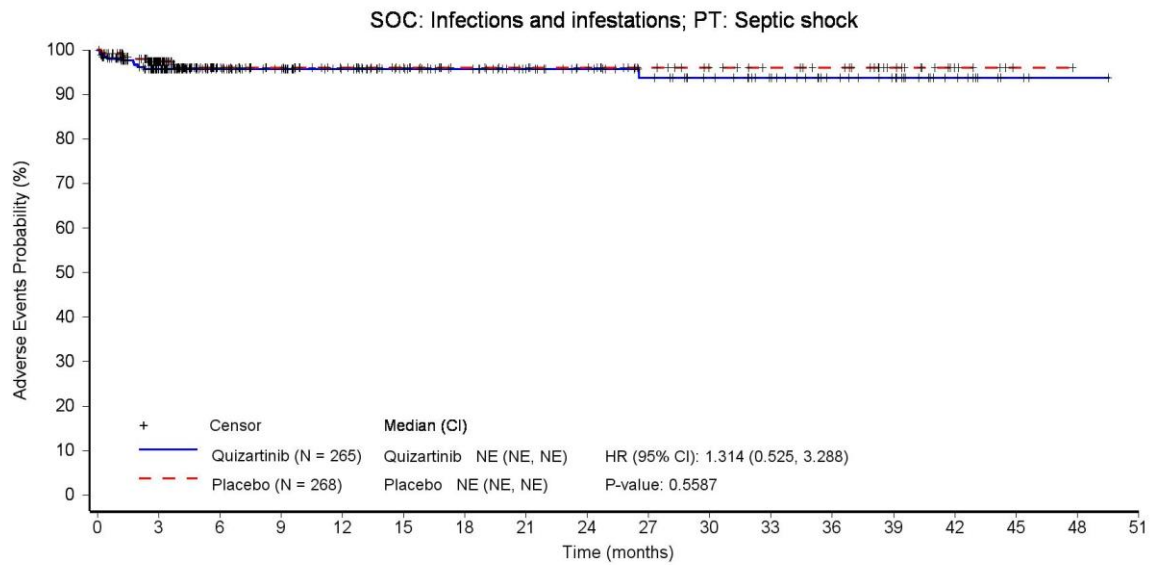
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	74	63	56	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	156	97	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

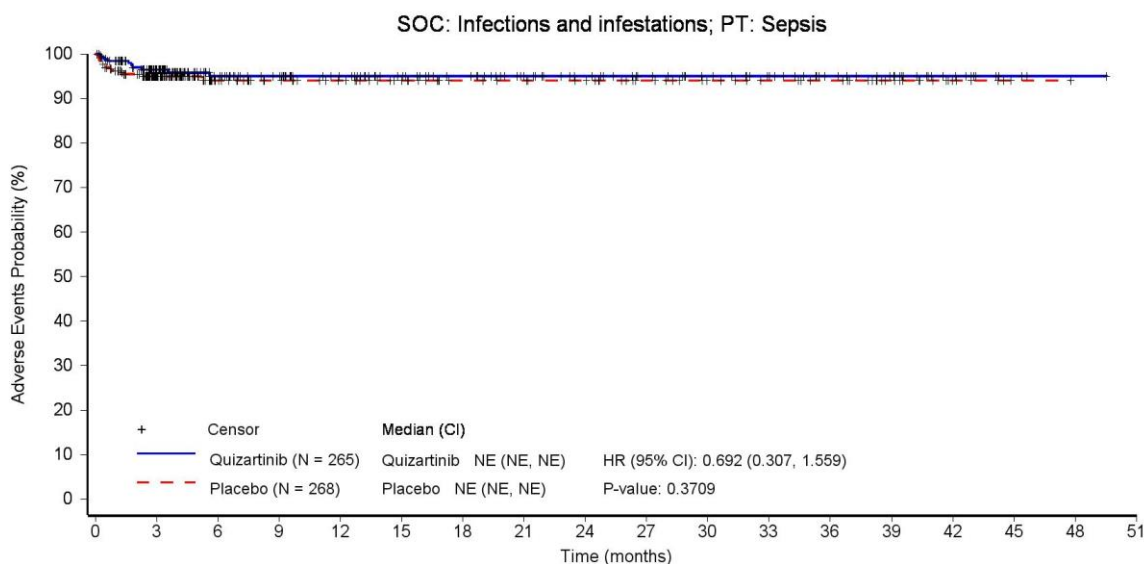
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	119	106	93	81	73	62	55	47	41	35	26	21	11	3	1	0
Placebo (N = 268)	268	151	94	80	71	62	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

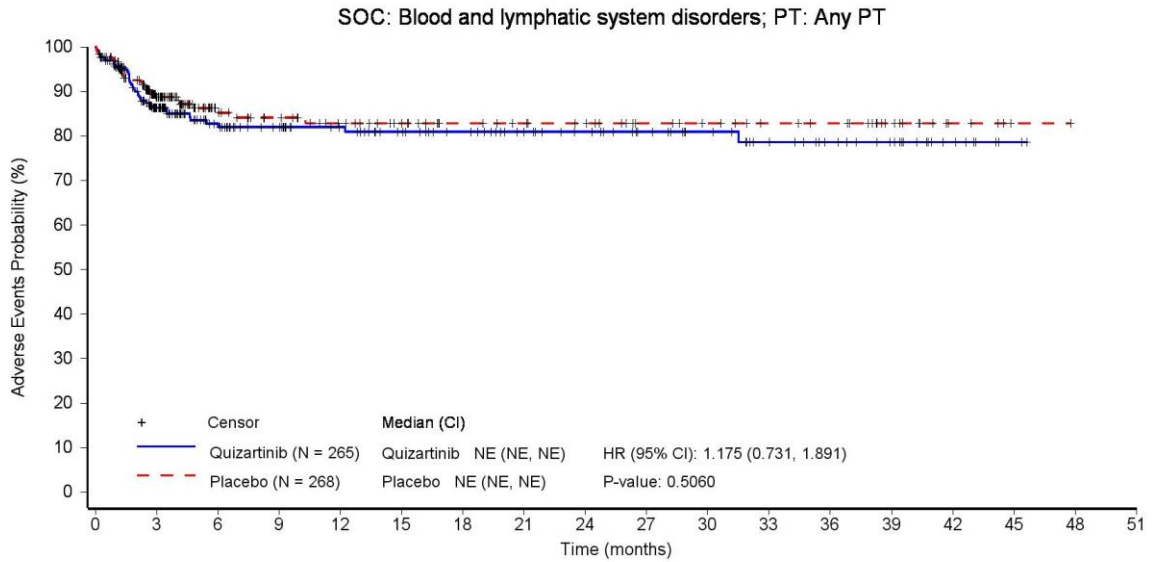
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	145	104	90	80	71	64	55	50	42	36	29	23	18	9	2	0	0
Placebo (N = 268)	268	138	82	70	60	52	44	41	38	30	27	23	21	13	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

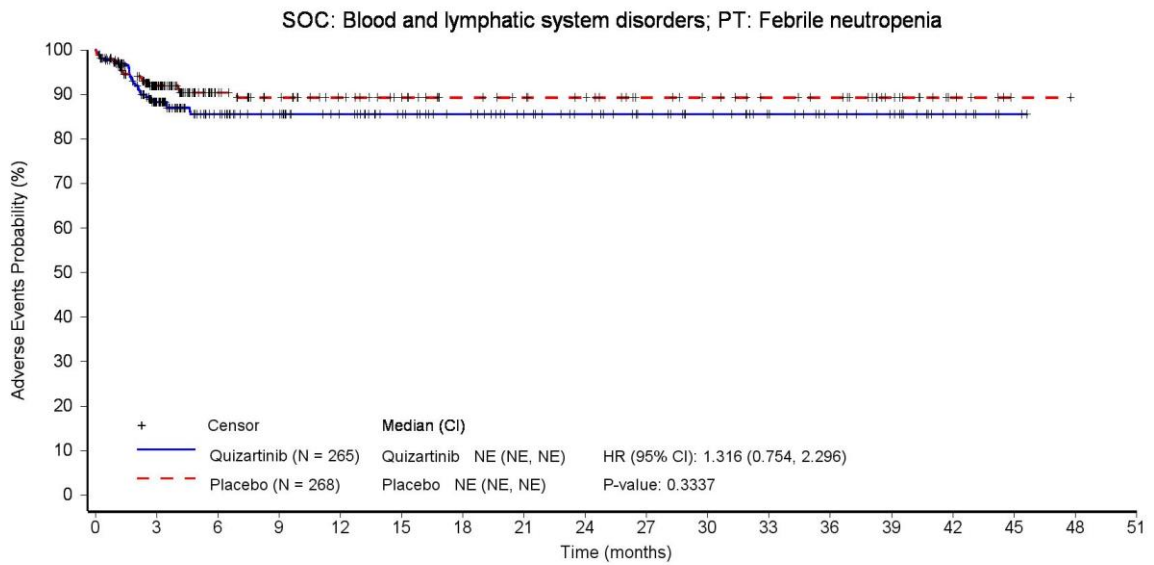
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	148	107	94	83	73	65	56	50	42	36	29	23	18	9	2	0	0
Placebo (N = 268)	268	142	86	73	62	54	46	43	40	32	29	25	23	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

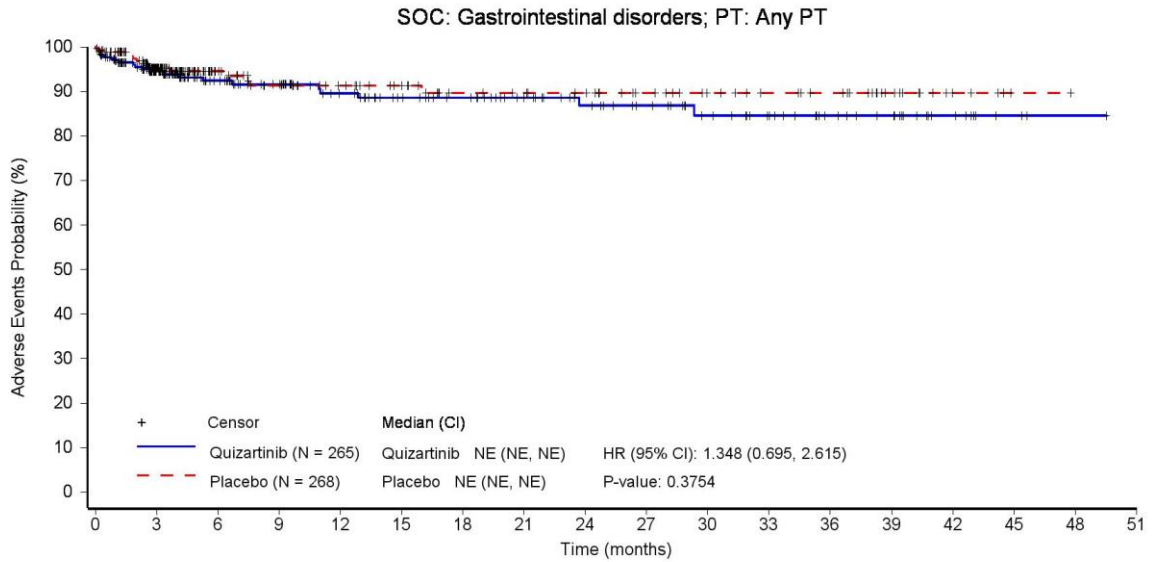
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\

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Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	160	117	103	88	75	69	59	51	44	36	30	22	18	9	3	1	0
Placebo (N = 268)	268	150	94	78	67	59	48	46	43	36	30	26	23	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

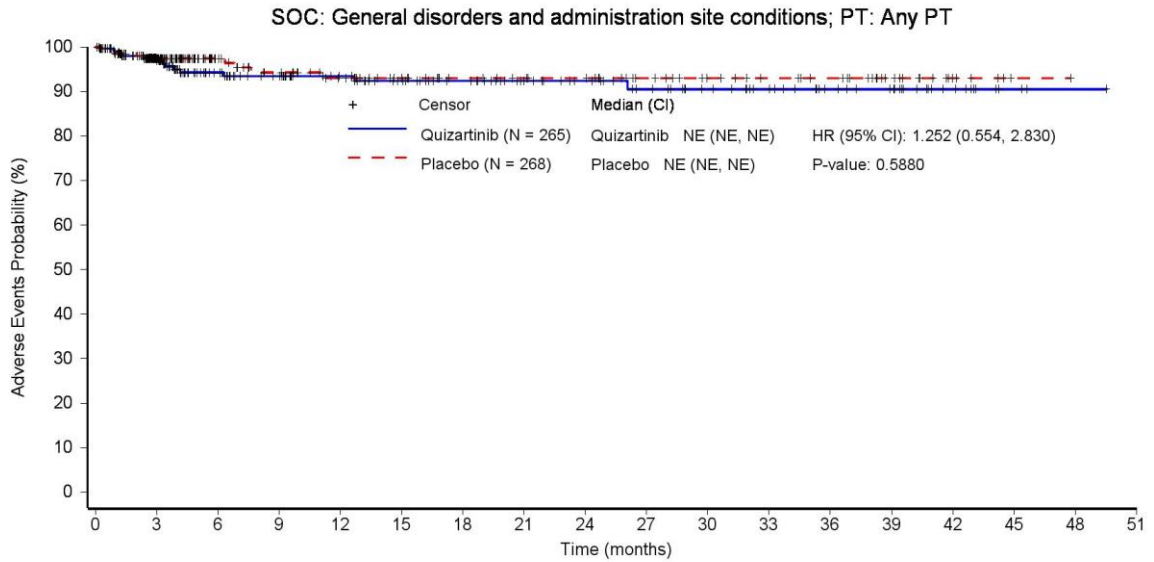
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

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Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	162	117	103	90	79	71	60	54	46	39	33	25	21	11	3	1	0
Placebo (N = 268)	268	153	97	82	71	61	52	49	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

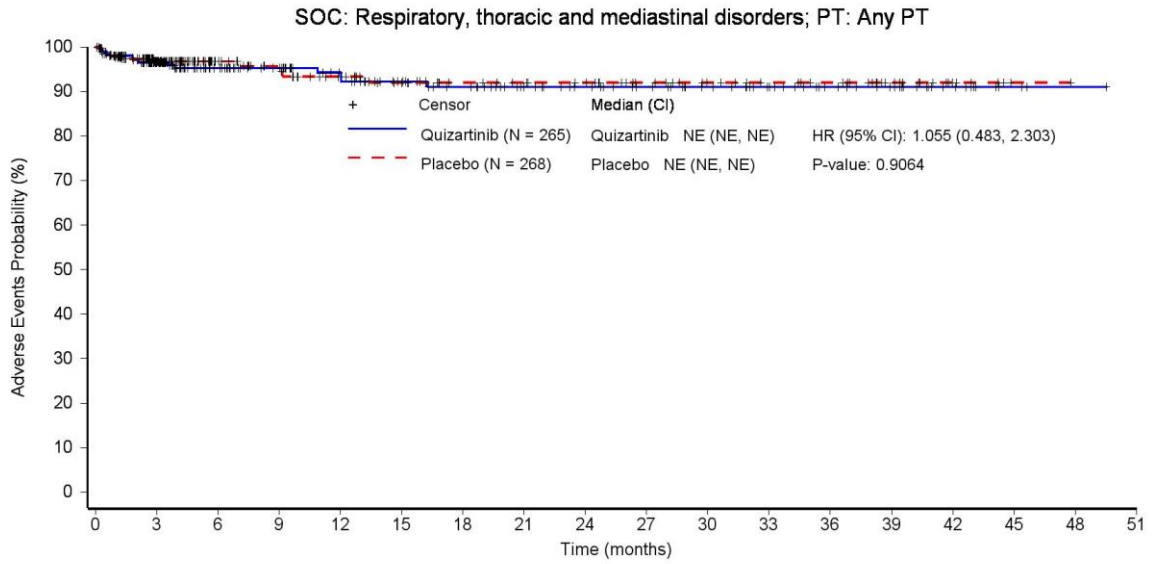
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	121	107	93	80	71	60	54	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	154	98	83	71	62	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

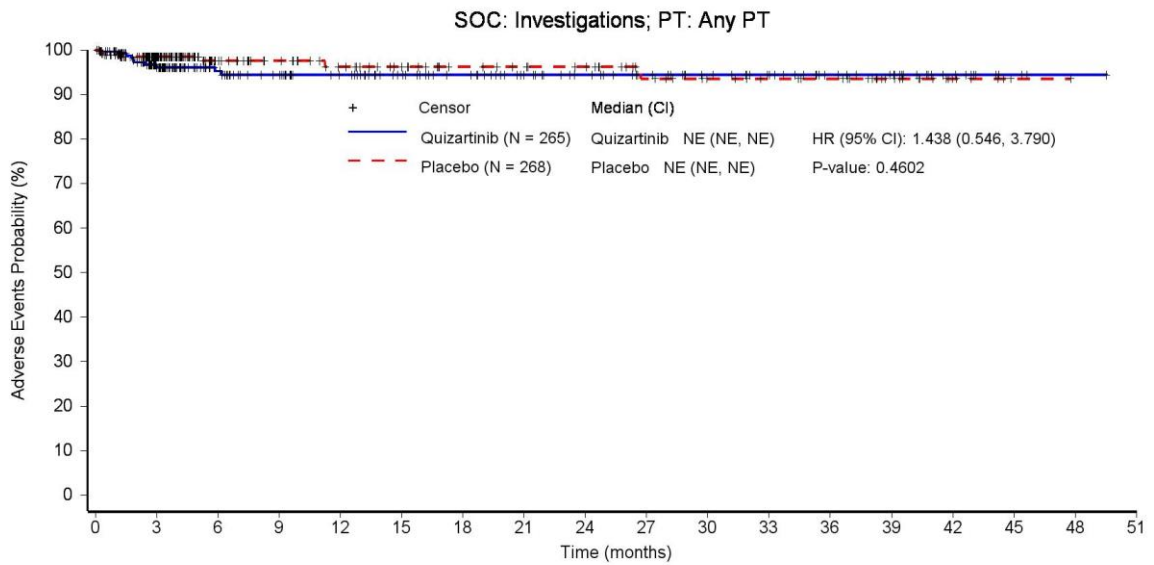
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	118	104	93	81	73	62	55	47	40	34	25	21	11	3	1	0
Placebo (N = 268)	268	153	95	81	70	61	51	48	45	35	30	27	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

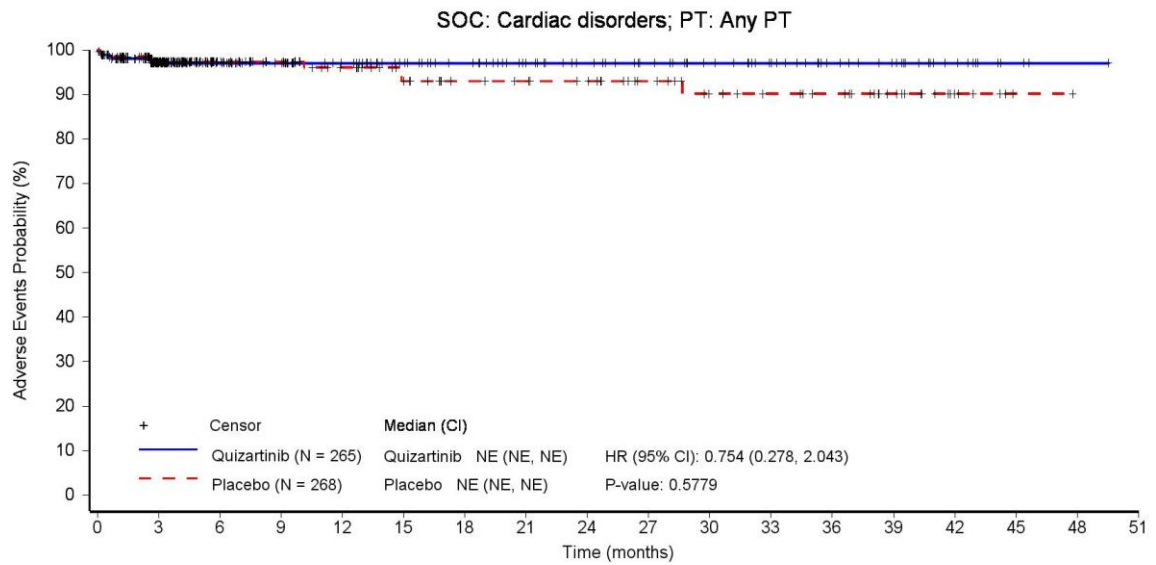
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.1 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	74	63	56	48	41	34	25	20	11	3	1	0
Placebo (N = 268)	268	154	96	82	70	59	51	49	46	37	30	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

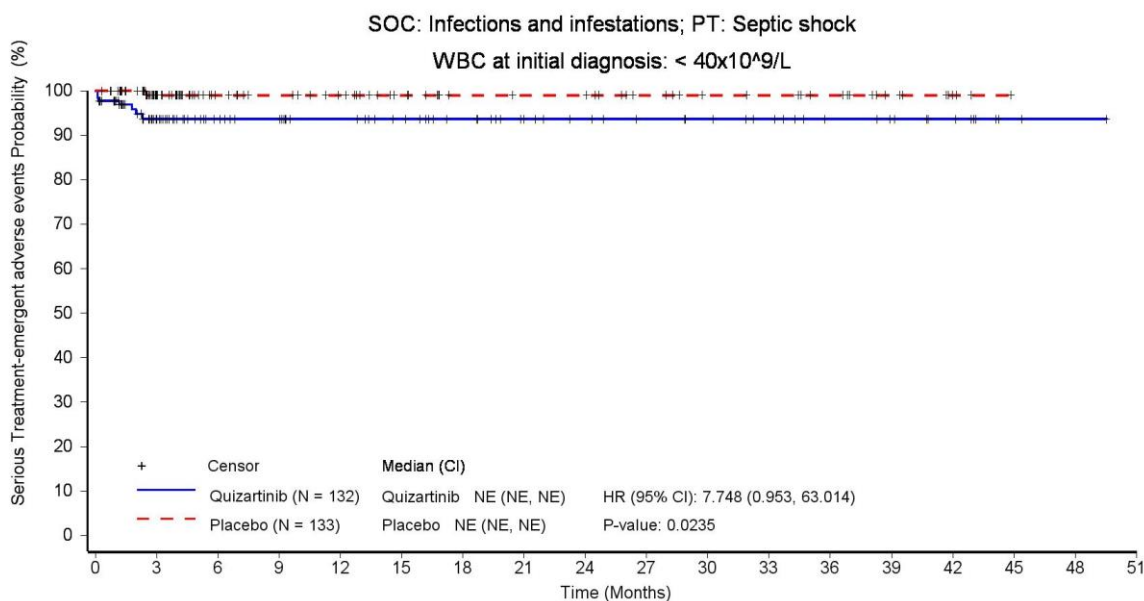
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Run date: 14JUL2023 – 16:40; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_12_1_TEAESERSOCPT_SAS.rtf

Anhang 4-G4: SUE nach SOC und PT – Subgruppenanalysen

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.2 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	75	57	53	47	42	36	29	26	23	21	18	13	11	8	2	1	0
Placebo (N = 133)	133	80	56	50	44	36	29	28	28	22	18	17	14	8	3	0	0	0

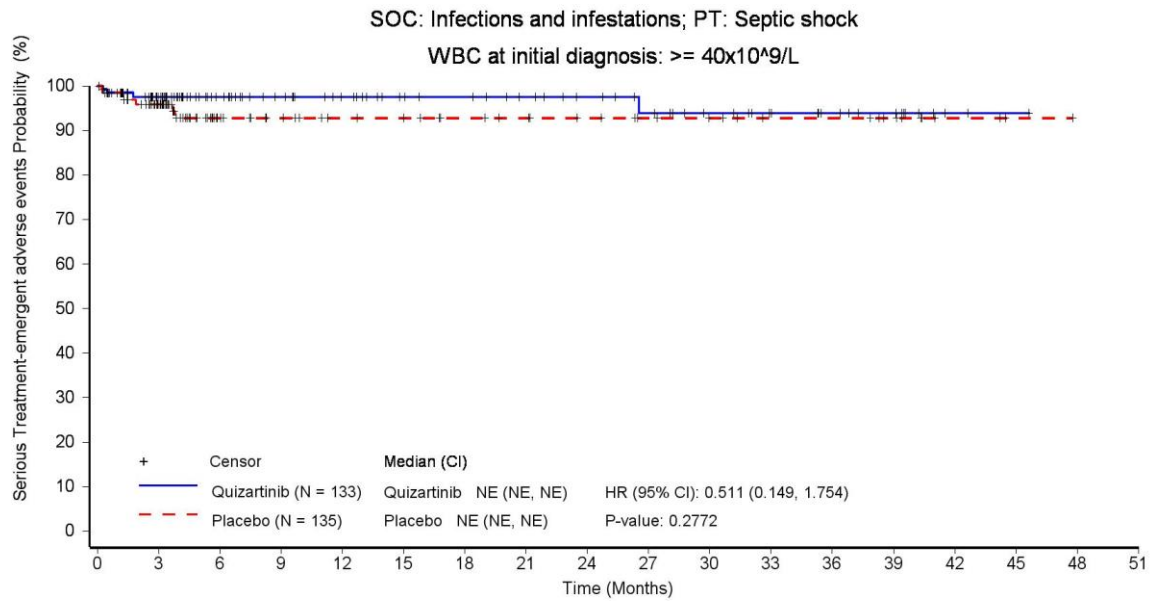
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\ Run date: 21JUL2023 – 22:29; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_12_2_TEAESERSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.2 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	89	65	55	48	40	38	34	30	26	21	17	13	10	3	1	0	0
Placebo (N = 135)	135	76	41	34	29	27	24	22	19	16	14	11	11	8	3	1	0	0

