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Patient-Reported Outcomes in Acute Myeloid Leukemia Patients with *FLT3*-ITD Mutation Receiving Quizartinib vs Standard Chemotherapy: Results from the QuANTUM-First Trial

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QuANTUM-FIRST STUDY

Background and Objective

BACKGROUND

- Based on the QuANTUM-First (NCT02668653) data[1]:
  - Quizartinib has been approved in the US,[2,3] EU,[4] and Japan[5] in combination with chemotherapy across induction, consolidation, and as maintenance monotherapy (but not after transplantation in the US) for the treatment of adult patients with newly diagnosed *FLT3*-ITD+ AML[1]

OBJECTIVE

- To assess the impact of quizartinib on patient-reported outcomes in the QuANTUM-First trial (exploratory endpoint)

AML, acute myeloid leukemia; EU, European Union; *FLT3*-ITD, FMS-like tyrosine kinase 3–internal tandem duplication; US, United States.

1. Erba HP, et al. *Lancet*. 2023. 2. Daiichi Sankyo Press Release. VANFLYTA® First FLT3 Inhibitor Approved in the U.S. Specifically for Patients with Newly Diagnosed FLT3-ITD Positive AML. Published July 20, 2023. 3. VANFLYTA® (quizartinib) package insert. Daiichi Sankyo, Inc. July 2023. 4. Daiichi Sankyo Press Release. VANFLYTA® Approved in the EU as the First FLT3 Inhibitor Specifically for Patients with Newly Diagnosed FLT3-ITD Positive AML. Published November 9, 2023.
5. Daiichi Sankyo Press Release. VANFLYTA® First FLT3 Inhibitor Approved in Japan for Patients with Newly Diagnosed FLT3-ITD Positive AML. Published May 25, 2023.

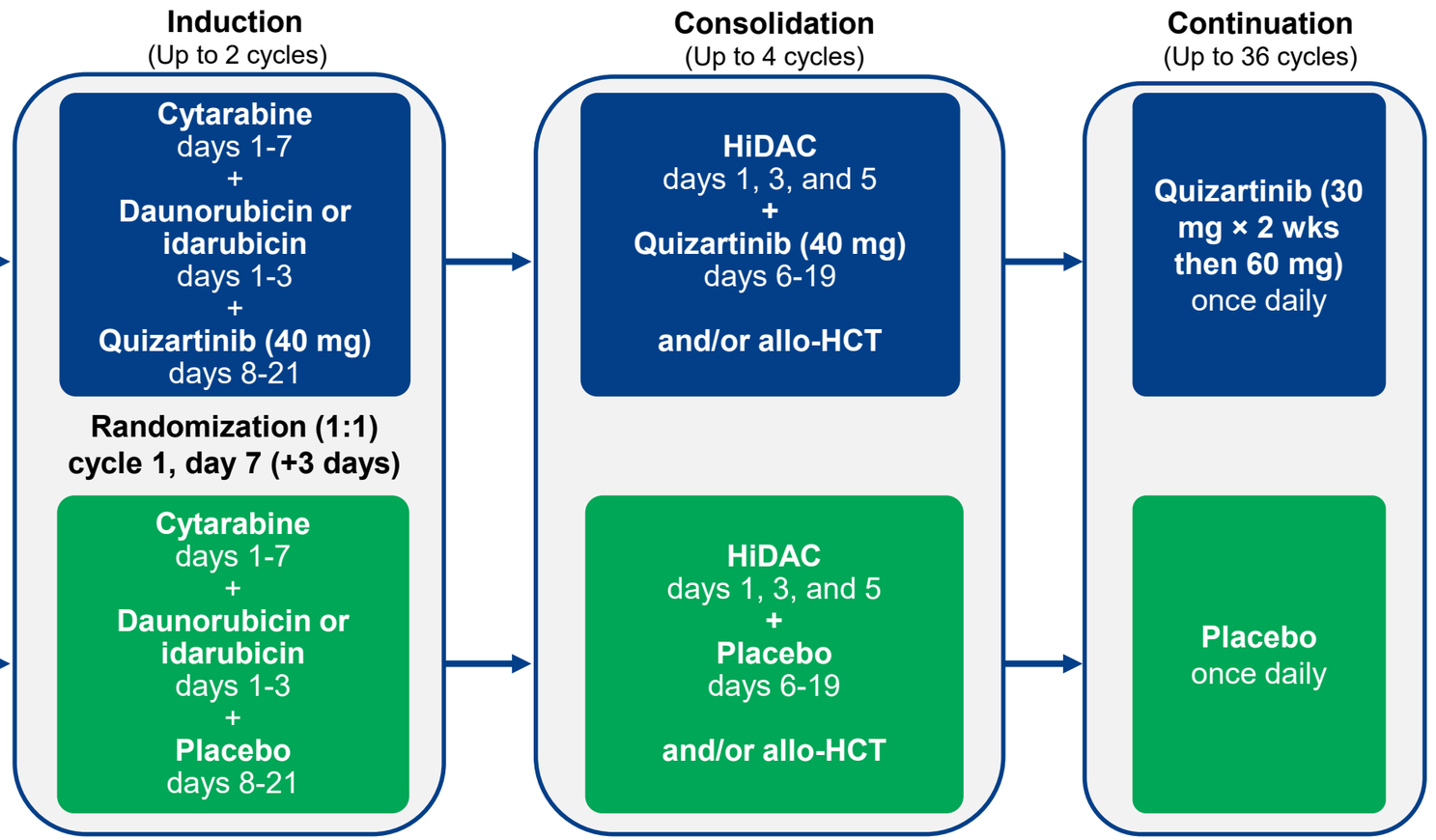
QuANTUM-First Phase 3 Trial: Quizartinib Plus Standard Induction Chemotherapy and Consolidation Followed by Single-Agent Quizartinib