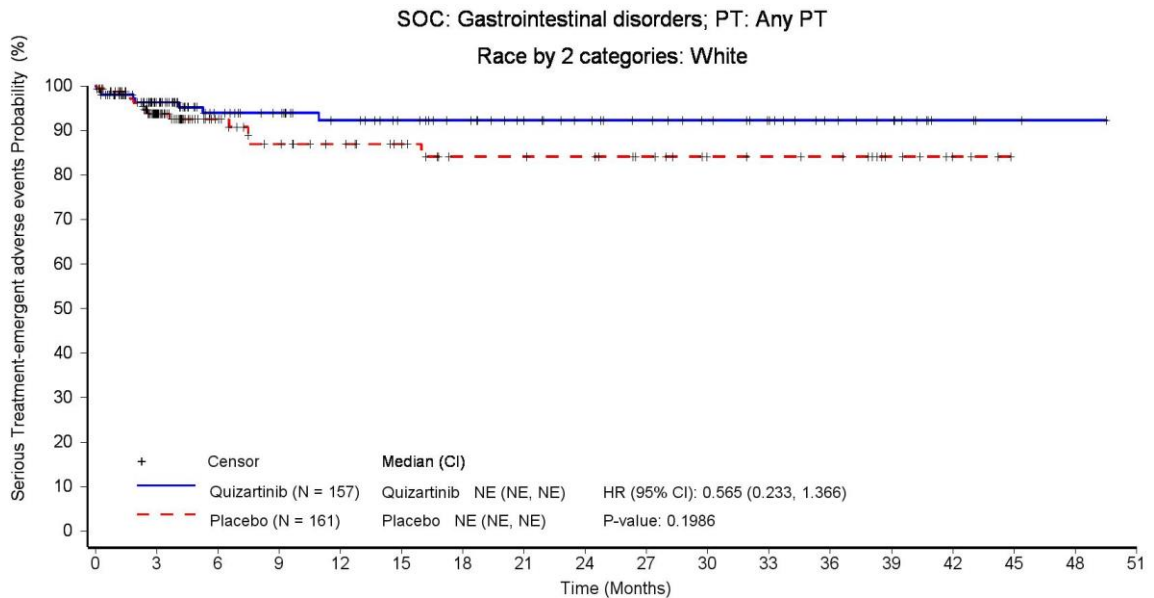
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.2 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 157)	157	99	69	62	54	48	43	36	32	28	24	20	14	11	4	2	1	0
Placebo (N = 161)	161	88	54	44	38	32	25	25	24	20	15	14	13	7	3	0	0	0

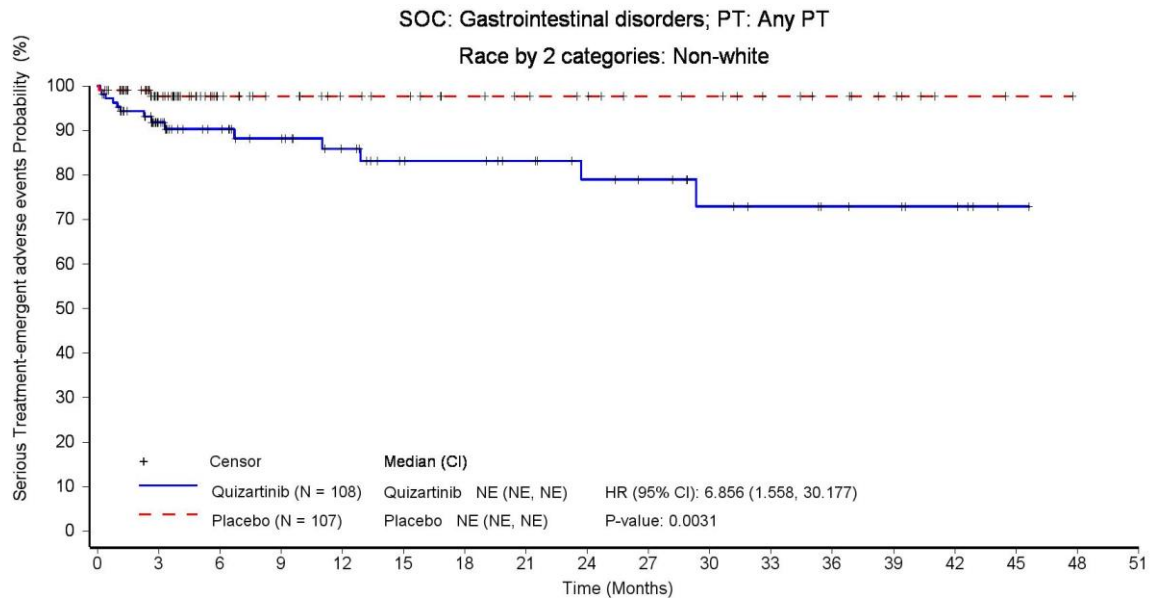
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:29; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_12_2_TEAESERSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.12.2 Serious Treatment-emergent adverse events by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	61	48	41	34	27	26	23	19	16	12	10	8	7	5	1	0	0
Placebo (N = 107)	107	62	40	34	29	27	23	21	19	16	15	12	10	7	2	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

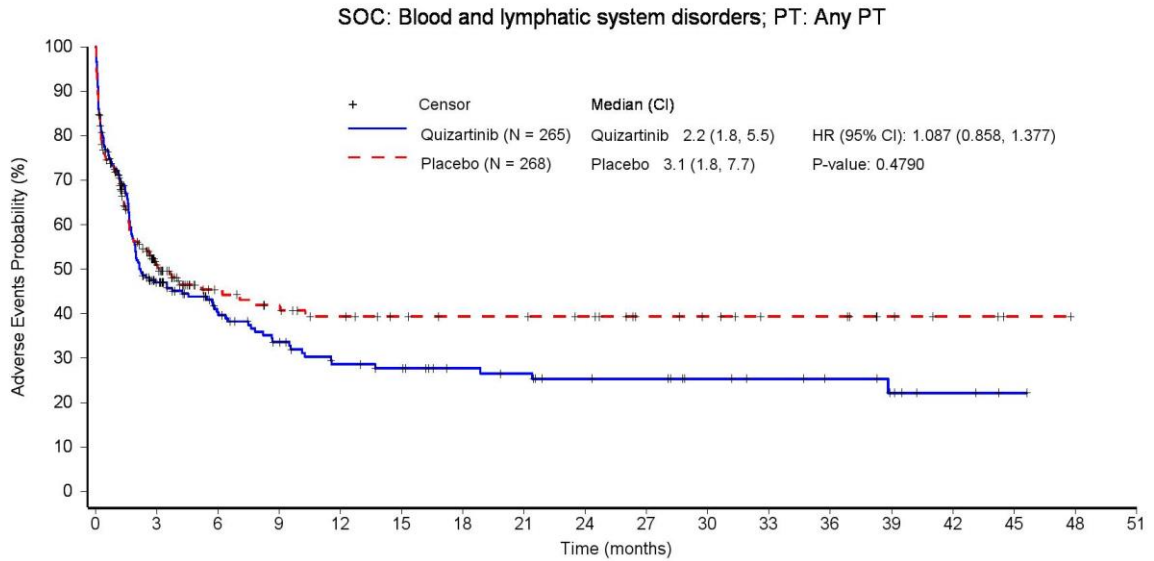
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
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Anhang 4-G5: Schwere UE nach SOC und PT (CTCAE-Grad ≥ 3)

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	83	57	43	33	30	24	22	18	17	13	11	9	6	3	1	0	0
Placebo (N = 268)	268	75	40	34	28	24	22	22	20	14	12	9	9	5	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

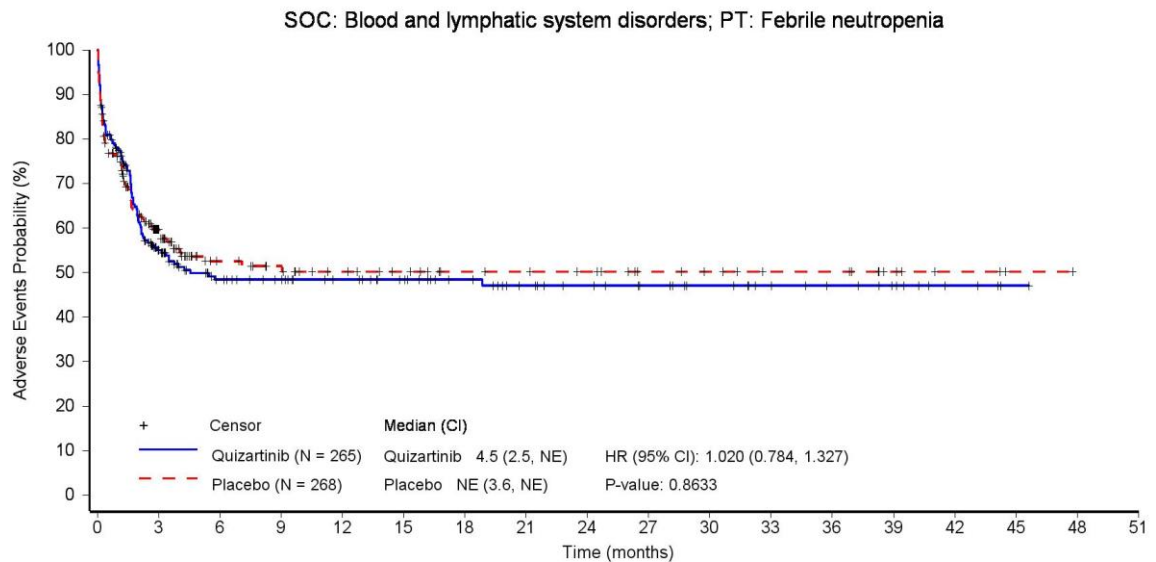
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESEVSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	94	65	58	51	45	38	31	27	23	19	15	12	9	4	1	0	0
Placebo (N = 268)	268	86	47	41	34	30	25	24	22	16	14	11	11	6	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

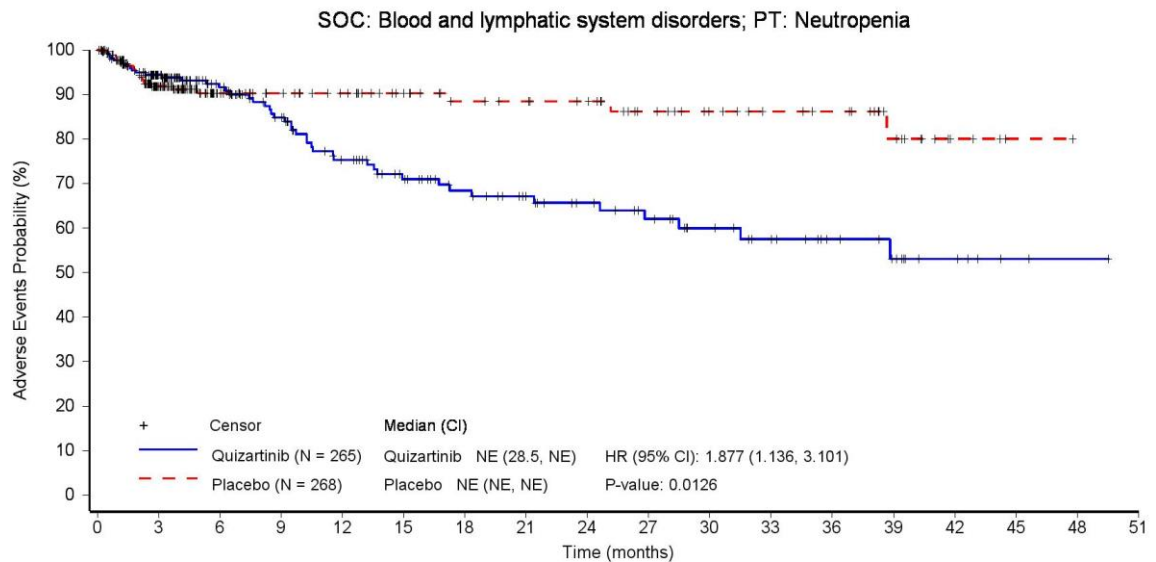
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	117	96	76	63	53	45	39	33	26	21	15	11	6	2	1	0
Placebo (N = 268)	268	146	89	76	67	57	48	46	43	33	27	23	21	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

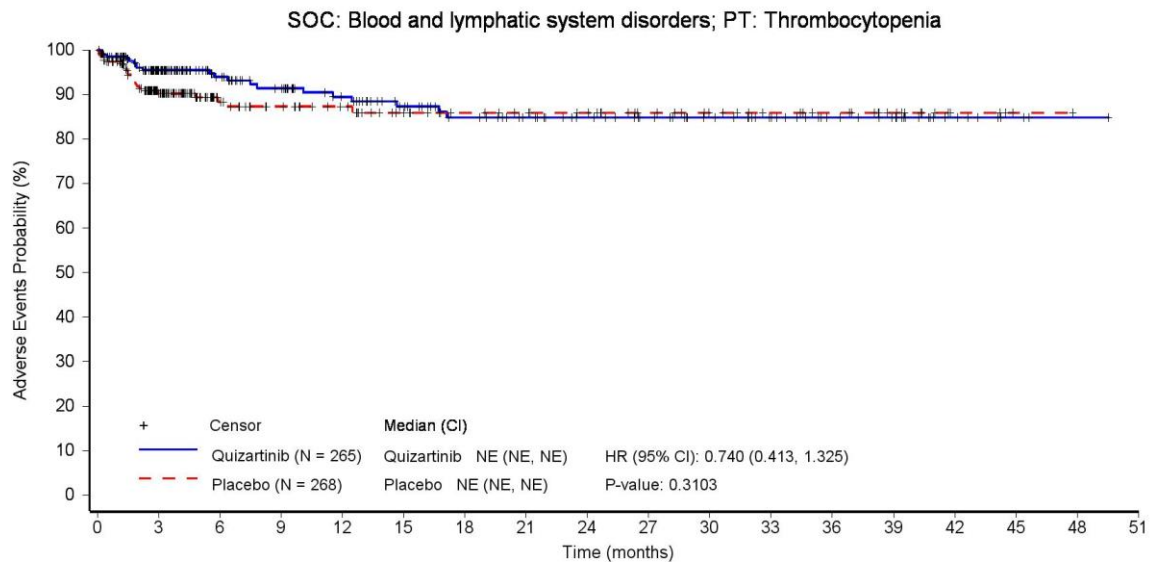
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	119	104	89	76	66	59	52	45	38	31	23	19	9	3	1	0
Placebo (N = 268)	268	142	86	73	63	52	45	42	39	31	26	22	19	13	4	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

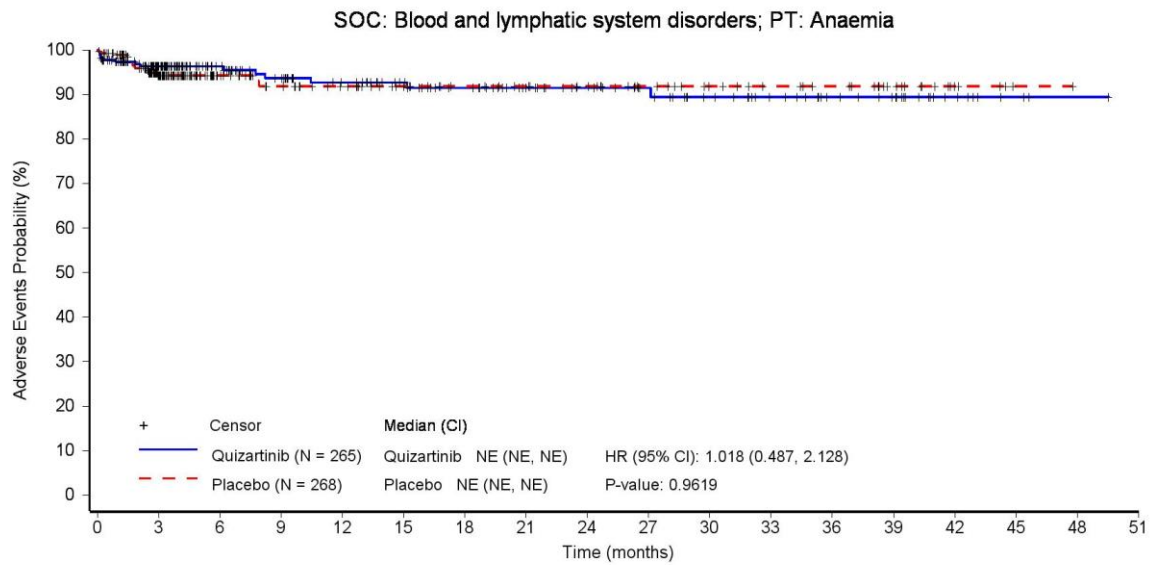
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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	118	102	90	79	70	59	52	45	37	30	23	19	9	3	1	0
Placebo (N = 268)	268	147	91	75	65	55	48	45	42	34	28	24	21	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

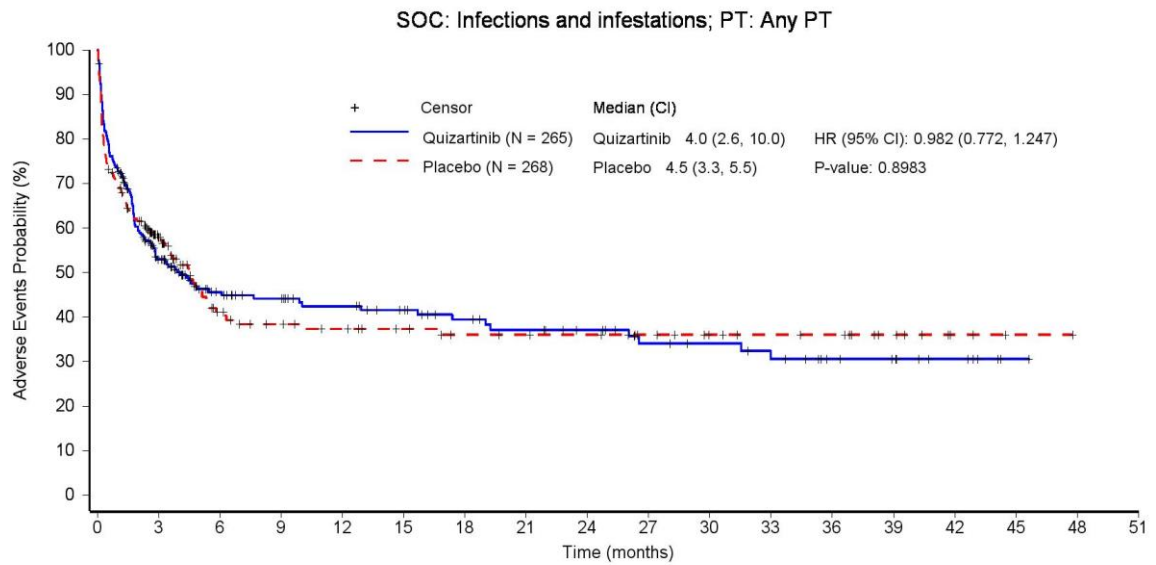
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Quizartinib (N = 265)	265	100	65	57	50	43	36	32	28	22	20	17	12	10	6	1	0	0
Placebo (N = 268)	268	91	47	38	34	30	26	25	24	20	16	14	13	8	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

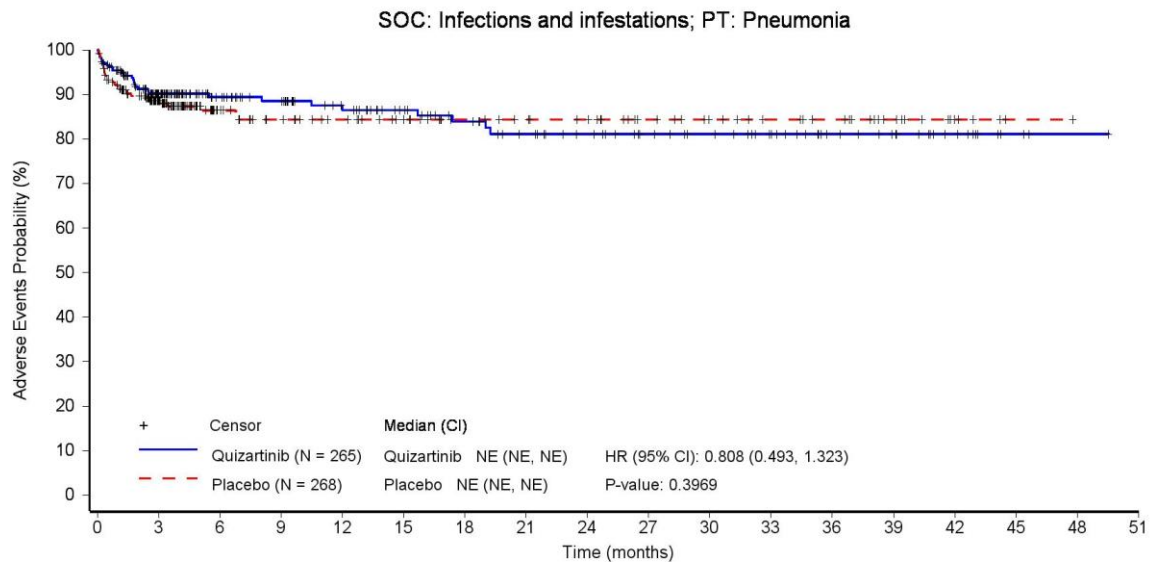
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	151	110	99	84	72	63	55	49	41	37	31	22	18	11	3	1	0
Placebo (N = 268)	268	143	86	72	63	55	46	43	40	31	26	22	19	12	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

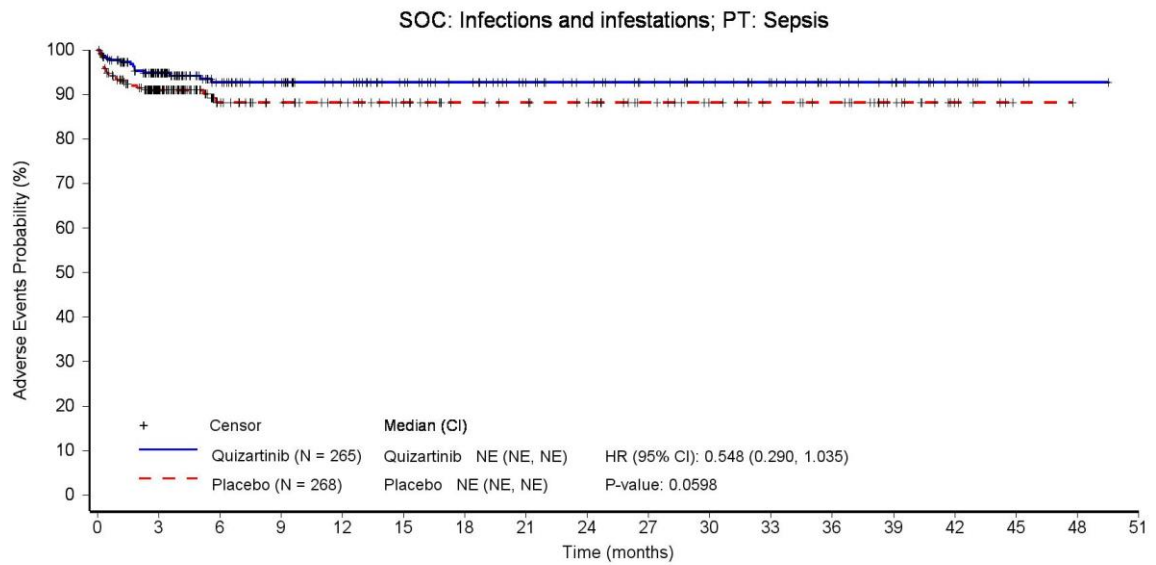
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	118	105	92	80	72	61	54	46	40	34	25	20	11	3	1	0
Placebo (N = 268)	268	146	91	78	70	62	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

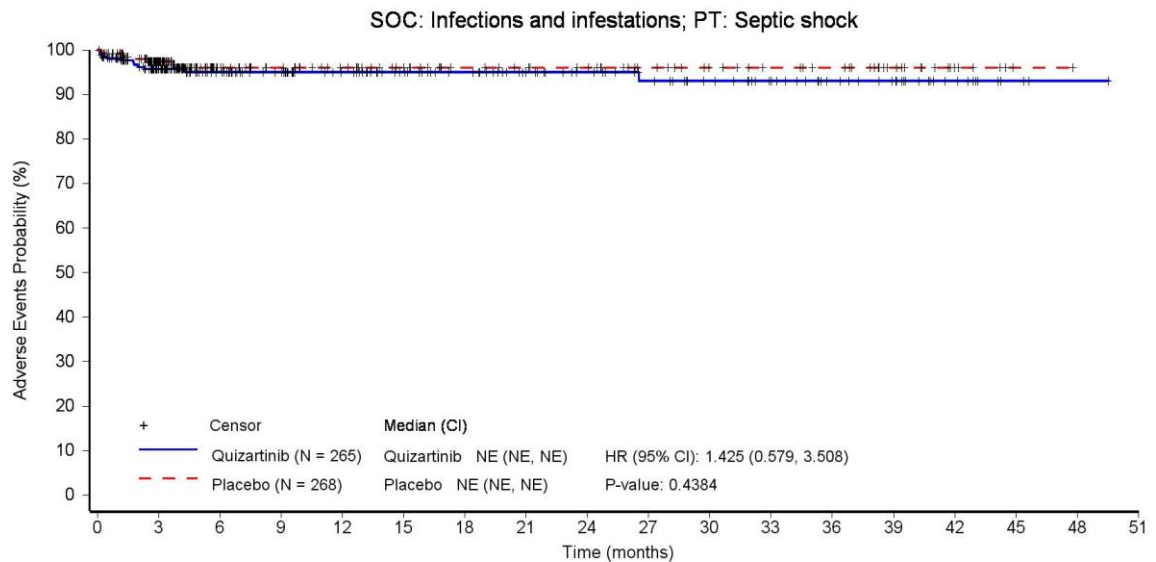
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESEVSOCPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	74	63	56	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	156	97	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