Key endpoints

- **Primary endpoint**: OS
- **Secondary endpoints**: EFS, CR, CRc, CR/CRc with MRD− end of induction, safety
- **Exploratory endpoints**: RFS, DoCR, PRO

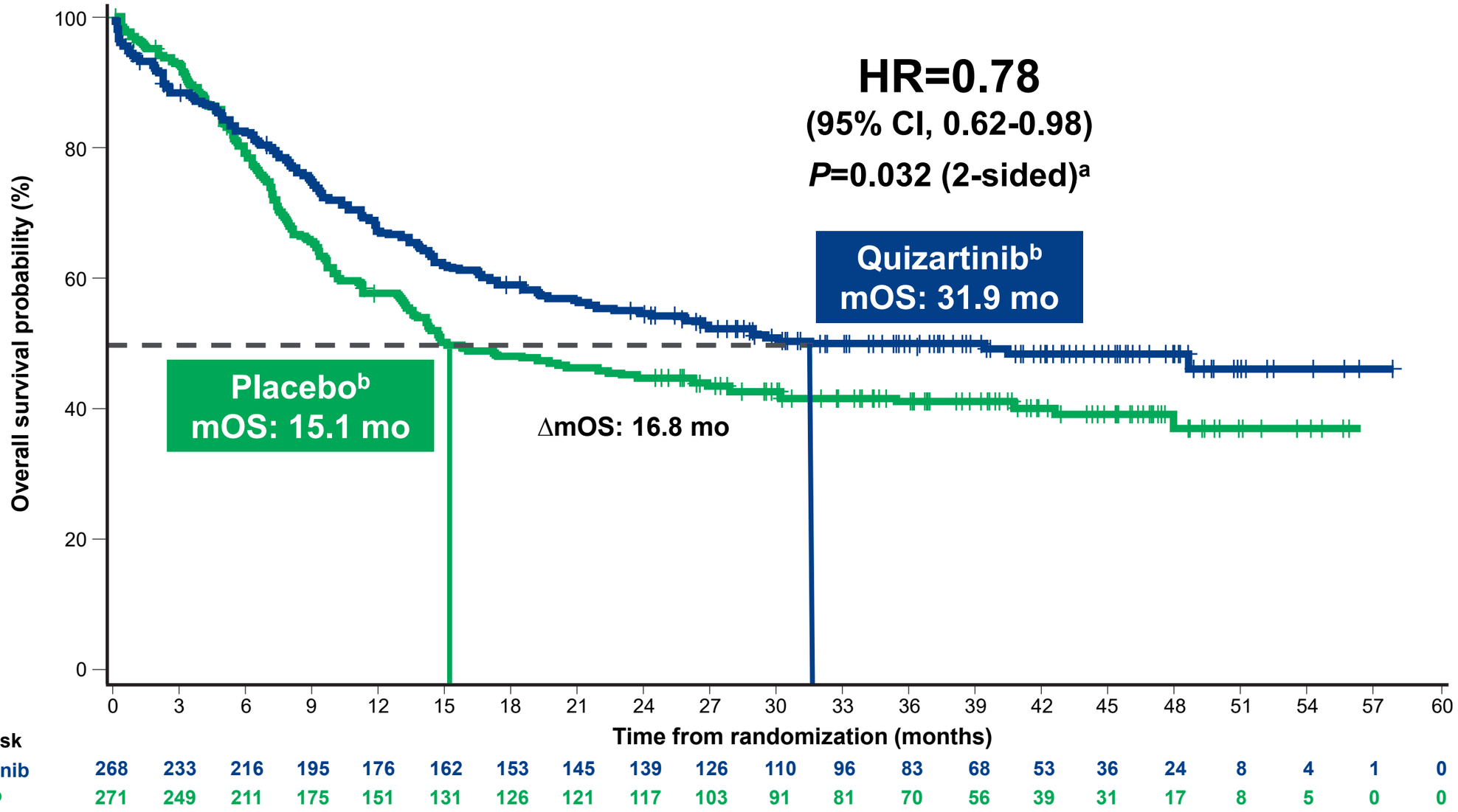
N=539

- Newly diagnosed *FLT3*-ITD+ AML
- 18-75 years of age
- ≥3% *FLT3*-ITD allelic frequency
- Patients begin 7+3 chemotherapy during screening



[a]Data on the EuroQol EQ-5D-5L questionnaire are not shown in this presentation. Allo-HCT, allogeneic hematopoietic cell transplantation; AML, acute myeloid leukemia; C, cycle; CR, complete remission; CRc, composite complete remission; D, day; DoCR, duration of complete remission; EFS, event-free survival; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 items; EuroQol EQ-5D-5L, European Quality of Life 5-Dimension 5-Level; *FLT3*-ITD, FMS-like tyrosine kinase 3–internal tandem duplication; HiDAC, high-dose cytarabine; MRD, measurable residual disease; OS, overall survival; PRO, patient-reported outcome; RFS, relapse-free survival. Erba HP, et al. *Lancet.* 2023.