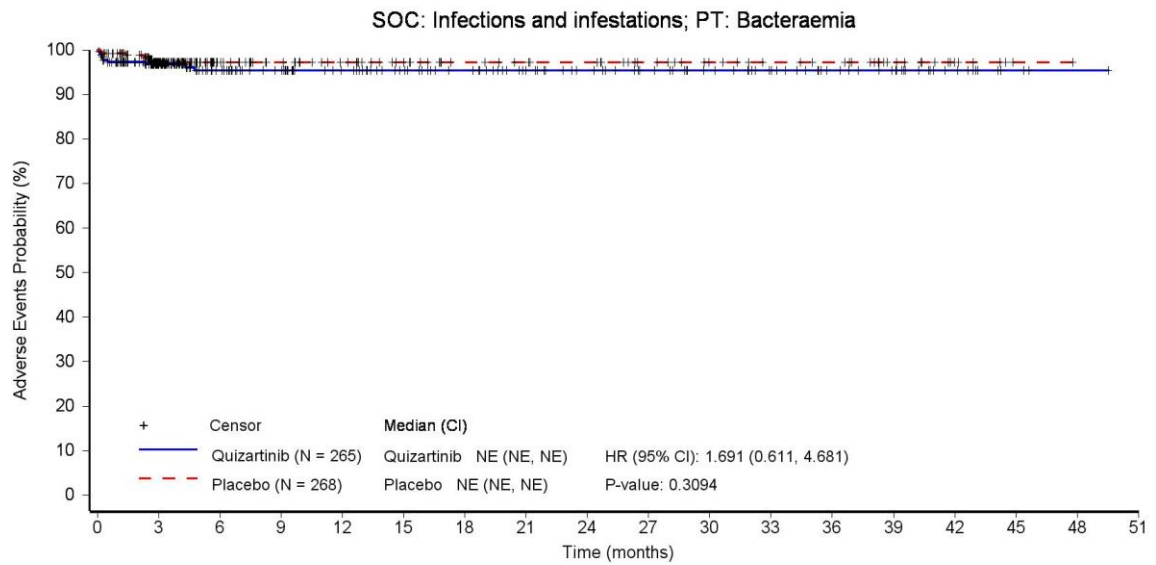
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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	122	108	95	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	152	93	79	68	58	48	45	43	35	29	25	23	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

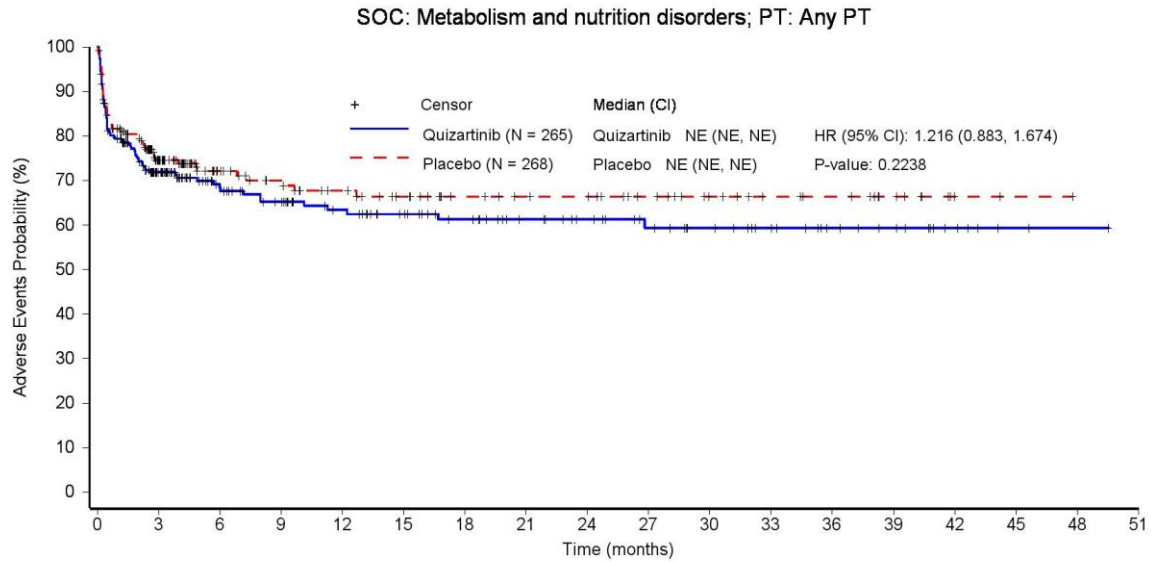
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	131	91	79	67	58	50	42	37	31	26	21	15	12	6	2	1	0
Placebo (N = 268)	268	115	73	62	52	45	36	33	32	26	20	16	14	9	2	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

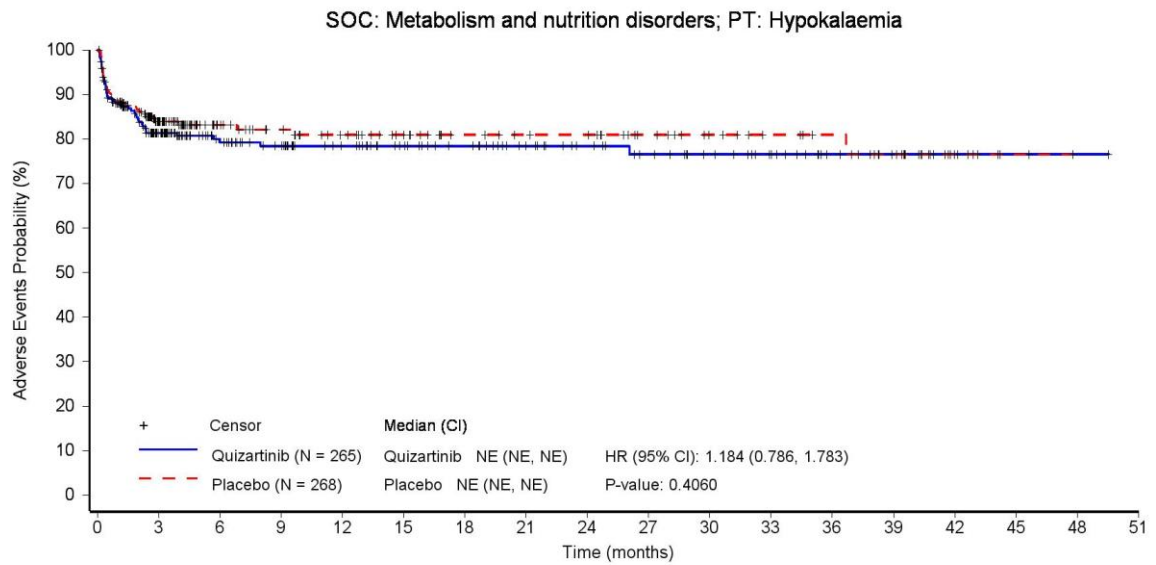
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	145	106	93	80	70	63	53	46	40	34	28	19	15	6	2	1	0
Placebo (N = 268)	268	131	85	73	62	53	43	40	39	31	25	21	18	12	3	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

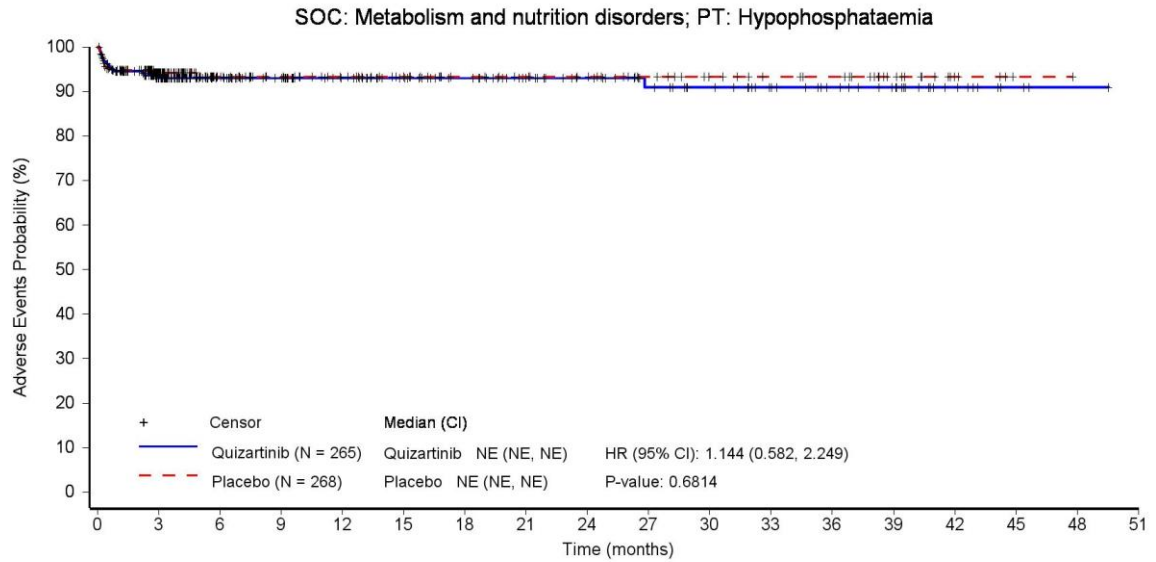
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	158	117	104	91	79	71	60	53	44	38	31	25	20	10	3	1	0
Placebo (N = 268)	268	146	91	77	67	58	49	46	43	35	29	25	23	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

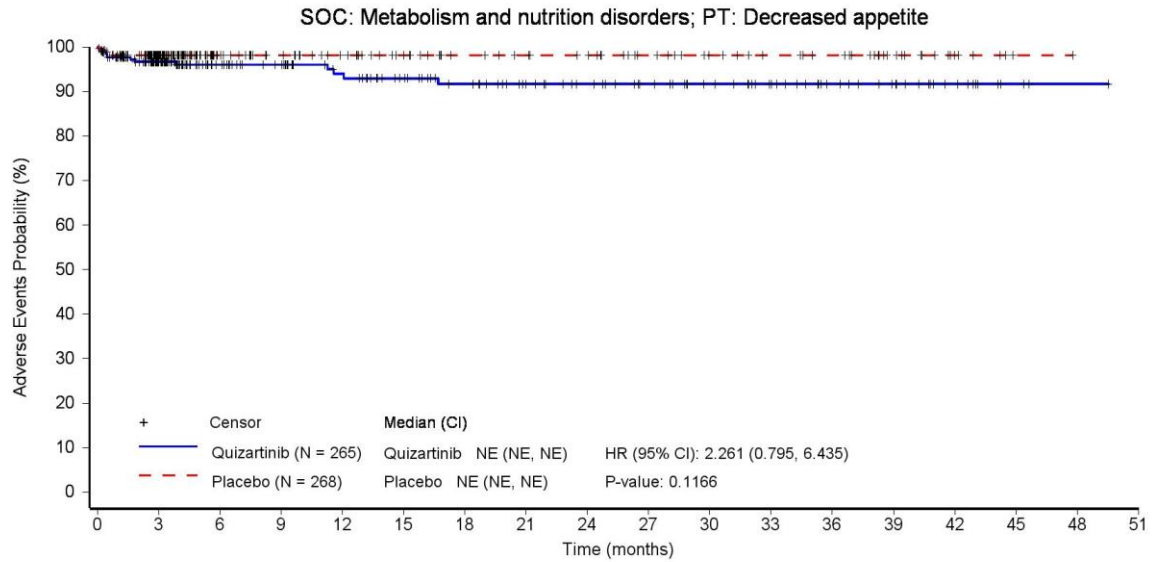
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	116	105	92	80	71	61	55	47	40	33	24	19	11	3	1	0
Placebo (N = 268)	268	156	97	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

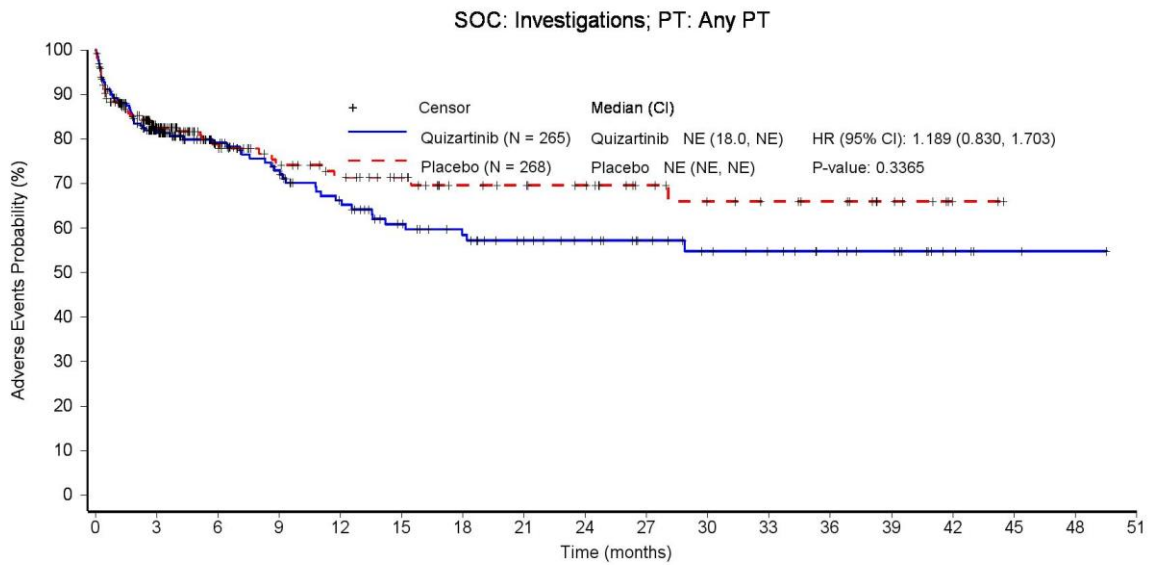
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	133	97	81	66	53	46	38	34	27	22	19	15	12	5	2	1	0
Placebo (N = 268)	268	126	76	60	51	43	34	32	29	21	17	15	13	8	2	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

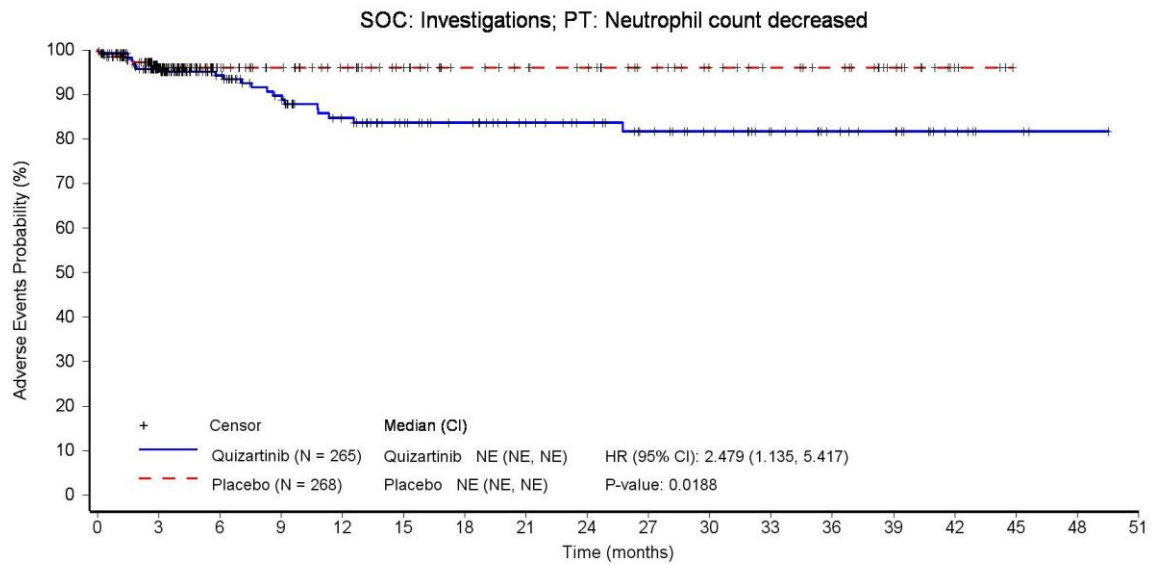
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	157	114	96	79	67	60	51	46	38	32	25	18	15	7	3	1	0
Placebo (N = 268)	268	150	92	79	68	58	48	45	42	34	28	24	21	13	4	0	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

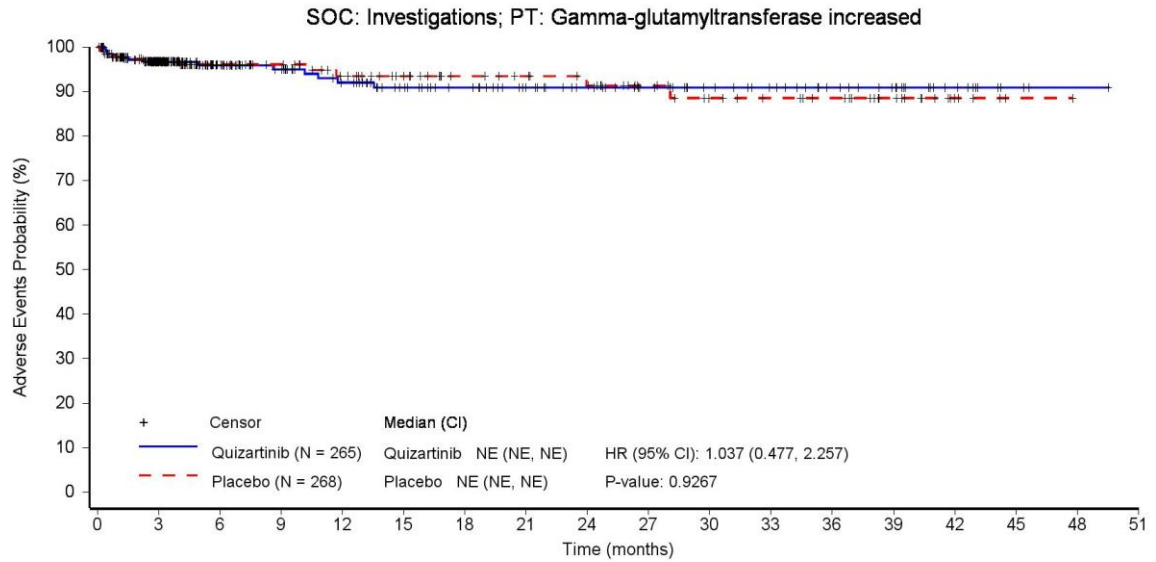
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	117	104	91	77	69	59	52	44	37	32	25	20	11	3	1	0
Placebo (N = 268)	268	151	94	81	69	60	50	47	43	34	28	25	22	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

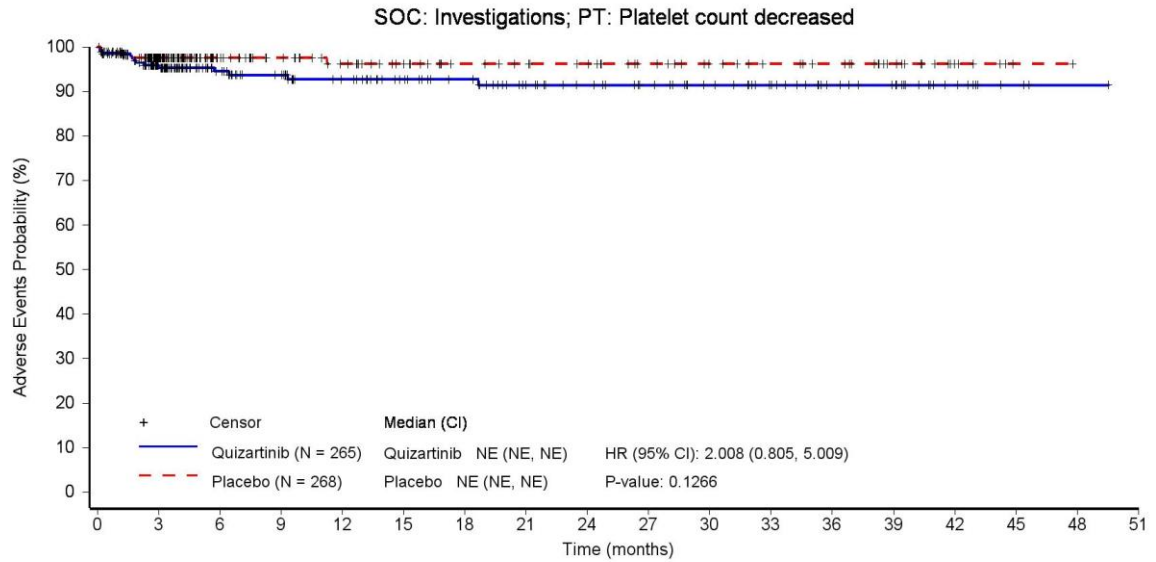
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	159	116	103	90	79	72	60	54	47	40	33	24	20	10	3	1	0
Placebo (N = 268)	268	152	94	80	69	59	50	47	44	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

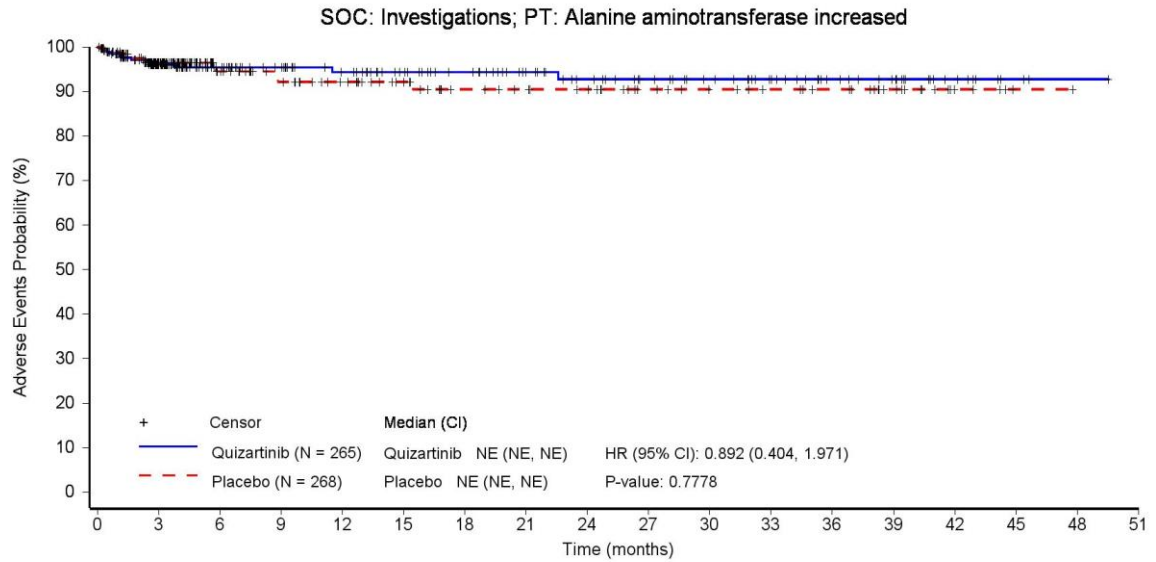
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	158	117	103	92	80	72	61	53	45	39	32	23	18	9	3	1	0
Placebo (N = 268)	268	152	93	78	67	57	47	44	41	32	28	25	22	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

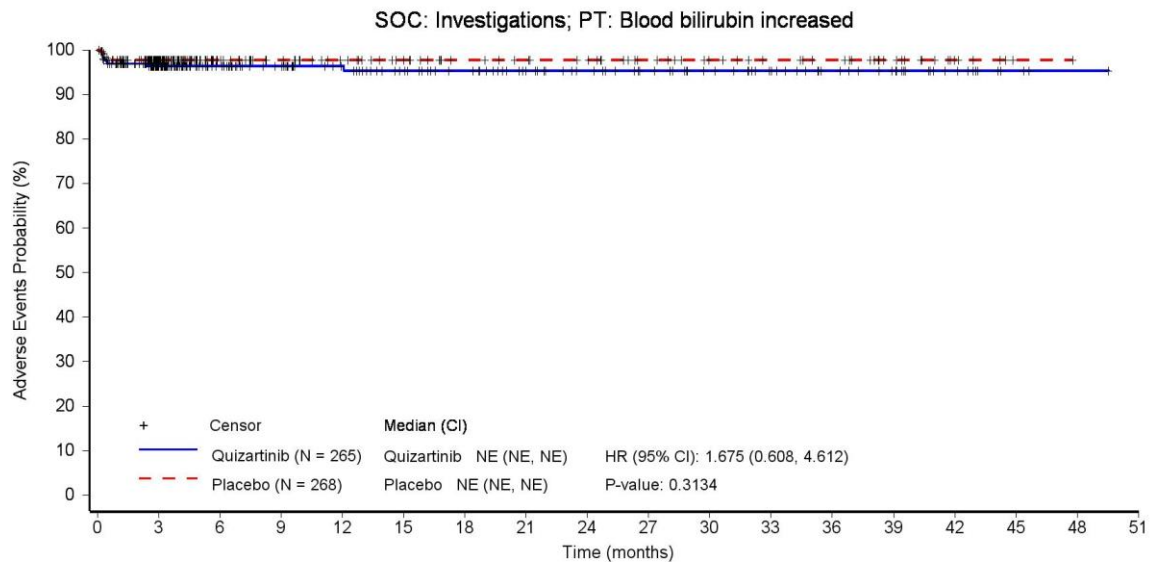
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	119	105	93	81	73	62	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	152	96	82	71	62	52	49	46	37	31	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

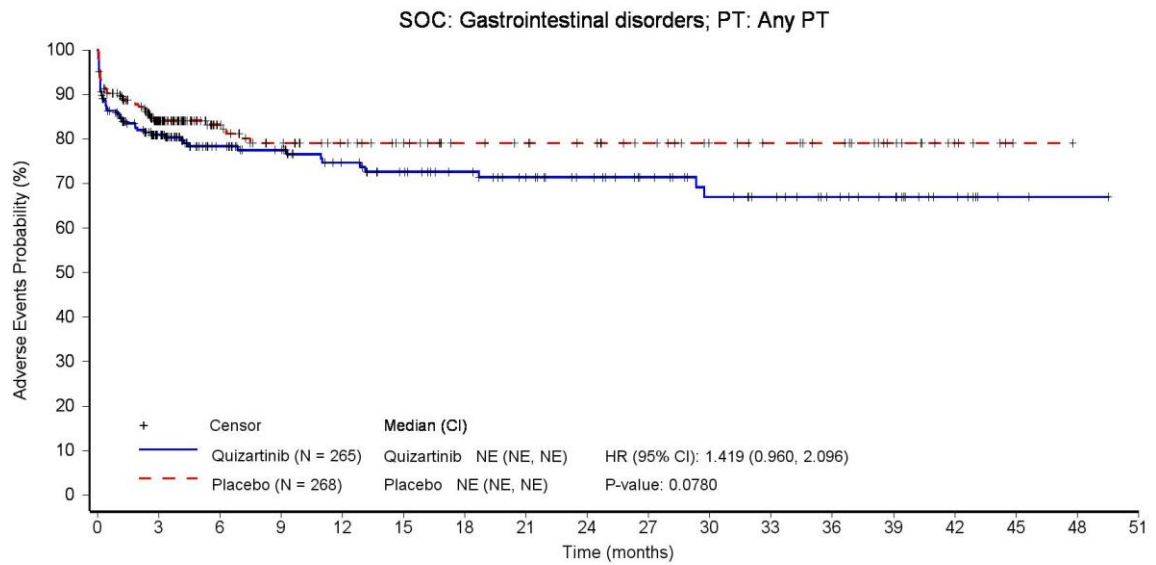
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	143	100	89	75	66	59	51	45	37	30	26	20	16	8	2	1	0
Placebo (N = 268)	268	136	85	69	59	52	43	41	38	33	27	24	21	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

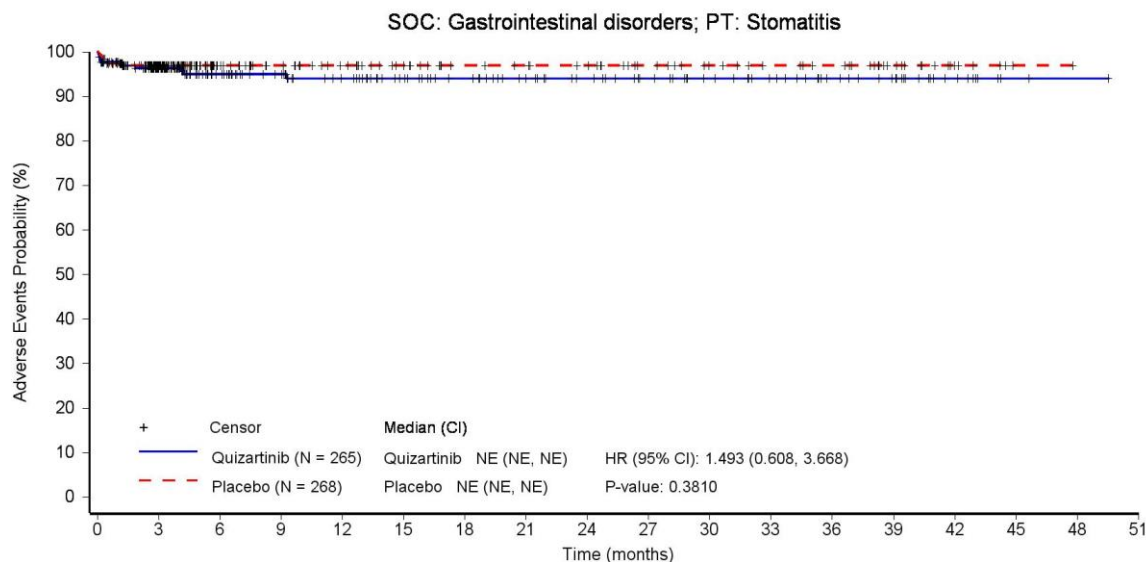
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	116	102	90	77	69	60	54	46	39	33	25	20	10	2	1	0
Placebo (N = 268)	268	155	97	83	72	62	52	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

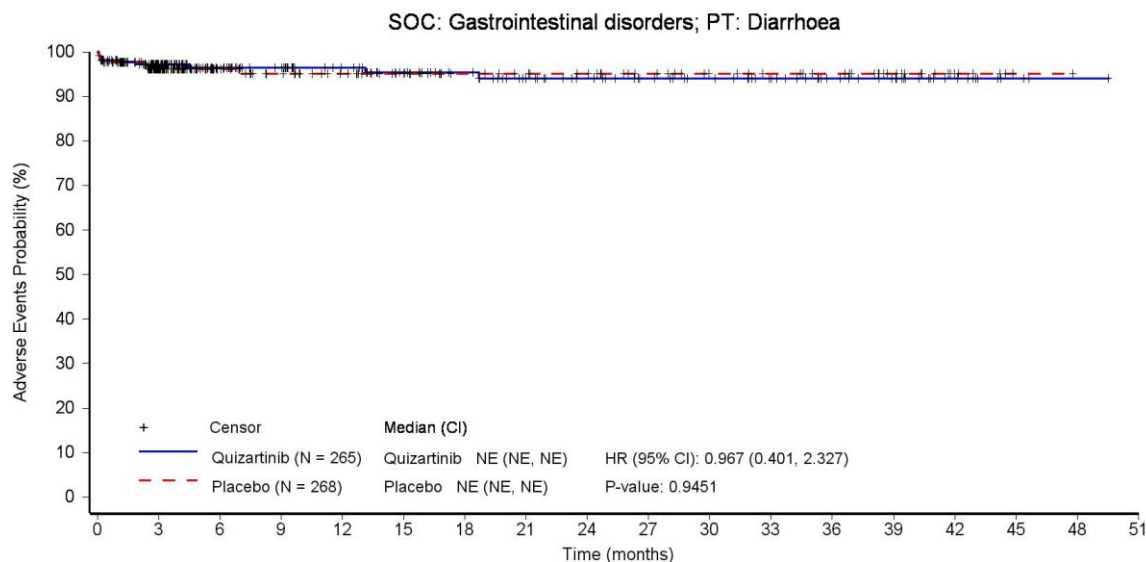
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	118	106	93	81	73	62	55	47	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	151	95	81	70	60	50	47	44	36	30	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

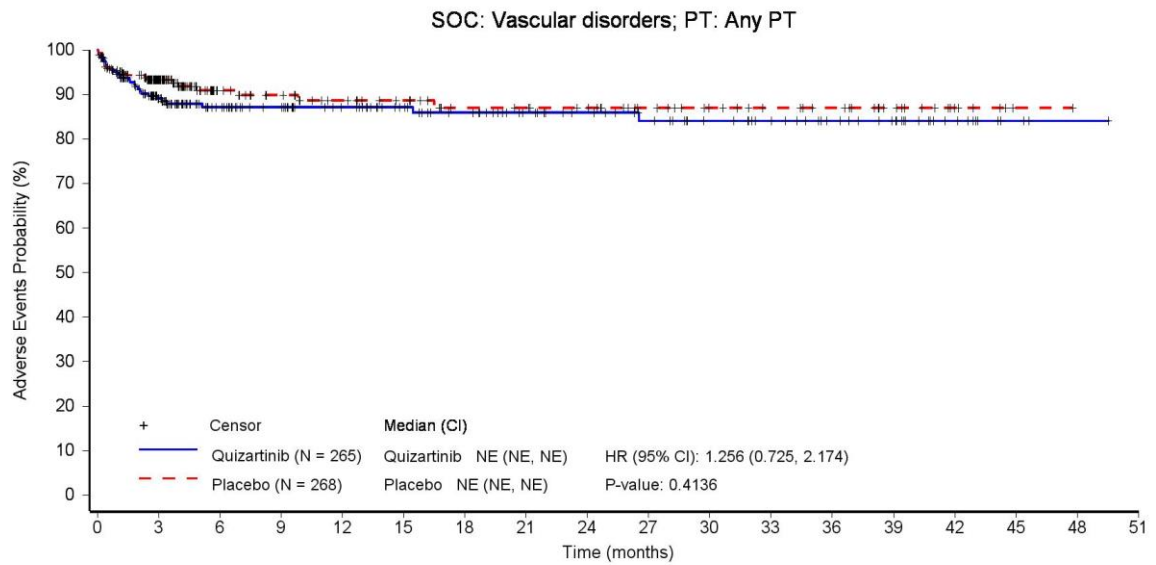
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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	152	111	98	86	74	66	56	50	44	37	32	25	20	10	3	1	0
Placebo (N = 268)	268	147	88	76	65	59	48	47	44	35	29	25	22	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

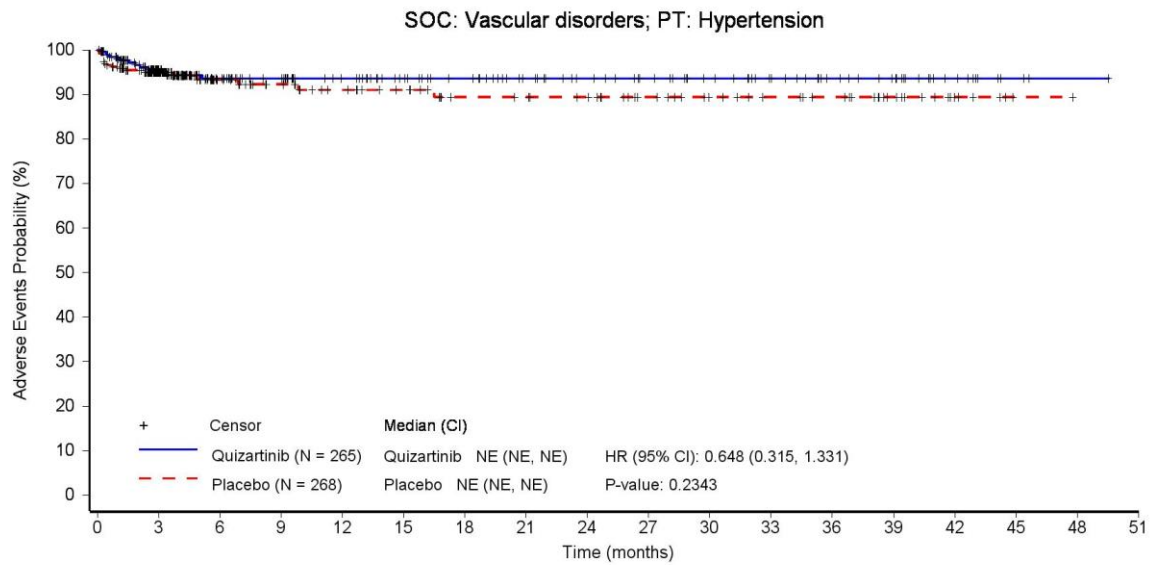
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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	117	104	91	79	72	62	55	48	41	34	26	21	11	3	1	0
Placebo (N = 268)	268	148	90	77	66	60	49	48	45	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

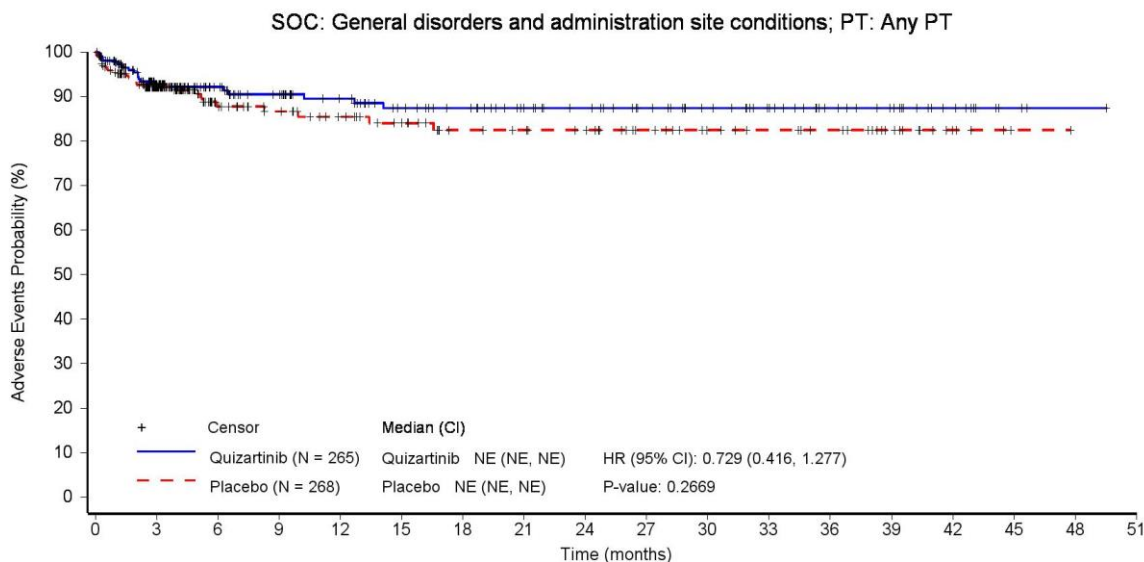
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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	156	116	101	88	75	69	59	54	46	39	32	23	18	10	3	1	0
Placebo (N = 268)	268	149	88	75	65	57	47	45	42	33	27	24	21	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

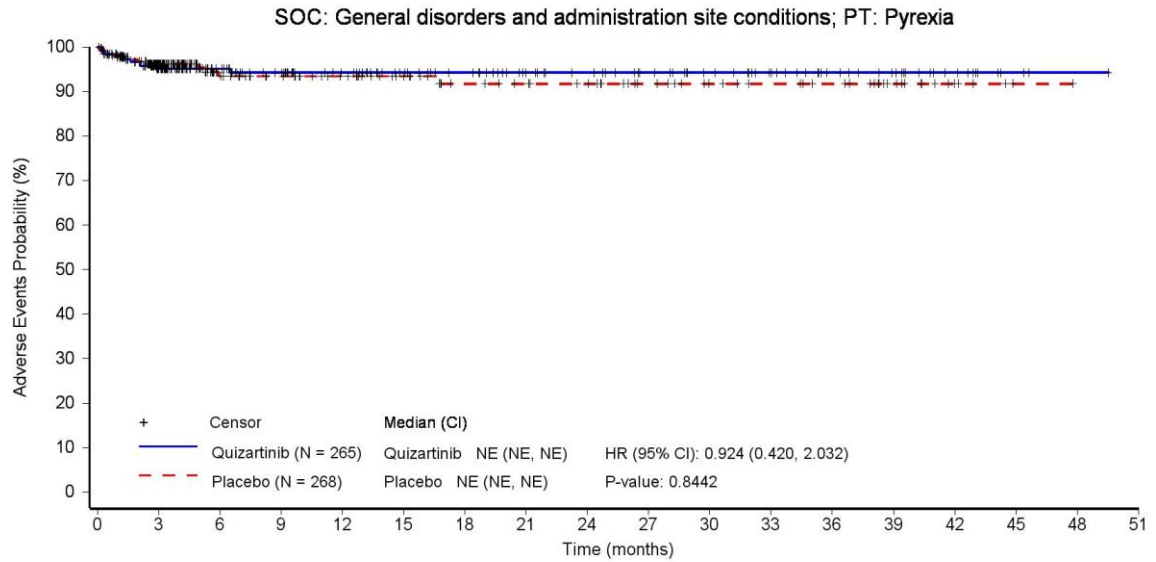
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	118	103	90	77	70	59	54	46	39	32	23	18	10	3	1	0
Placebo (N = 268)	268	152	92	80	70	60	49	46	43	34	28	25	22	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

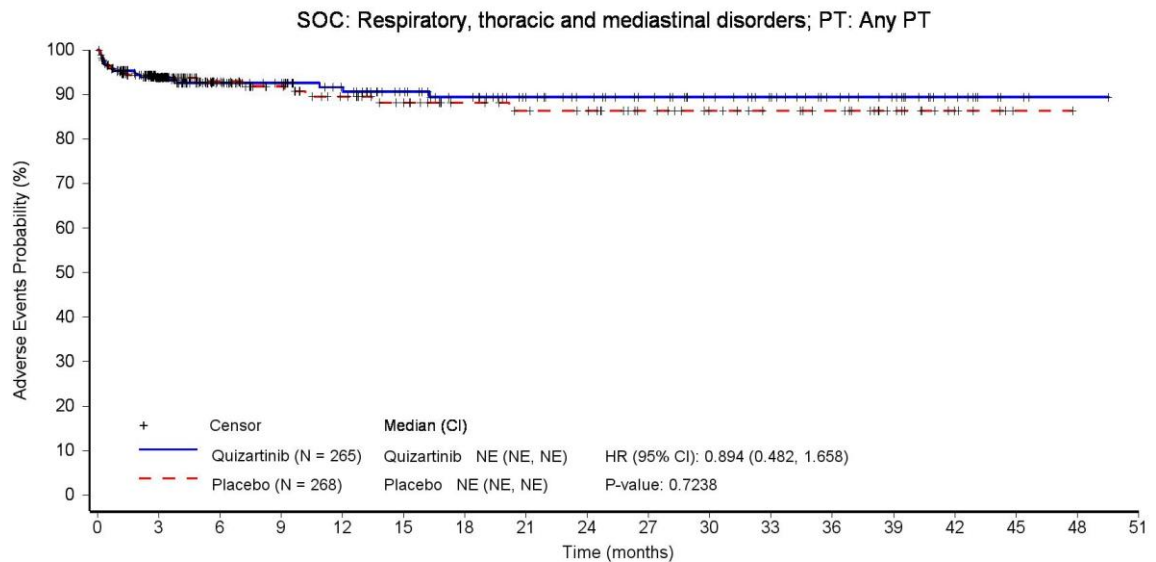
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	119	105	92	79	70	59	53	46	39	33	25	20	11	3	1	0
Placebo (N = 268)	268	149	97	82	70	60	51	47	45	36	30	26	23	15	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

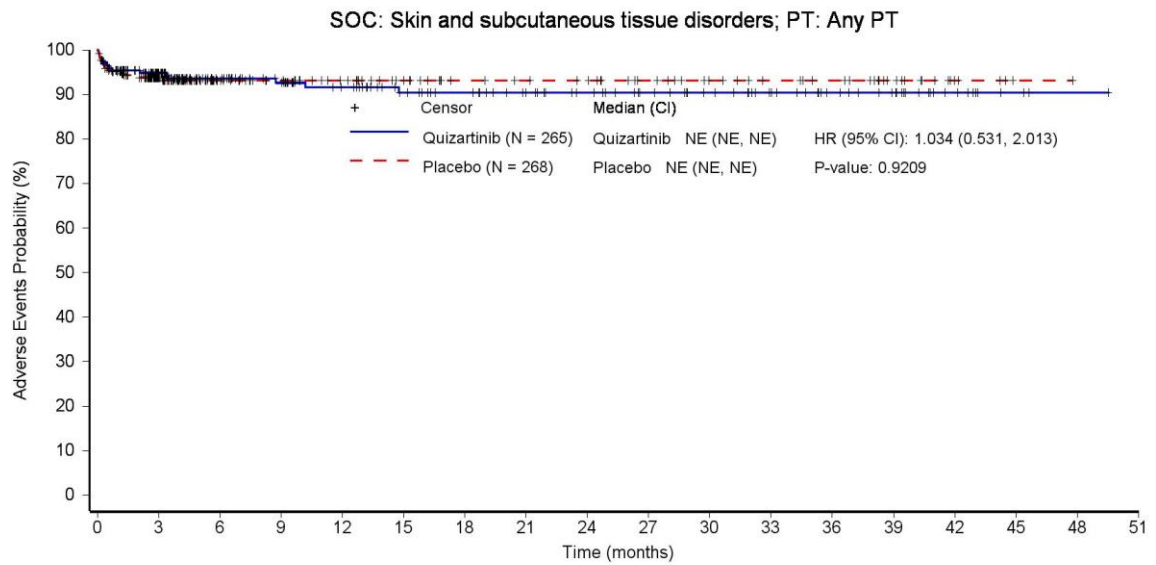
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Quizartinib (N = 265)	265	156	113	99	86	74	68	60	54	46	40	33	25	20	10	3	1	0
Placebo (N = 268)	268	144	91	78	68	58	48	46	44	36	30	26	23	15	5	1	0	0

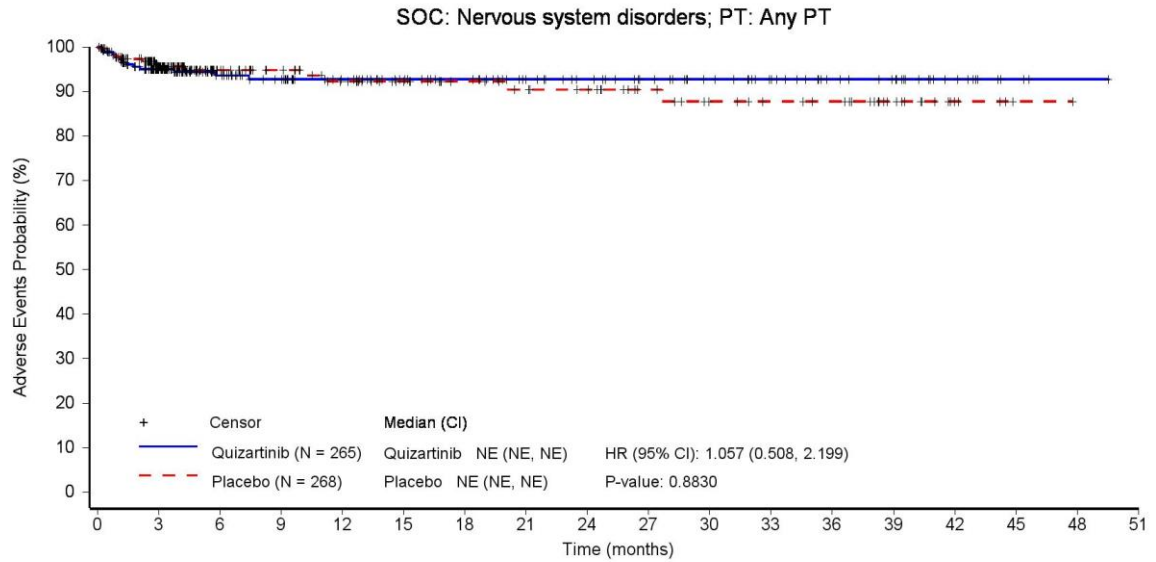
Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESEVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
 Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

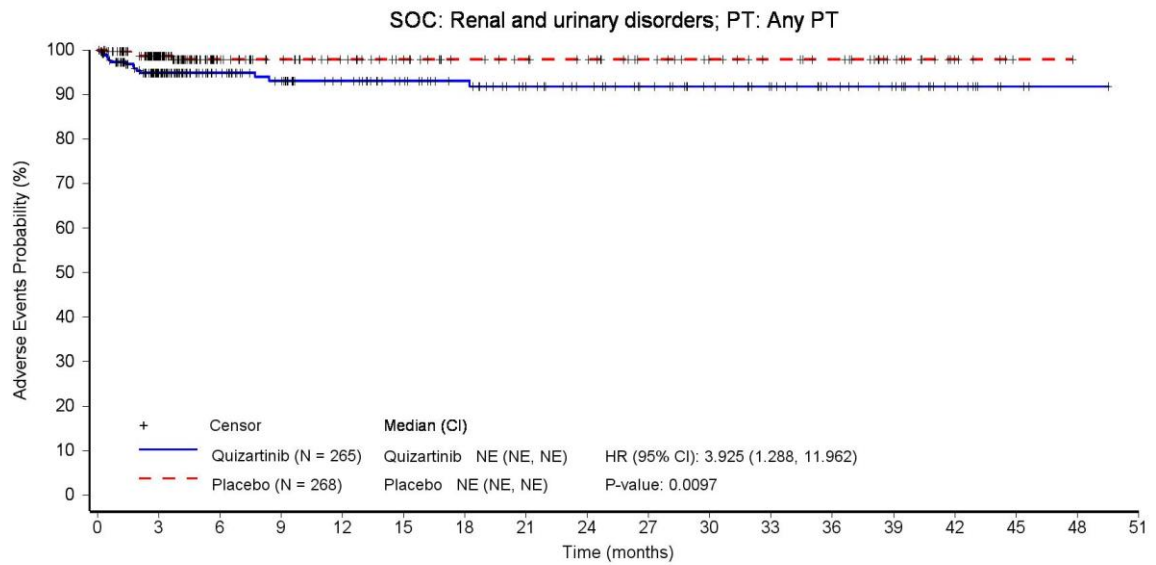
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	118	104	91	79	73	62	56	48	41	34	25	21	11	3	1	0
Placebo (N = 268)	268	151	95	81	70	60	51	47	44	35	29	26	24	15	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.
 CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
 Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	160	118	104	91	79	71	60	54	46	39	33	25	20	11	3	1	0
Placebo (N = 268)	268	155	97	83	72	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

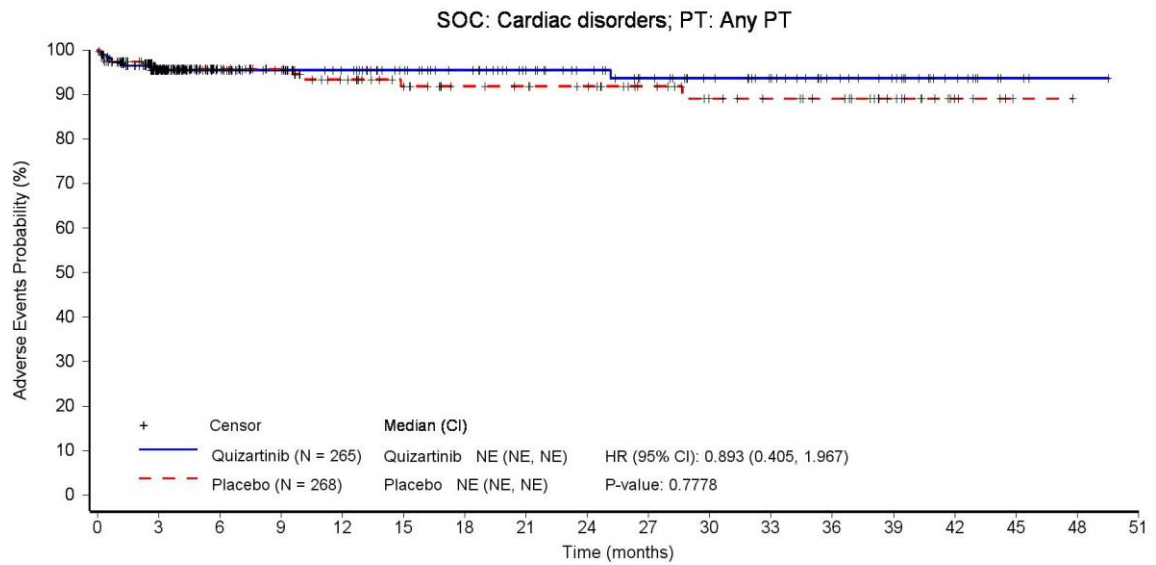
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	122	108	95	82	74	63	56	47	40	34	25	20	11	3	1	0
Placebo (N = 268)	268	154	96	83	70	60	51	49	46	37	30	27	24	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

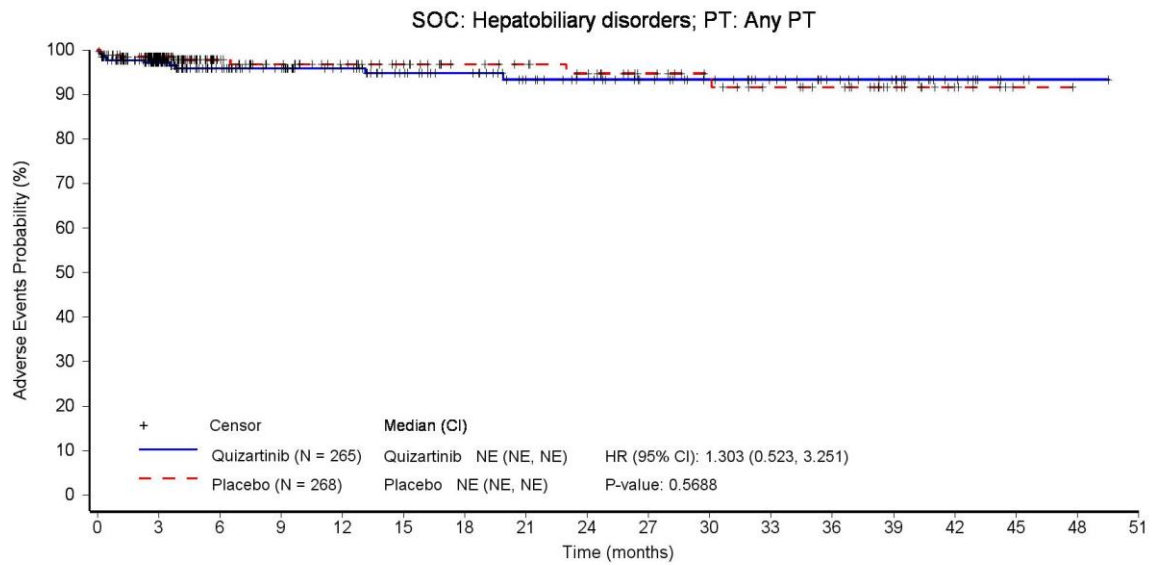
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESEVSOCPT_SAS.rtf

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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	120	106	93	79	72	60	54	46	40	33	26	21	11	3	1	0
Placebo (N = 268)	268	157	97	83	72	62	52	49	45	36	31	26	23	14	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

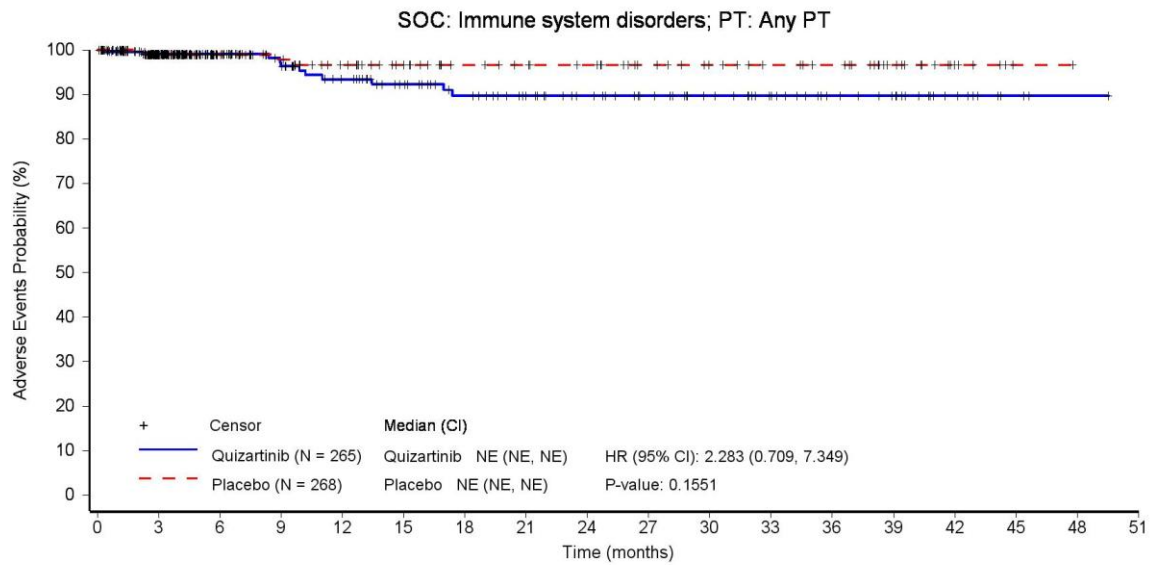
CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

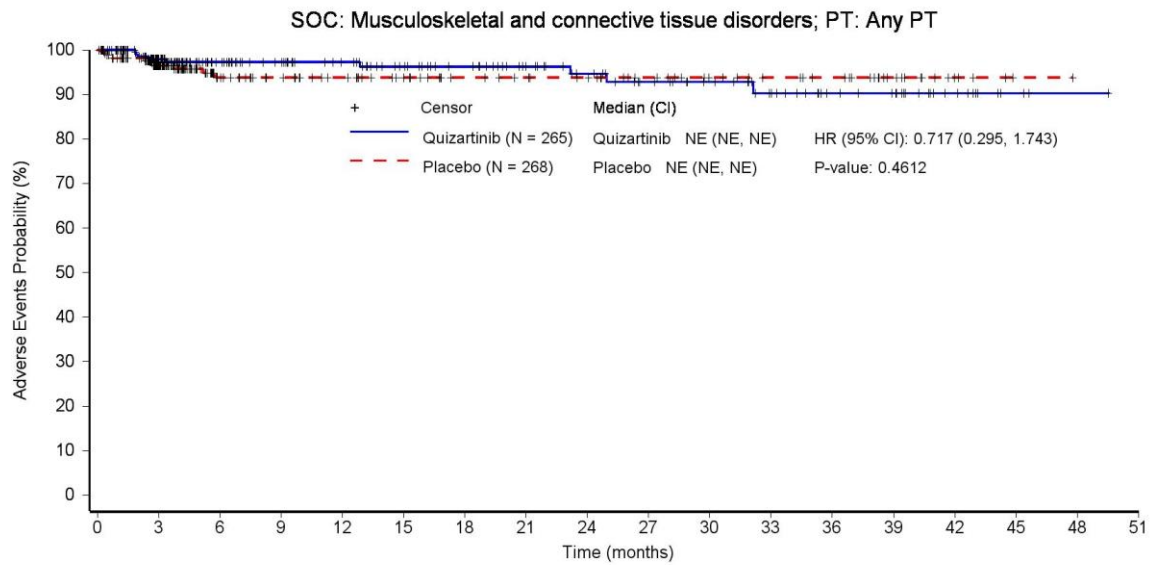
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	165	122	105	92	79	69	60	53	45	38	31	23	19	10	3	1	0
Placebo (N = 268)	268	155	98	83	71	61	51	48	45	37	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test. CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrect_eg\rstrect_20211102_eg\rstrect_valos\20230516_AMNOG\ADAM\
Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESVSOCPPT_SAS.rtf

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Figure 3.13.1 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	121	107	96	83	75	64	56	47	41	33	24	21	11	3	1	0
Placebo (N = 268)	268	152	91	79	69	60	50	47	44	36	30	26	23	14	5	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval, PT: Preferred Term, SOC: System Organ Class.

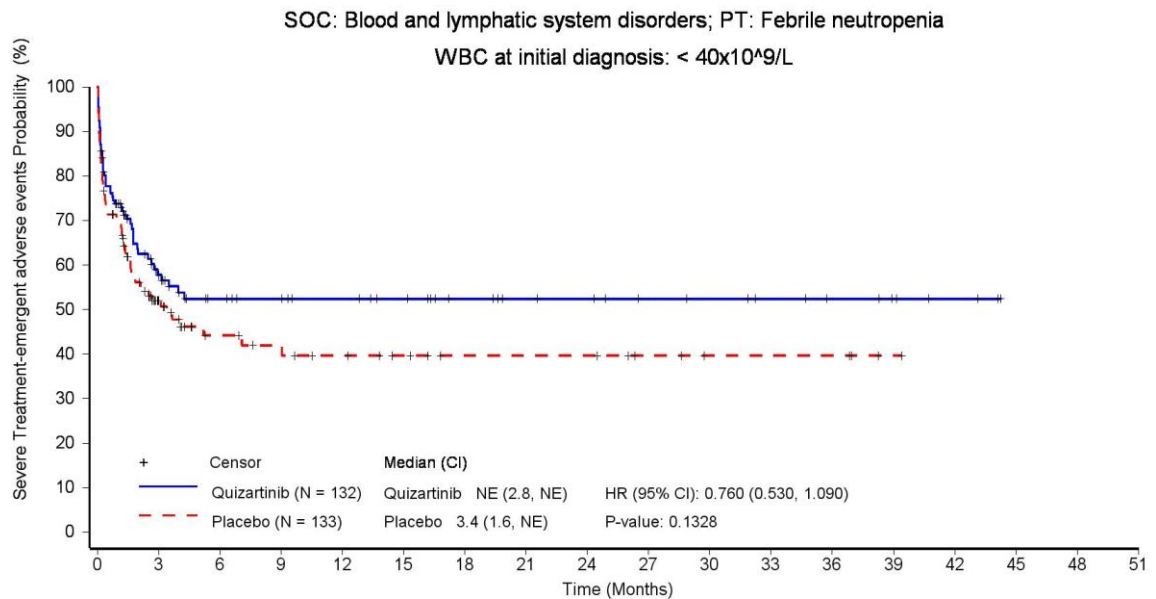
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Run date: 14JUL2023 – 16:41; Program name: DE_F_3_11_1.sas; Output name: DE_F_3_13_1_TEAESEVSOCPT_SAS.rtf

Anhang 4-G6: Schwere UE nach SOC und PT (CTCAE-Grad ≥ 3) – Subgruppenanalysen

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Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and ≥ 1% of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

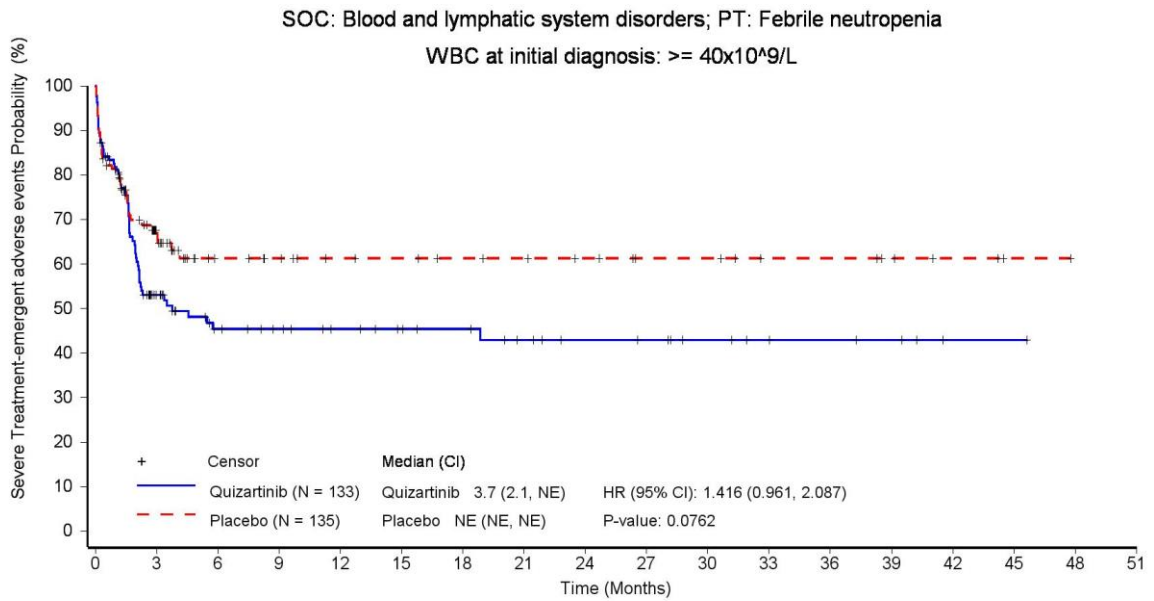
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	46	33	30	27	24	19	16	15	12	11	9	7	5	3	0	0	0
Placebo (N = 133)	133	38	21	18	15	12	9	9	9	6	4	4	4	1	0	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_valos\20230516_AMNOG\ADAM\ Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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 Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Quizartinib (N = 133)	133	48	32	28	24	21	19	15	12	11	8	6	5	4	1	1	0	0
Placebo (N = 135)	135	48	26	23	19	18	16	15	13	10	10	7	7	5	3	1	0	0

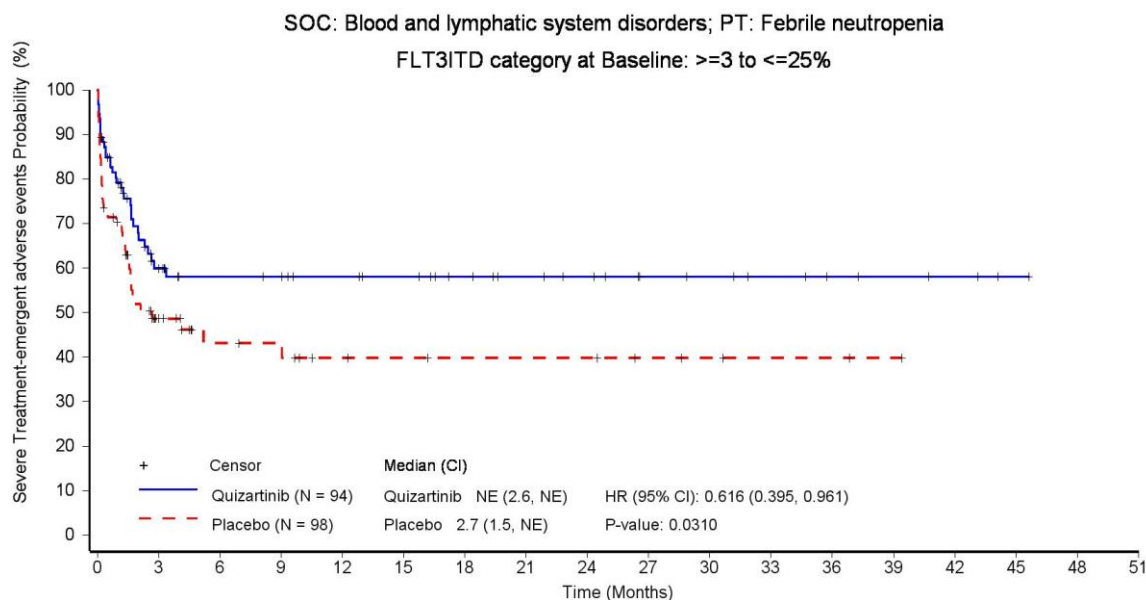
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 94)	94	35	29	28	25	23	19	16	14	10	9	7	5	4	3	1	0	0
Placebo (N = 98)	98	24	14	13	9	8	7	7	7	4	3	2	2	1	0	0	0	0

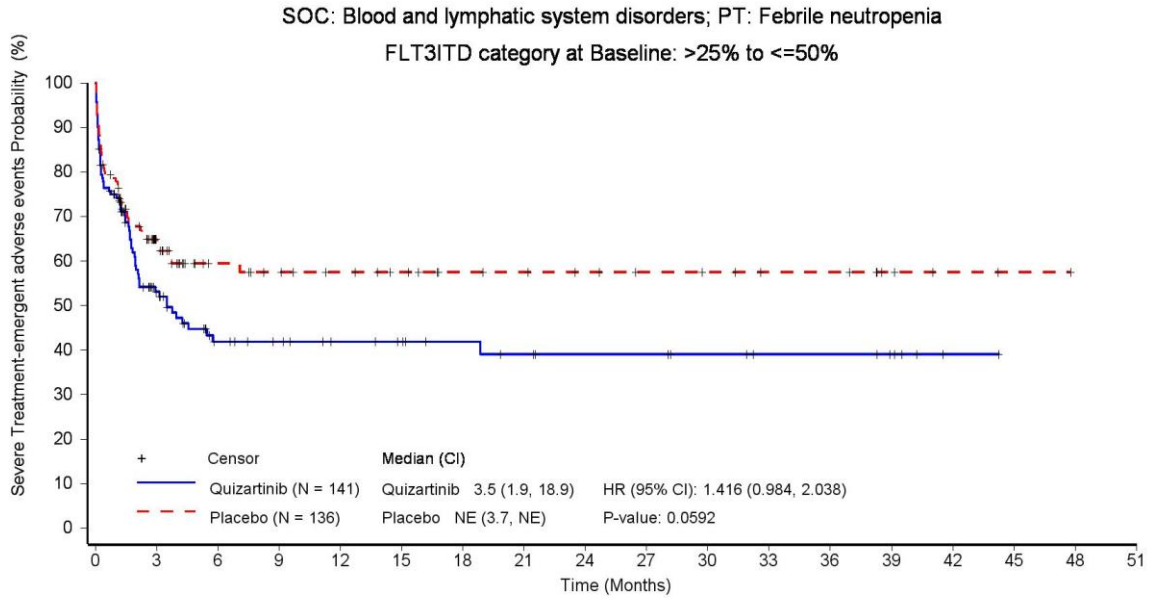
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\ Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

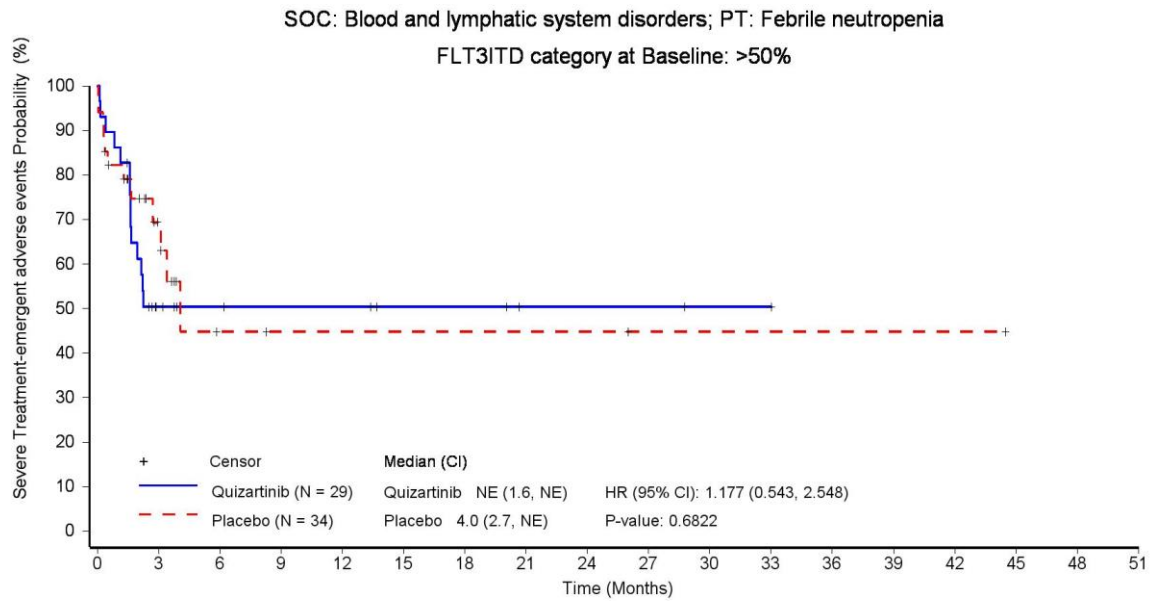
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48
Quizartinib (N = 141)	141	48	28	24	20	18	15	13	11	11	9	7	7	5	1	0	0
Placebo (N = 136)	136	51	30	26	23	20	16	15	13	11	10	8	8	4	2	1	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
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Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
 Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 29)	29	10	7	6	6	4	4	2	2	2	1	1	0	0	0	0	0	0
Placebo (N = 34)	34	11	3	2	2	2	2	2	2	1	1	1	1	1	1	0	0	0

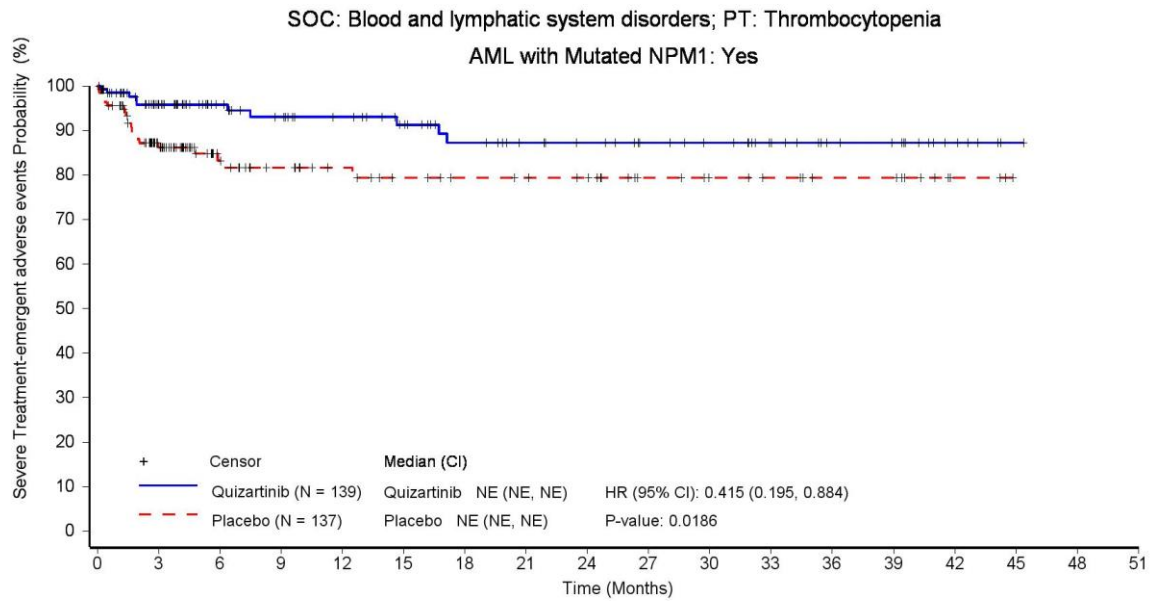
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

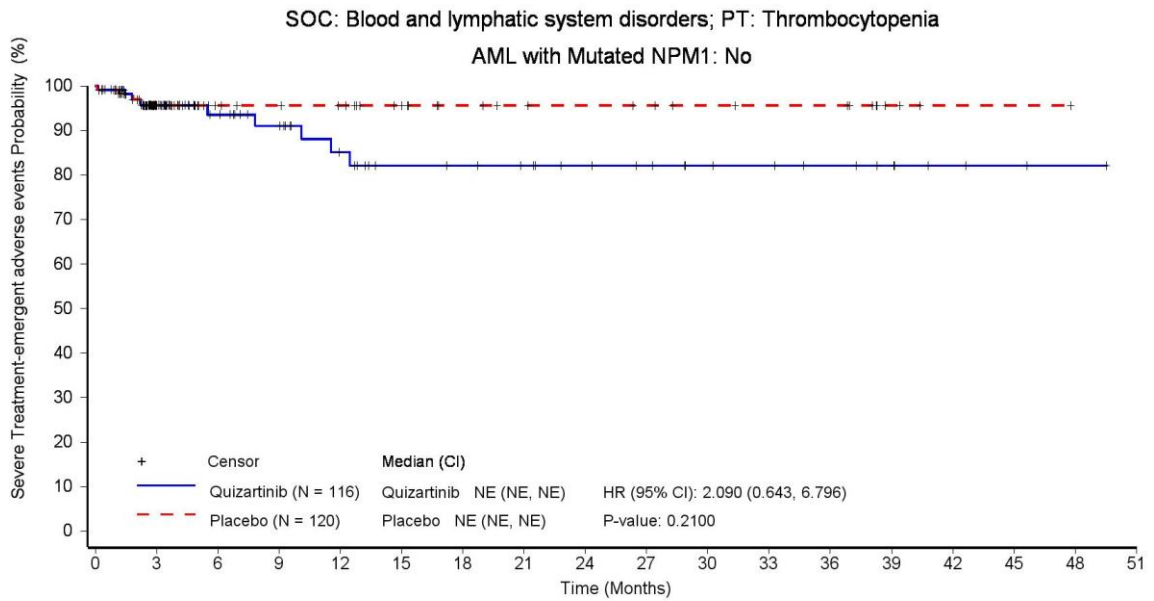
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 139)	139	94	72	64	58	51	43	38	35	30	27	21	15	13	6	1	0	0
Placebo (N = 137)	137	85	53	44	36	31	28	27	25	18	15	13	10	10	3	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\ Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 116)	116	59	43	36	28	22	21	19	16	14	11	10	8	6	3	2	1	0
Placebo (N = 120)	120	50	31	28	26	20	16	14	13	12	10	9	9	3	1	1	0	0

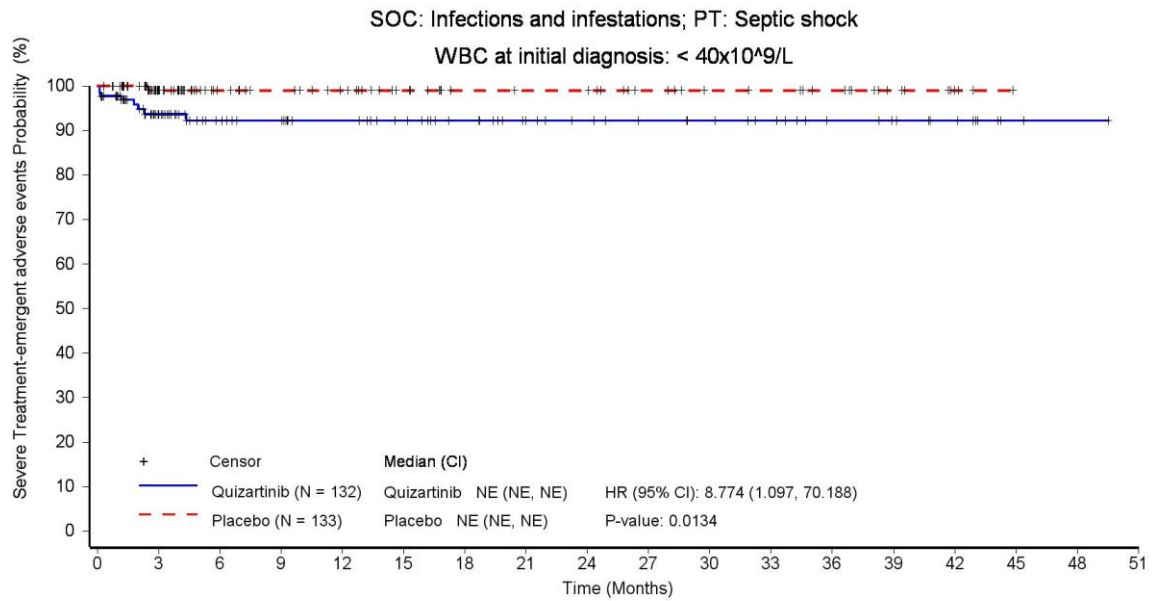
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	75	57	53	47	42	36	29	26	23	21	18	13	11	8	2	1	0
Placebo (N = 133)	133	80	56	50	44	36	29	28	28	22	18	17	14	8	3	0	0	0

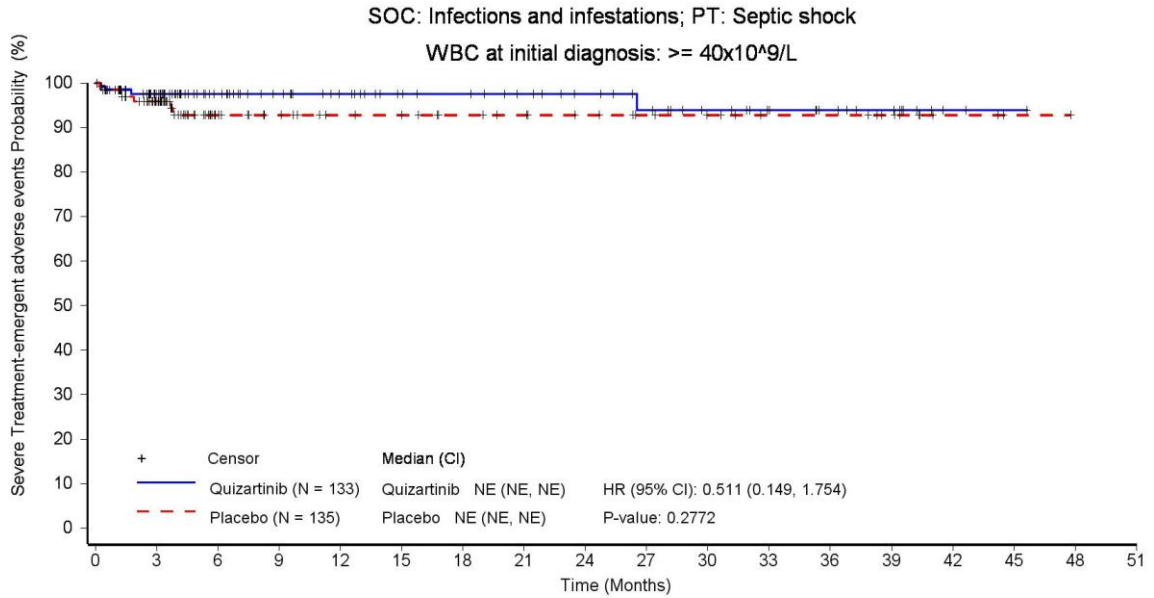
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Patients still at risk:

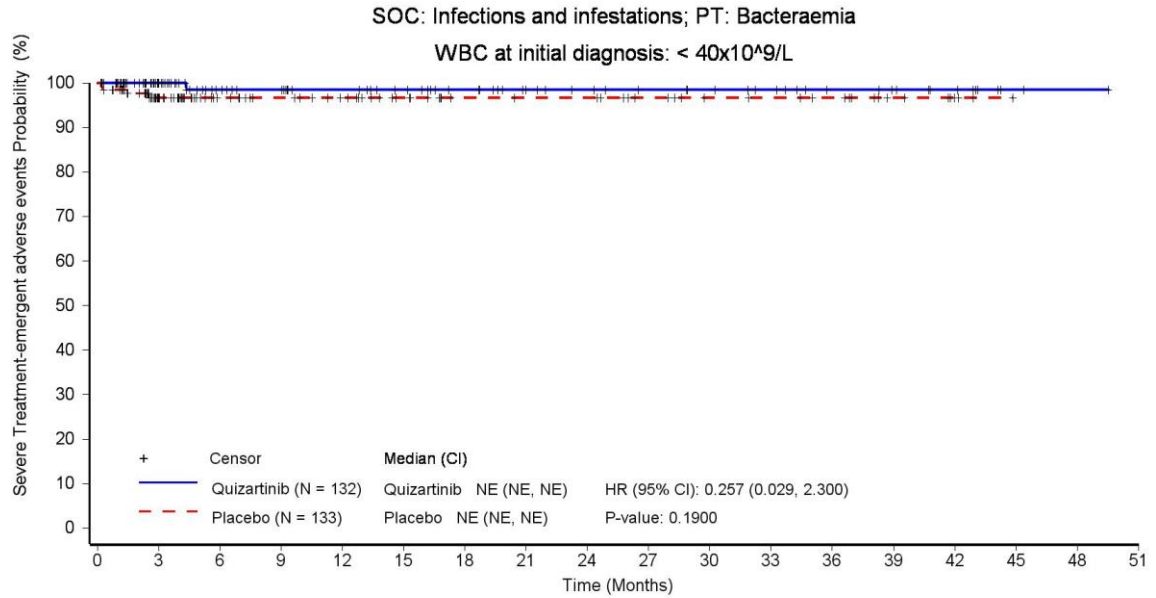
Quizartinib (N = 133)	133	89	65	55	48	40	38	34	30	26	21	17	13	10	3	1	0	0
Placebo (N = 135)	135	76	41	34	29	27	24	22	19	16	14	11	11	8	3	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 132)	132	77	58	54	48	43	37	30	27	23	21	18	13	11	8	2	1	0
Placebo (N = 133)	133	78	54	47	41	33	26	25	25	20	16	15	13	7	3	0	0	0

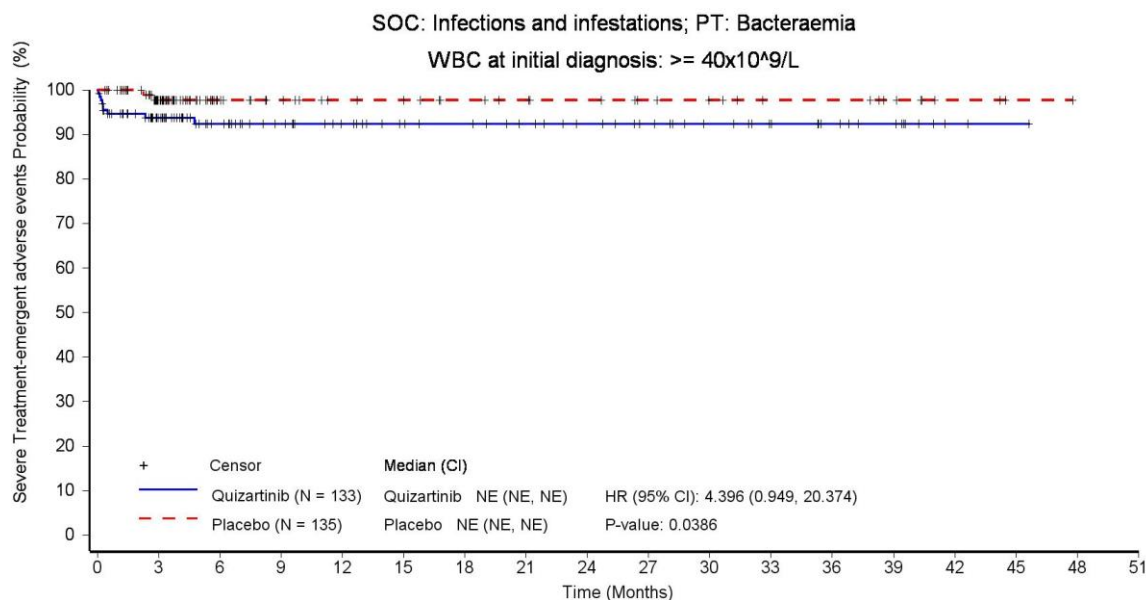
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Patients still at risk:

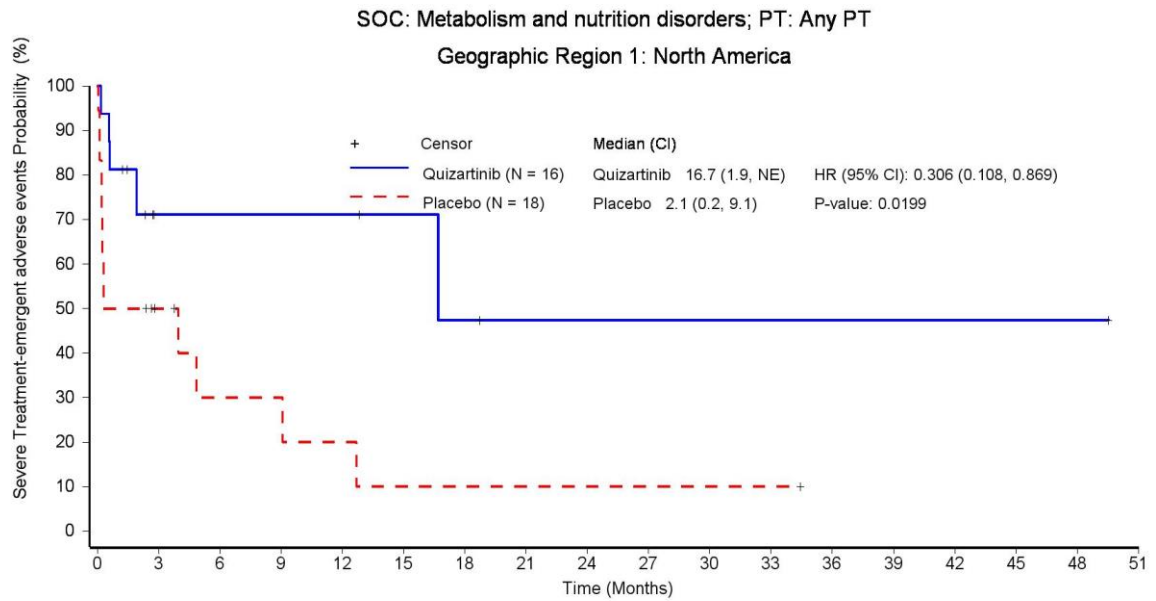
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 133)	133	86	64	54	47	40	38	34	30	26	21	17	13	10	3	1	0	0
Placebo (N = 135)	135	74	39	32	27	25	22	20	18	15	13	10	10	7	3	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	
Quizartinib (N = 16)	16	4	4	4	4	3	2	1	1	1	1	1	1	1	1	1	1	1	0
Placebo (N = 18)	18	6	3	3	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0

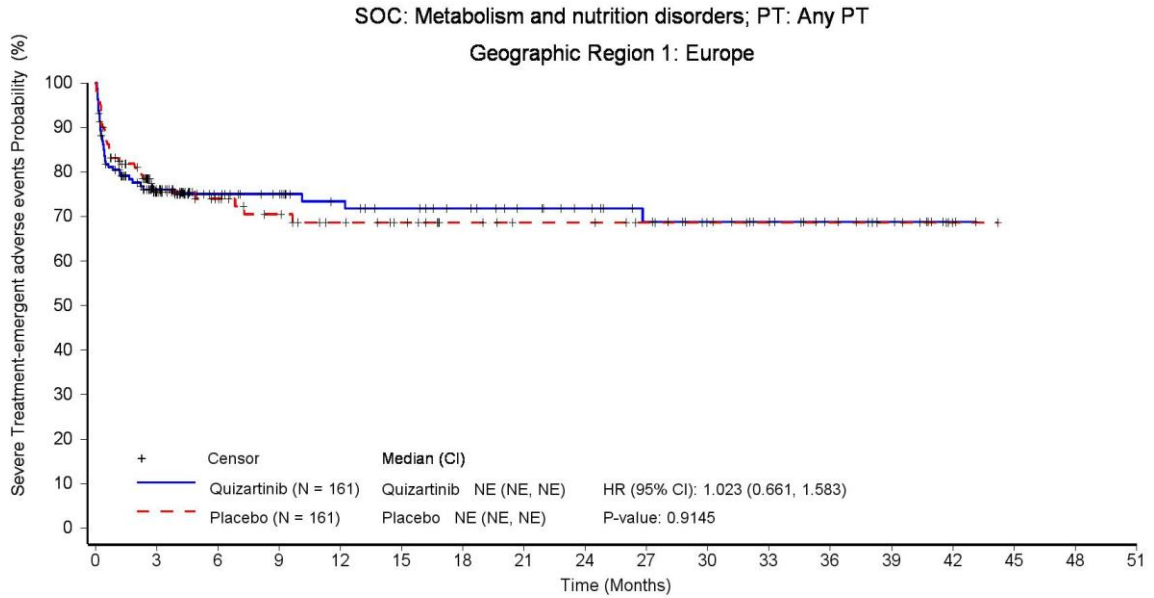
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Patients still at risk:

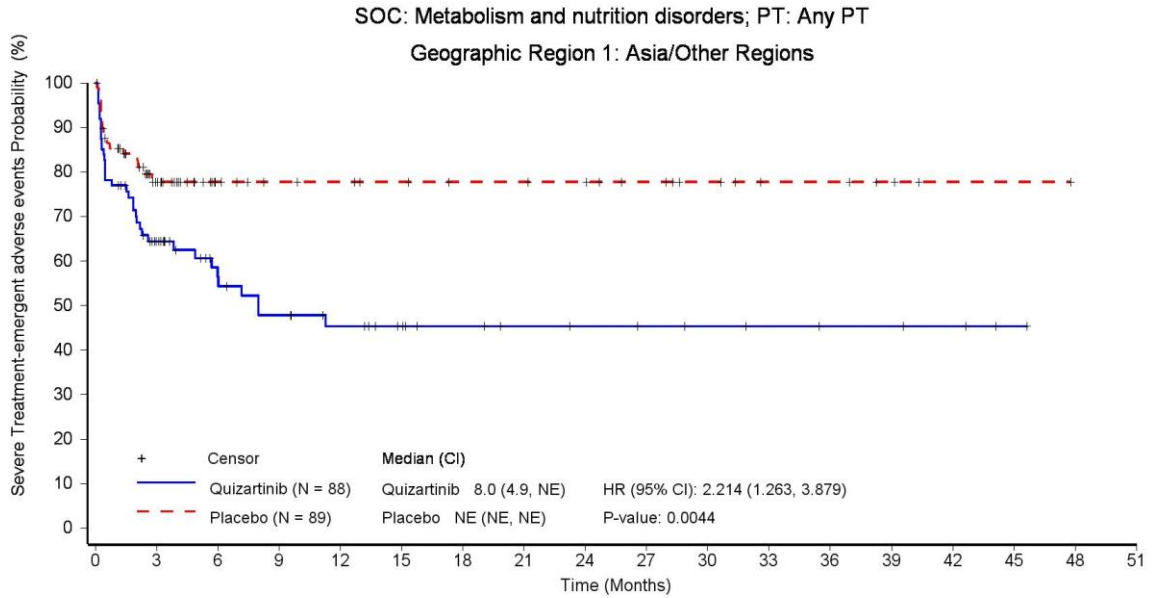
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 161)	161	86	60	53	45	41	37	32	28	23	19	15	10	7	2	0	0	0
Placebo (N = 161)	161	68	46	39	31	27	20	17	17	14	11	10	9	6	1	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 88)	88	41	27	22	18	14	11	9	8	7	6	5	4	4	3	1	0	0
Placebo (N = 89)	89	41	24	20	19	17	15	15	14	11	8	5	5	3	1	1	0	0

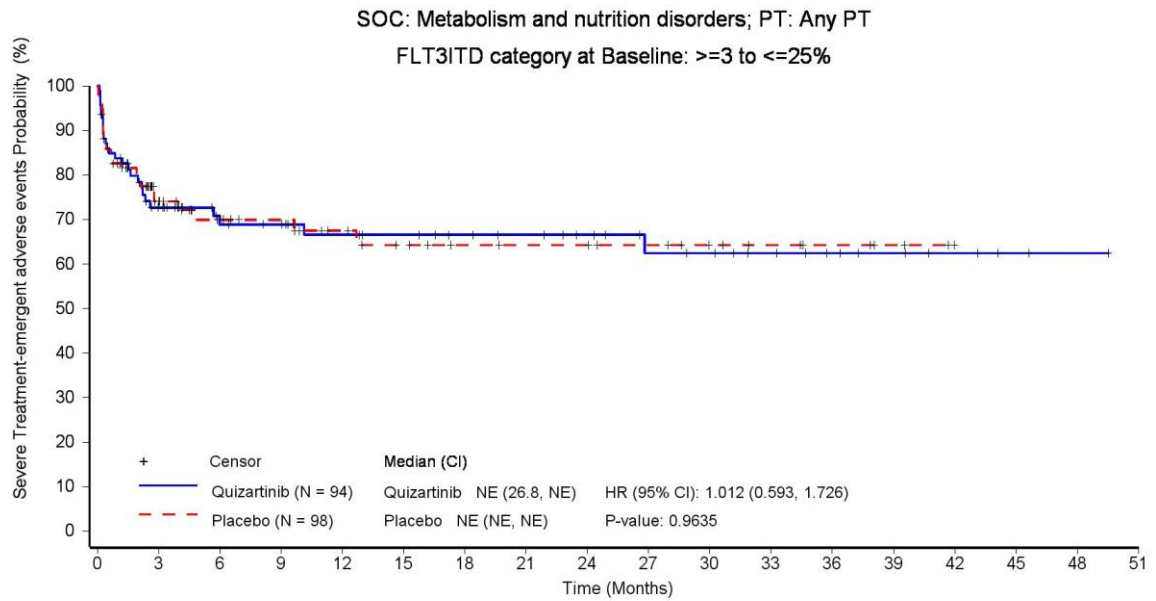
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Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 94)	94	48	36	34	29	27	24	22	19	15	14	11	8	6	4	2	1	0
Placebo (N = 98)	98	42	31	28	22	18	15	14	14	12	9	7	5	3	0	0	0	0

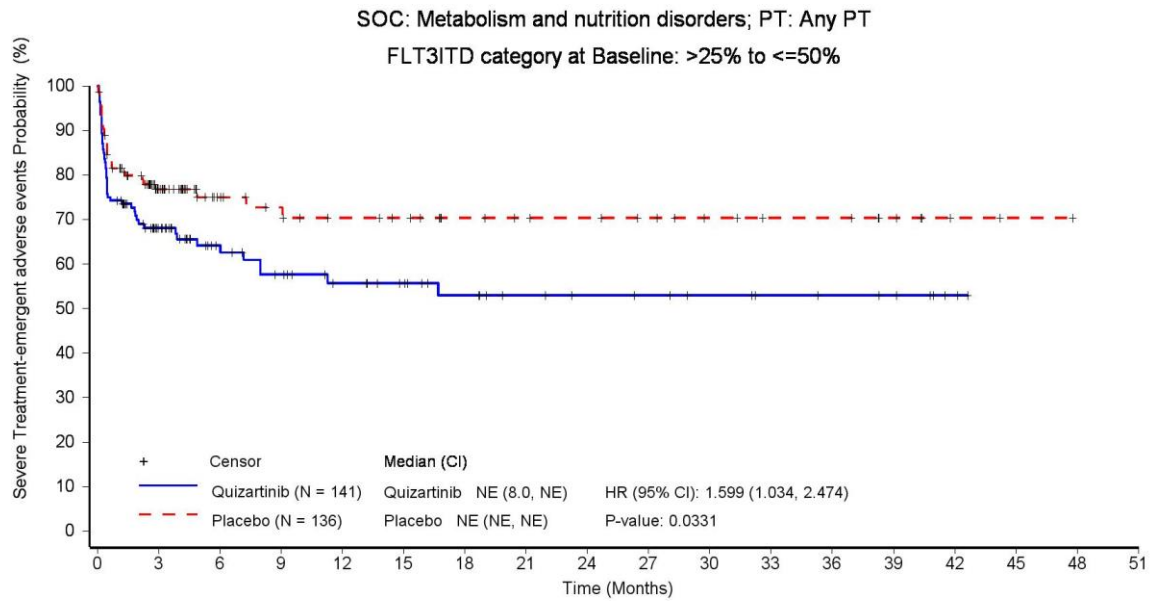
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Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	62	41	34	28	24	19	15	13	12	10	8	7	6	2	0	0	0
Placebo (N = 136)	136	61	36	31	27	25	19	17	16	14	11	9	9	6	2	1	0	0

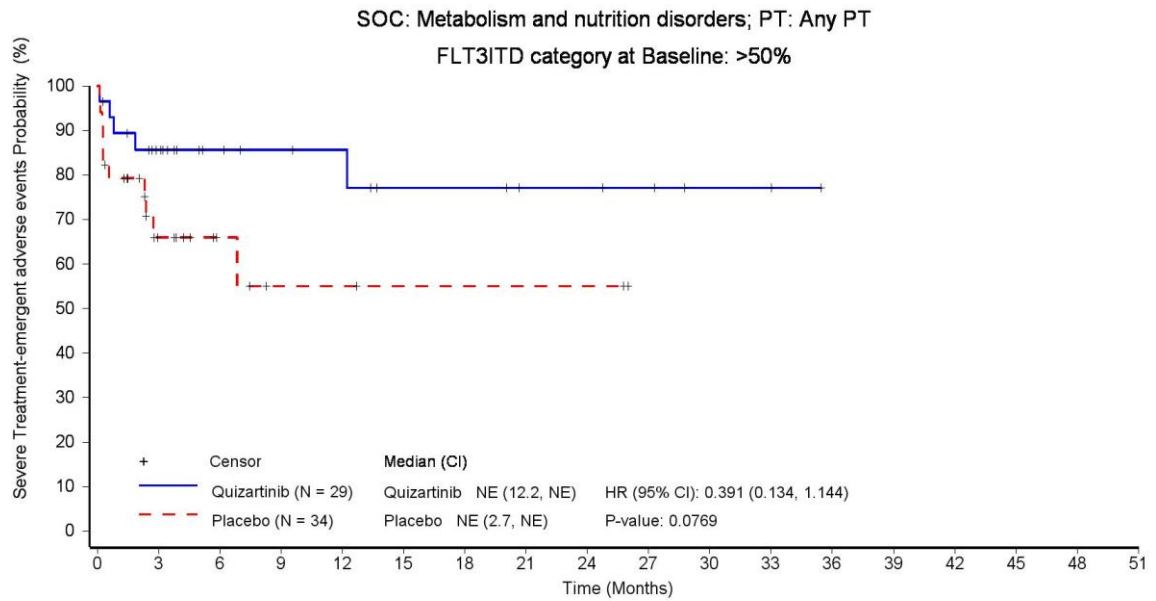
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 29)	29	20	13	11	10	7	7	5	5	4	2	2	0	0	0	0	0	0
Placebo (N = 34)	34	12	6	3	3	2	2	2	2	0	0	0	0	0	0	0	0	0

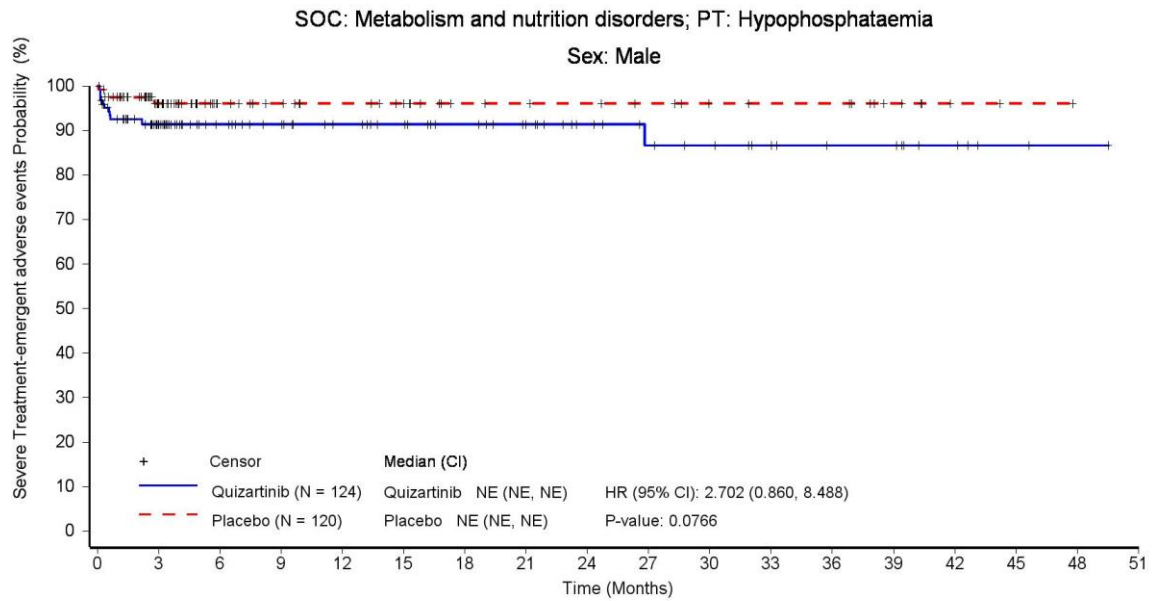
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 124)	124	72	54	48	42	38	33	28	22	18	16	13	10	10	6	2	1	0
Placebo (N = 120)	120	62	38	33	29	25	19	18	17	15	12	11	11	6	2	1	0	0

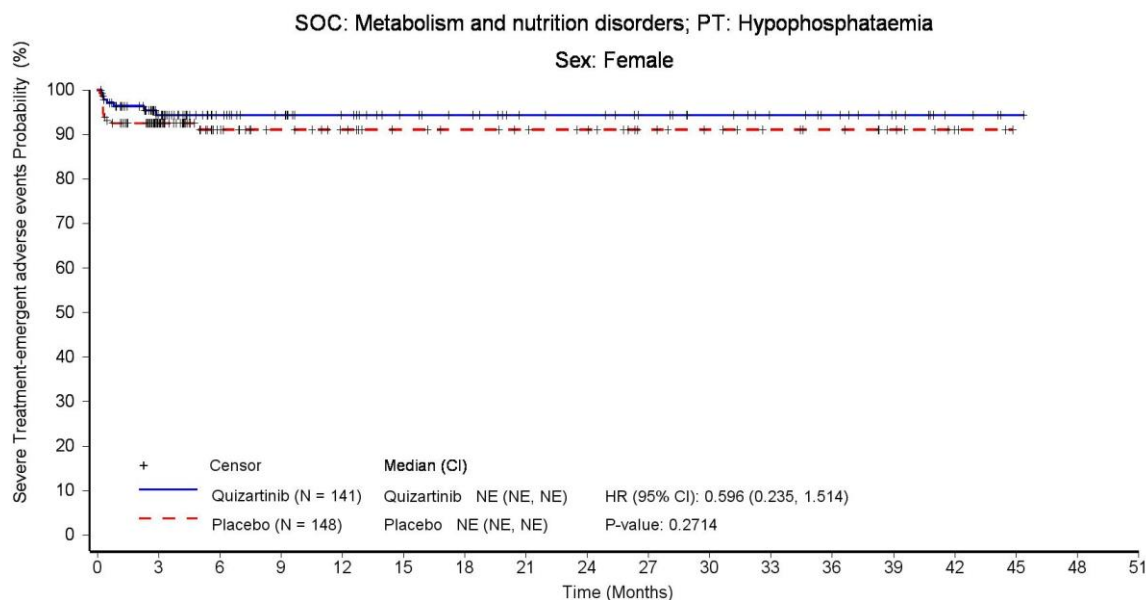
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	86	63	56	49	41	38	32	31	26	22	18	15	10	4	1	0	0
Placebo (N = 148)	148	84	53	44	38	33	30	28	26	20	17	14	12	8	3	0	0	0

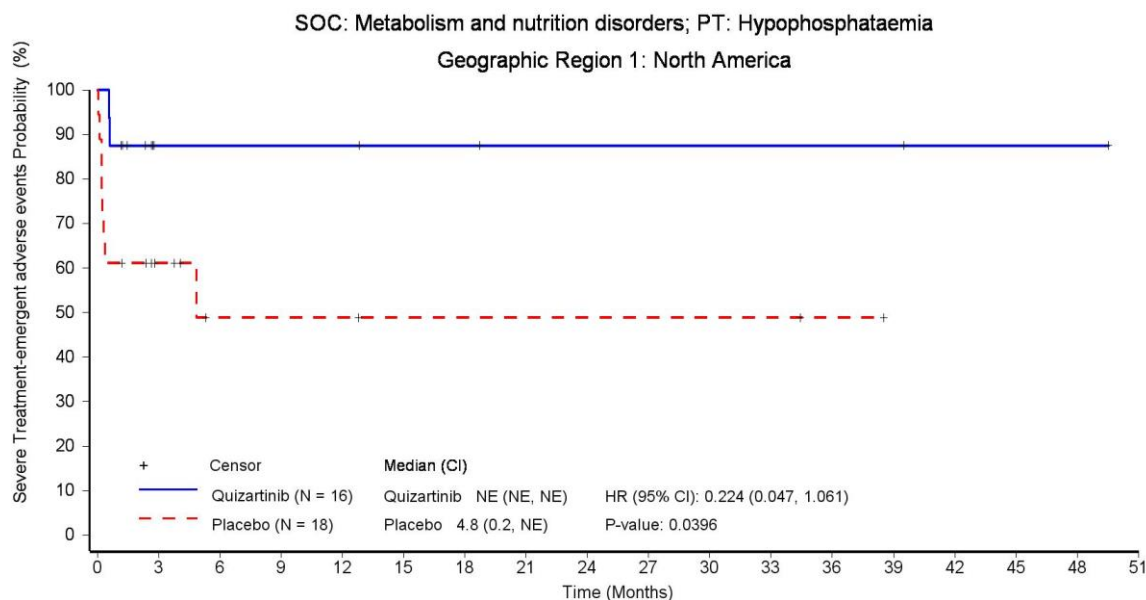
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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 16)	16	4	4	4	4	3	3	2	2	2	2	2	2	2	1	1	1	0
Placebo (N = 18)	18	7	3	3	3	2	2	2	2	2	2	2	1	0	0	0	0	0

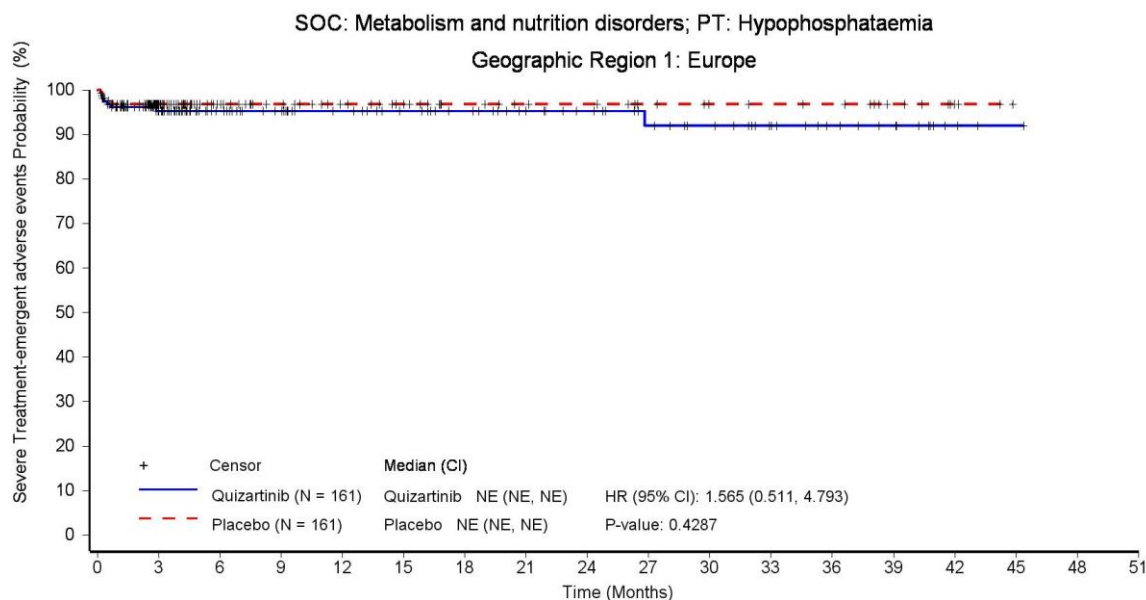
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

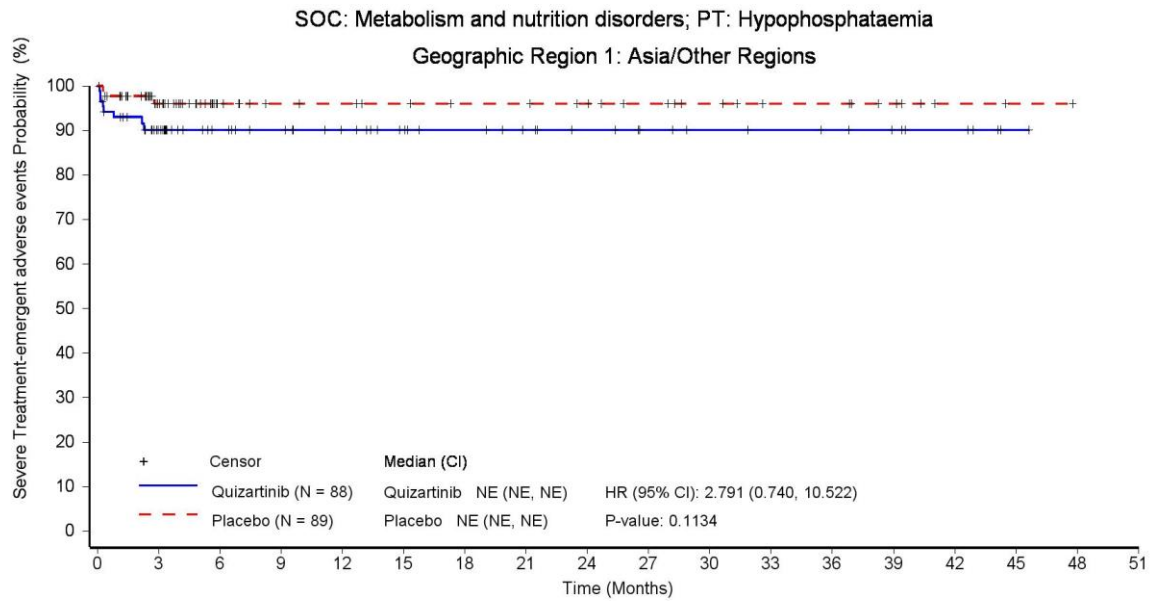
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	
Quizartinib (N = 161)	161	101	73	64	56	50	45	38	34	28	24	18	13	10	3	1	0
Placebo (N = 161)	161	88	58	49	40	34	27	24	23	18	15	14	13	8	3	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 88)	88	53	40	36	31	26	23	20	17	14	12	11	10	8	6	1	0	0
Placebo (N = 89)	89	51	30	25	24	22	20	20	18	15	12	9	9	6	2	1	0	0

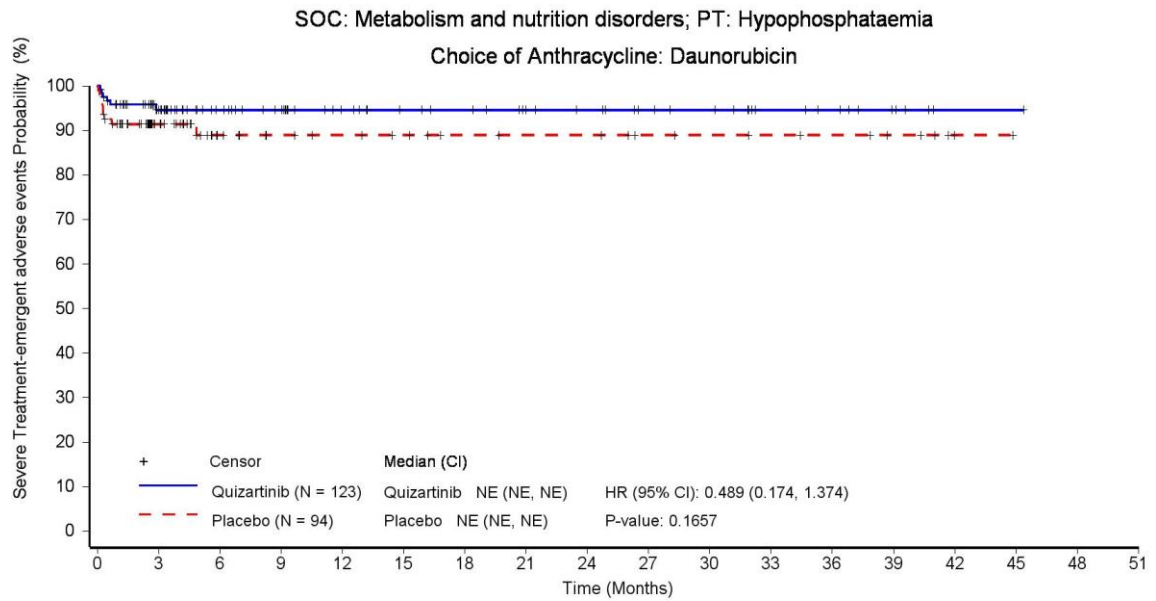
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 123)	123	73	55	48	38	33	31	26	24	19	17	11	9	5	1	1	0	0
Placebo (N = 94)	94	48	29	23	21	19	15	14	14	10	9	8	7	5	1	0	0	0

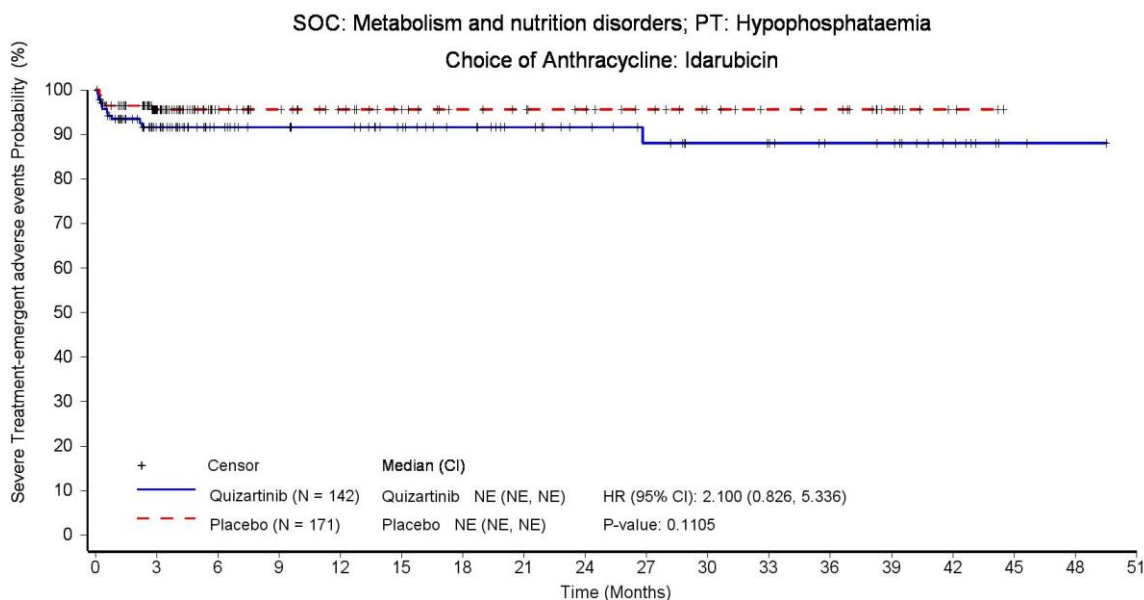
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 142)	142	85	62	56	53	46	40	34	29	25	21	20	16	15	9	2	1	0
Placebo (N = 171)	171	96	61	53	45	38	33	31	28	24	19	16	15	8	3	0	0	0

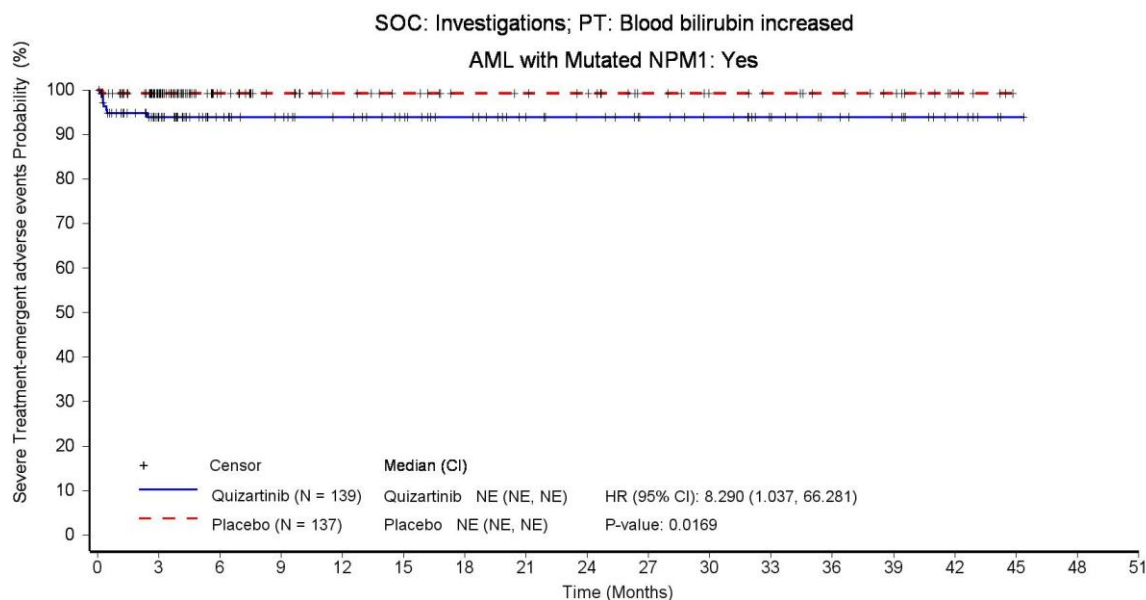
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 139)	139	93	70	64	59	52	46	38	35	30	27	21	16	13	7	1	0	0
Placebo (N = 137)	137	96	62	52	43	39	34	33	31	24	20	18	15	12	5	0	0	0

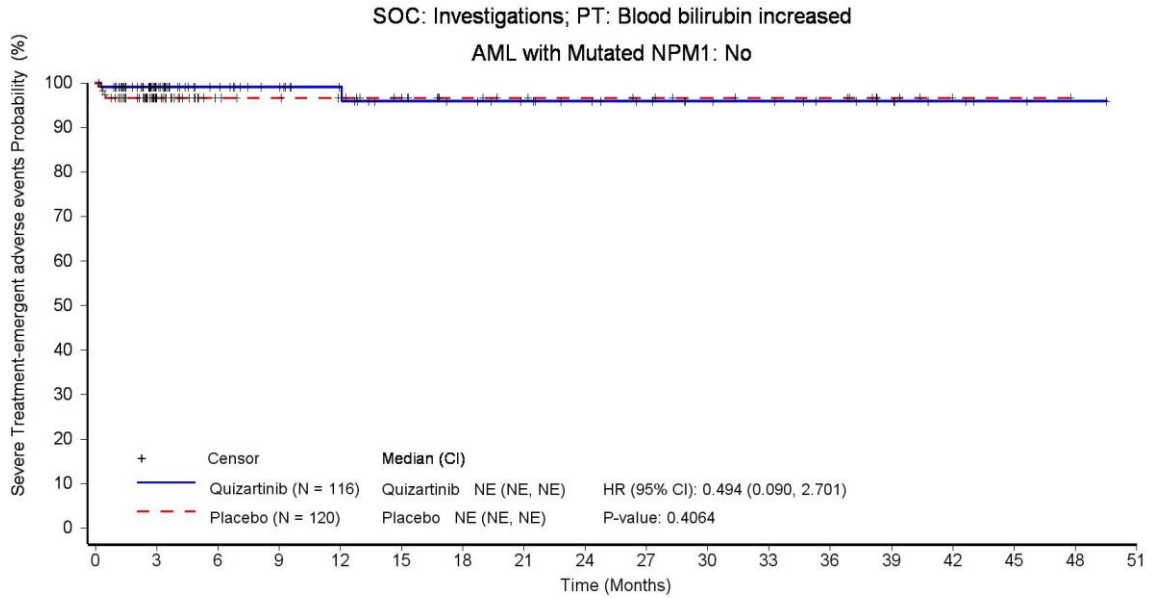
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

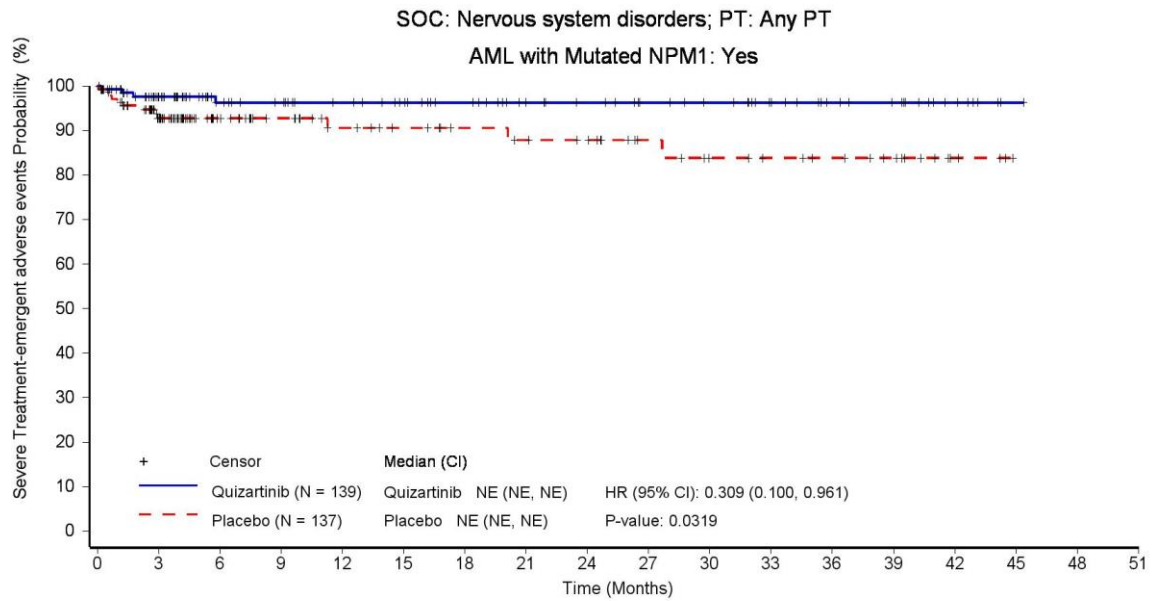
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 116)	116	61	44	37	31	26	25	22	19	16	13	12	9	7	4	2	1	0
Placebo (N = 120)	120	49	31	28	26	21	16	14	13	12	10	9	9	4	1	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
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Patients still at risk:

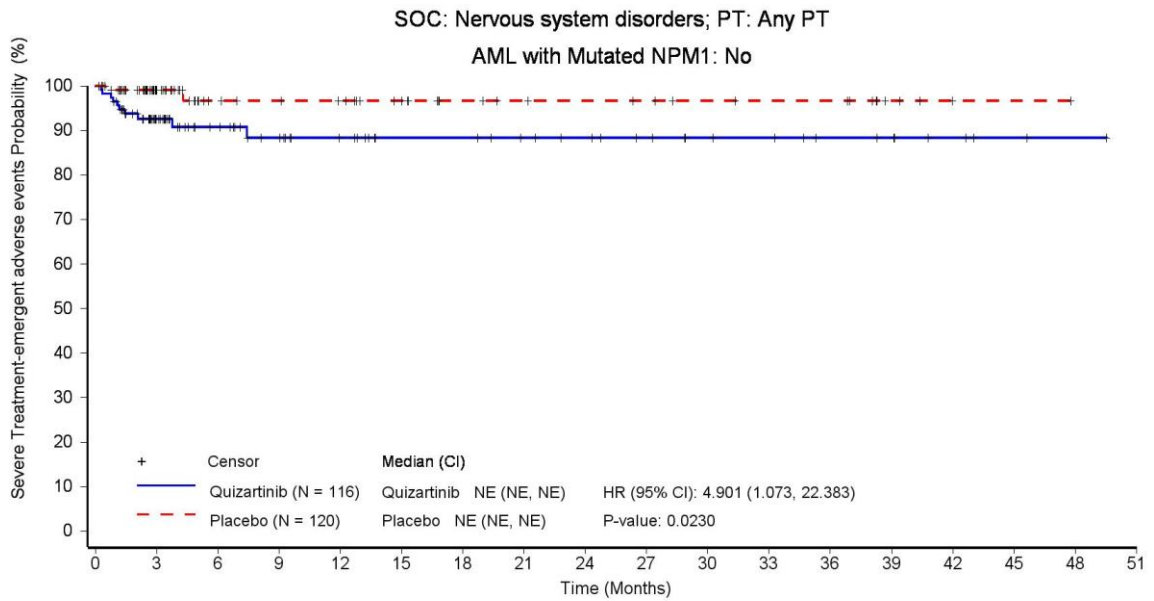
Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45		
Quizartinib (N = 139)	139	96	71	66	60	54	48	40	37	32	29	23	17	14	7	1	0	0
Placebo (N = 137)	137	91	59	49	41	37	33	31	29	22	18	16	14	11	4	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
 Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

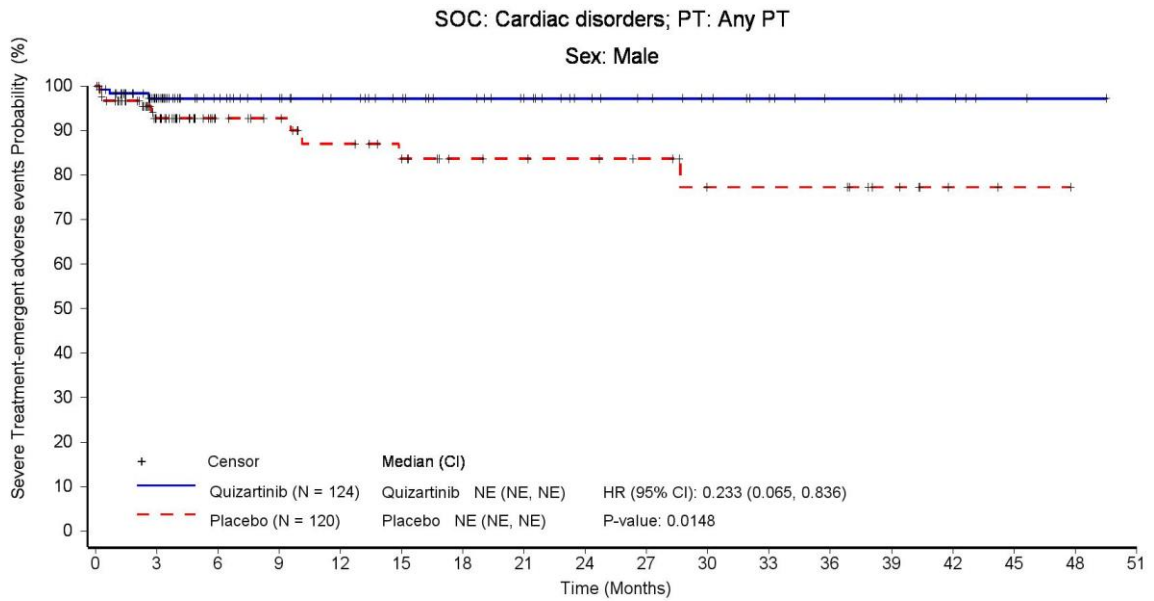
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 116)	116	60	43	35	29	23	23	20	18	15	12	11	8	7	4	2	1	0
Placebo (N = 120)	120	52	33	30	28	22	17	15	14	13	11	10	10	4	1	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
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Patients still at risk:

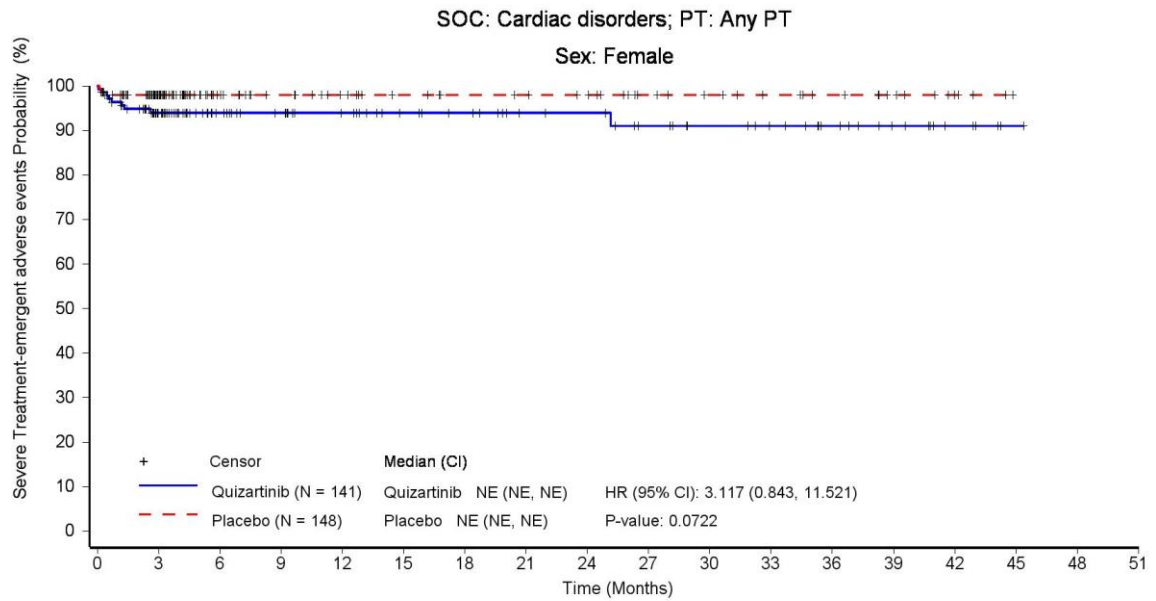
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 124)	124	75	57	50	44	39	34	29	23	20	17	14	10	10	6	2	1	0
Placebo (N = 120)	120	63	39	35	29	24	19	18	17	15	11	11	11	7	2	1	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

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Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 141)	141	89	65	58	51	43	40	34	33	27	23	20	15	10	5	1	0	0
Placebo (N = 148)	148	91	57	48	41	36	32	31	29	22	19	16	13	9	4	0	0	0

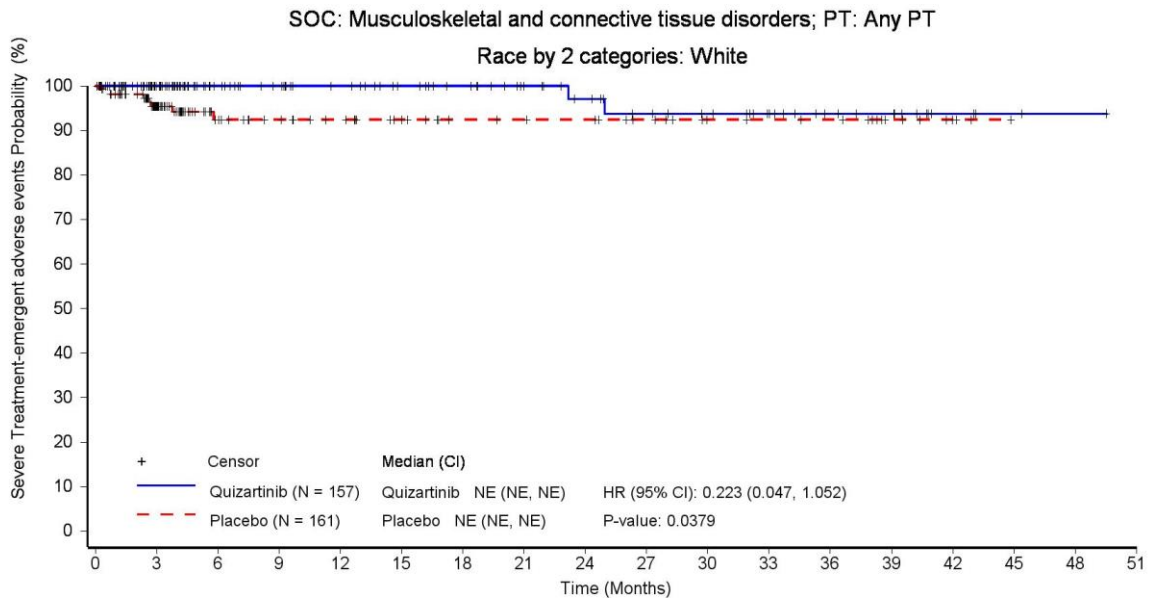
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Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

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Patients still at risk:

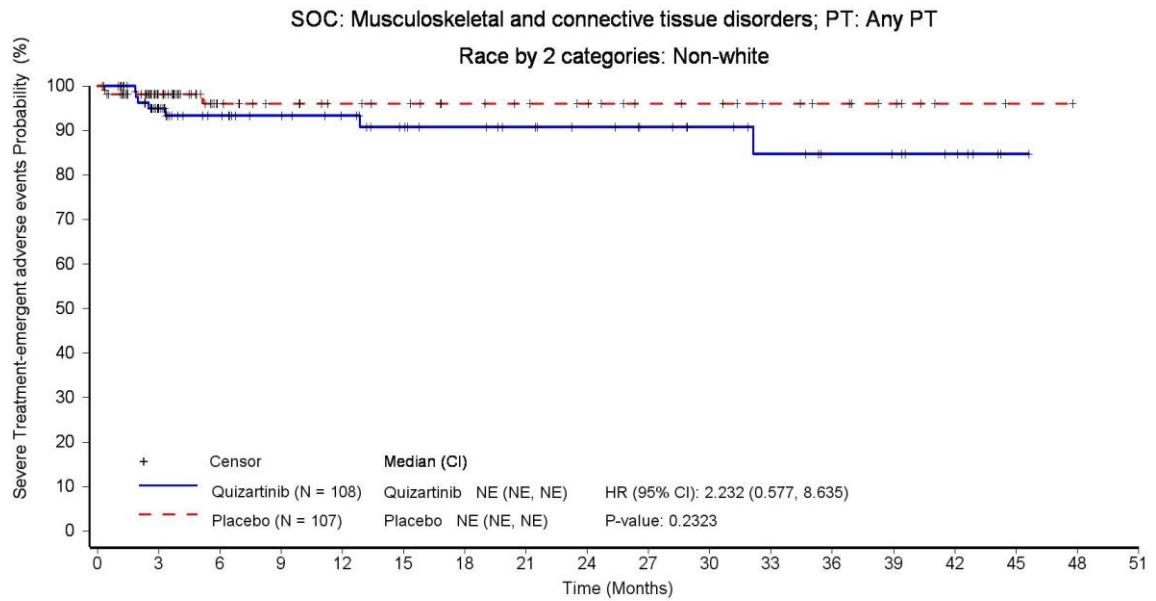
	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 157)	157	102	72	64	57	50	45	37	32	27	24	19	13	11	4	2	1	0
Placebo (N = 161)	161	89	52	45	39	32	26	25	24	20	15	14	13	7	3	0	0	0

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)
 Figure 3.13.2 Severe Treatment-emergent adverse events (NCI CTCAE grade ≥ 3) by system organ class (SOC) and preferred term (PT) observed for ≥ 10 patients in at least one arm and $\geq 1\%$ of the patients in at least one arm - Kaplan-Meier plot - subgroup analysis - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

Time (Months)	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 108)	108	62	49	43	39	33	30	27	24	20	17	14	11	10	7	1	0	0
Placebo (N = 107)	107	63	39	34	30	28	24	22	20	16	15	12	10	7	2	1	0	0

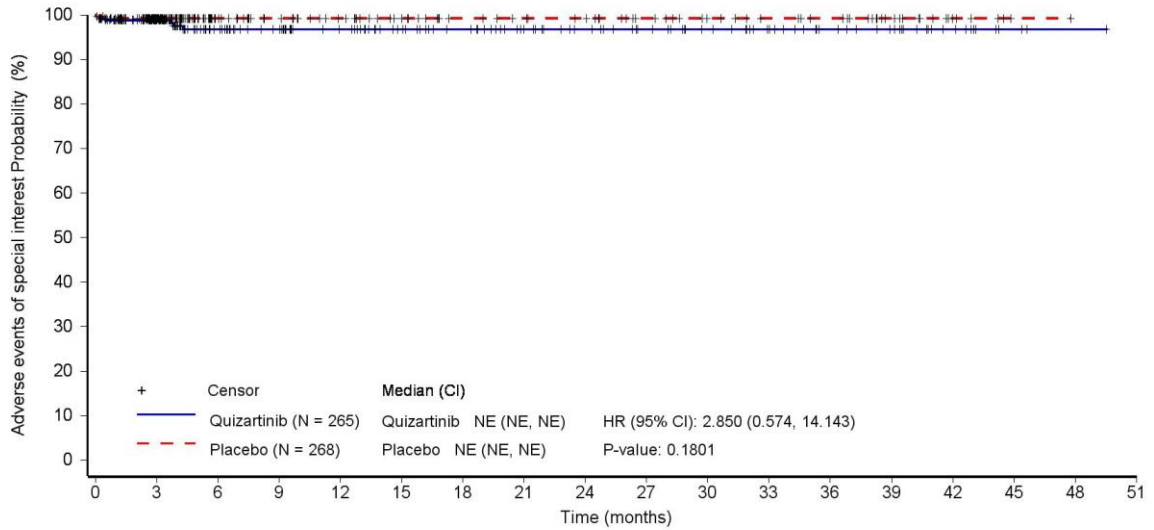
Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Hazard ratio (HR) is from unstratified Cox proportional hazards model and two-sided p-value is based on unstratified log-rank test. CI: confidence interval. PT: Preferred Term, SOC: System Organ Class.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\
 Run date: 21JUL2023 – 22:33; Program name: DE_F_3_11_2.sas; Output name: DE_F_3_13_2_TEAESEVSOCPT_SUB_SAS.rtf

Anhang 4-G7: UE von besonderem Interesse mit statistisch nicht signifikantem Behandlungseffekt (alle Schweregrade)

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 Figure 3.5.1 Adverse events of special interest - QTcF prolongation ≥ Grade 3 - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

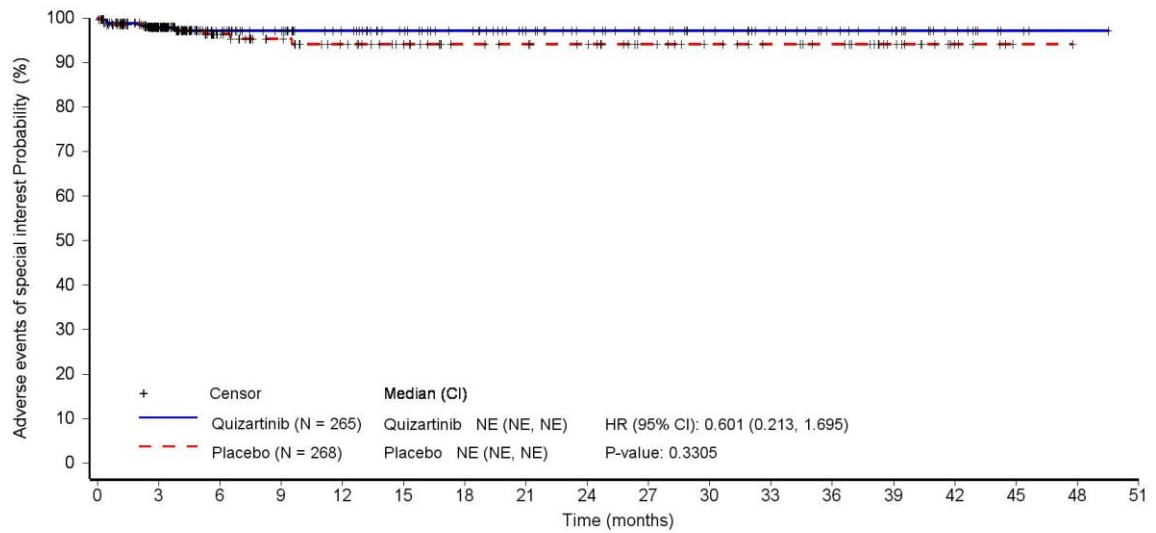
Quizartinib (N = 265)	265	164	119	106	94	81	73	62	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	157	98	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.
 CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\
 Run date: 14JUL2023 – 16:39; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_5_1_AESI1_SAS.rtf

Daiichi Sankyo | Data Intelligence – Evidence Generation | Final | AC220-A-U302 QUANTUM-First (DCO 13 Aug 2021) | Statistical analyses for AMNOG (HTA Germany)

Figure 3.6.1 Adverse events of special interest - Combined Elevations of Aminotransferases and Bilirubin - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	161	118	104	92	80	72	61	54	46	39	32	25	20	11	3	1	0
Placebo (N = 268)	268	153	96	81	70	61	51	49	46	37	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

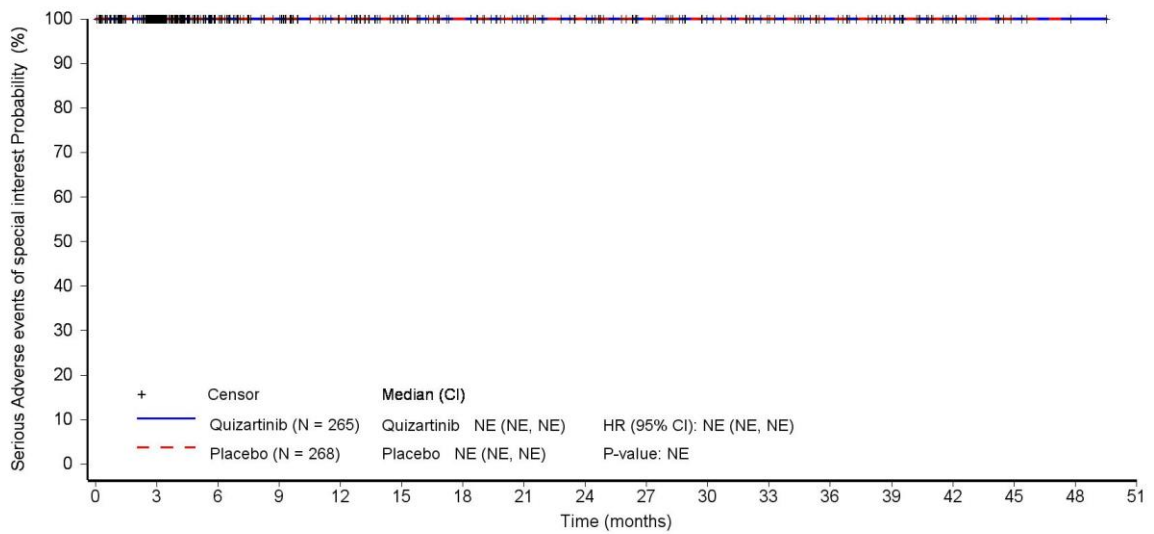
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Run date: 14JUL2023 – 16:39; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_6_1_AESI2_SAS.rtf

Anhang 4-G8: Schwerwiegende UE von besonderem Interesse mit statistisch nicht signifikantem Behandlungseffekt

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Figure 3.7.1 Serious Adverse events of special interest - QTcF prolongation ≥ Grade 3 - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	166	123	109	96	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	157	98	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

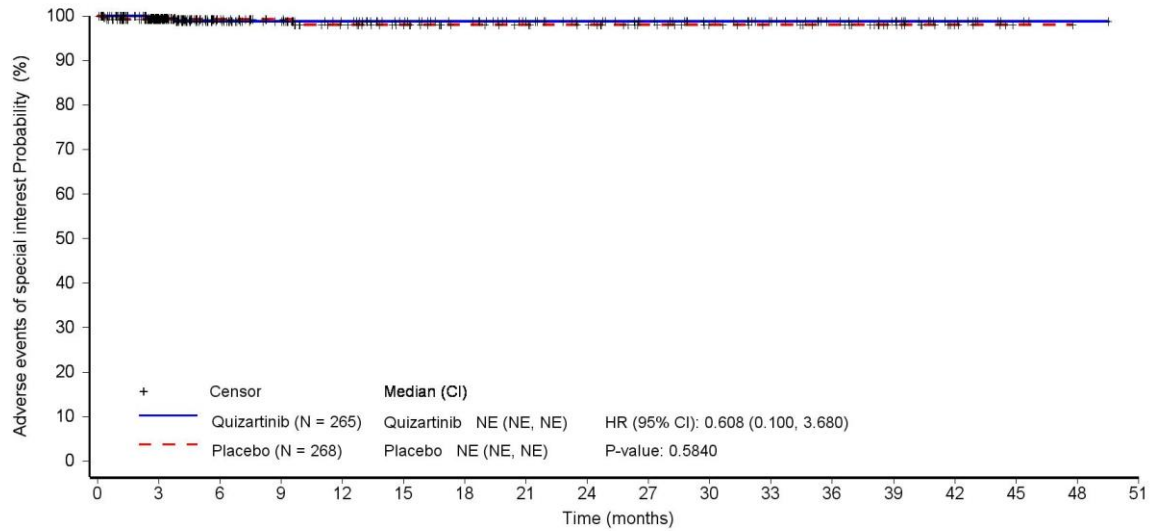
CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:40; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_7_1_AESIISER_SAS.rtf

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Figure 3.8.1 Adverse events of special interest - Combined Elevations of Aminotransferases and Bilirubin - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	165	122	108	96	83	75	64	57	49	42	35	26	21	11	3	1	0
Placebo (N = 268)	268	155	97	83	72	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

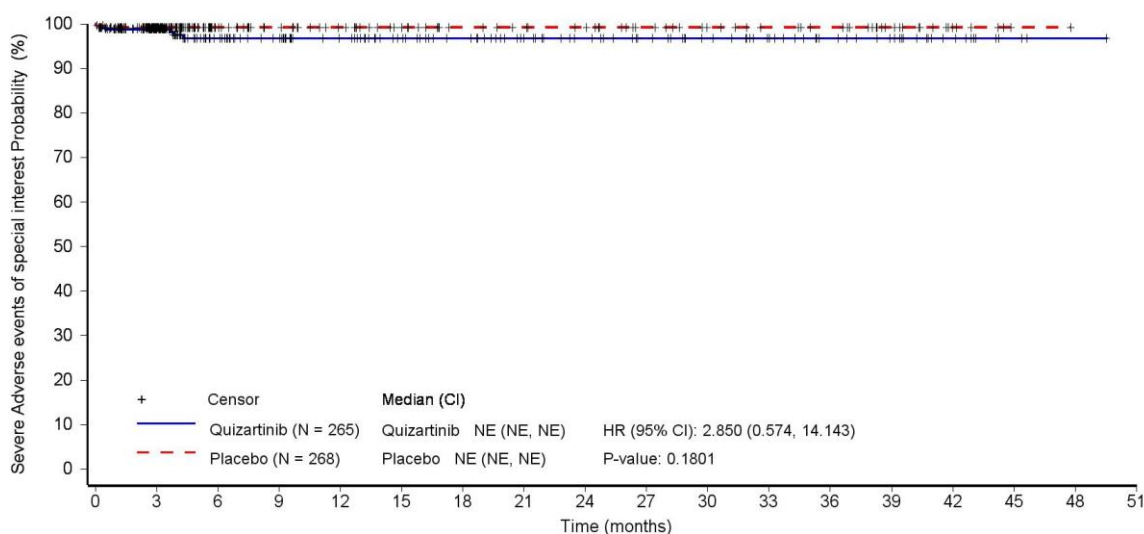
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Run date: 14JUL2023 – 16:40; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_8_1_AESI2SER_SAS.rtf

Anhang 4-G9: Schwere UE von besonderem Interesse mit statistisch nicht signifikantem Behandlungseffekt (CTCAE-Grad ≥ 3)

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Figure 3.9.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - QTcF prolongation ≥ Grade 3 - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	164	119	106	94	81	73	62	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	157	98	84	73	63	53	50	47	38	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

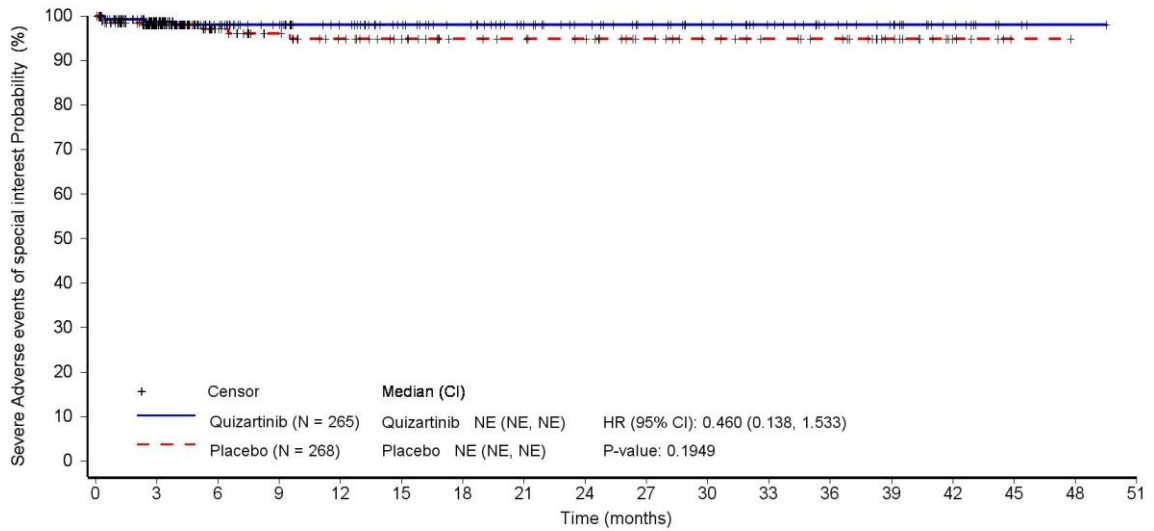
CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstret_eg\rstret_20211102_eg\rstret_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:40; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_9_1_AESI1SEV_SAS.rtf

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Figure 3.10.1 Severe Adverse events of special interest (CTCAE Grade ≥ 3) - Combined Elevations of Aminotransferases and Bilirubin - Kaplan-Meier plot - DCO 13-Aug-2021 - Safety Analysis Set



Patients still at risk:

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51
Quizartinib (N = 265)	265	163	120	106	94	81	73	62	55	47	40	33	25	20	11	3	1	0
Placebo (N = 268)	268	153	96	81	70	61	51	49	46	37	32	28	25	16	6	1	0	0

Hazard ratio (HR) is from stratified Cox proportional hazards model and two-sided p-value is based on stratified log-rank test.

CI: confidence interval. Only treatment-emergent adverse events of special interest are considered.

Data source: \\AC220-A-U302\Production\Raw\Data_Restricted\rstrct_eg\rstrct_20211102_eg\rstrct_valos\20230516_AMNOG\ADAM\

Run date: 14JUL2023 – 16:40; Program name: DE_F_2_1_1_EQ5D_FD_PROITT.sas; Output name: DE_F_3_10_1_AESI2SEV_SAS.rtf