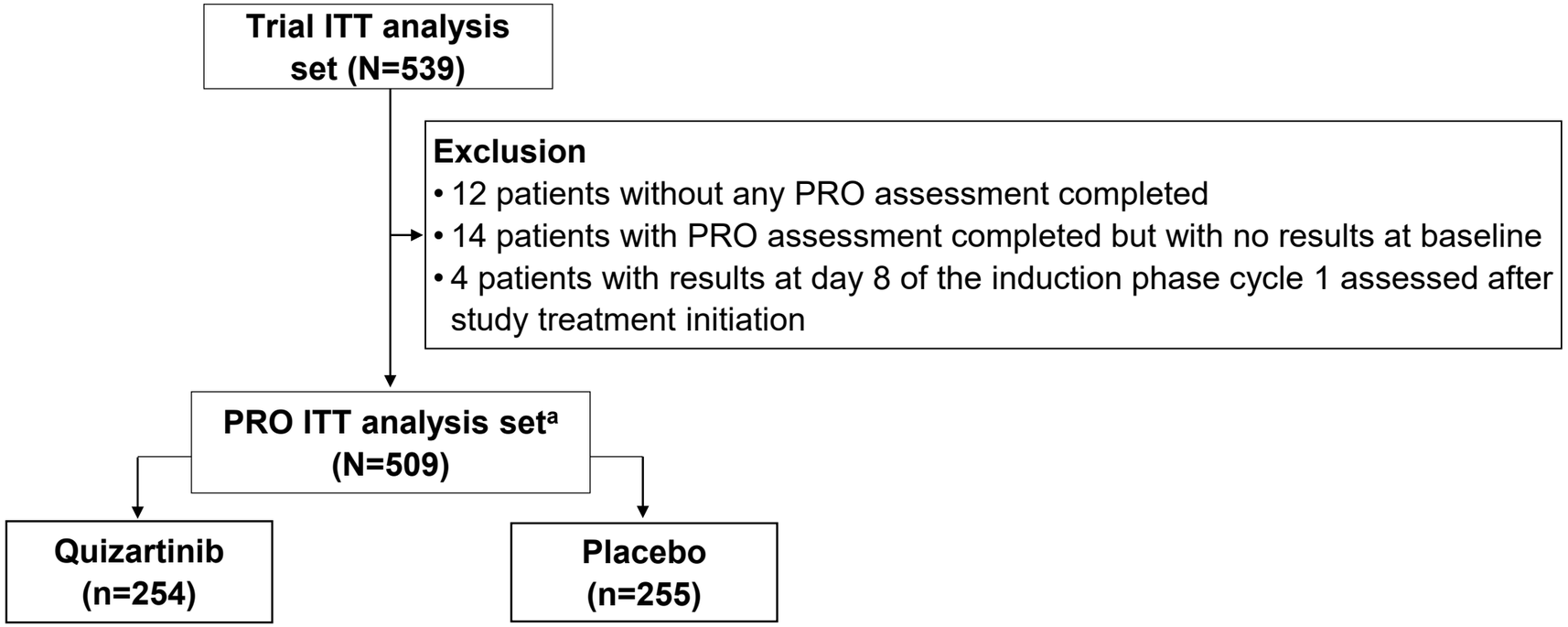
Primary Endpoint: Overall Survival



[a]*P* value was calculated using a stratified log-rank test. [b]Median follow-up time for both arms was 39.2 months. HR, hazard ratio; mOS, median overall survival. Erba H, et al. *Lancet*. 2023.

Patient Inclusion in PRO Analysis

- 94.4% of the ITT analysis set patients completed relevant PRO assessment on day 8 of induction phase cycle 1 (baseline)



[a]Defined as all randomized patients with complete EORTC QLQ-C30 assessments at baseline. EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaire-Core 30 items; ITT, intent-to-treat; PRO, patient-reported outcome.

Assessment of EORTC QLQ-C30 Scores

- EORTC QLQ-C30 scores were calculated and reported as mean (95% CI, *P* value) and mean change from baseline score for each domain of the EORTC QLQ-C30 questionnaire, at each time point
  - **Baseline Score**: calculated on day 8 of induction cycle 1
- A minimal clinically important difference (MCID) score ≥10 points for each domain of the EORTC QLQ-C30, was defined as previously reported[1]
- A MMRM on change from baseline and survival analyses (Cox model and Kaplan-Meier estimates) on time until definitive deterioration (TUDD) were used to assess the longitudinal impact of treatment on PROs
  - **TUDD[a]**: the time from baseline PRO score to first deterioration of the score beyond the MCID relative to baseline without further improvement of >1 MCID relative to the reference score or without any further available score
- The analyses were not powered for statistical significance

EORTC QLQ-C30
Global health status/QoL
Functional subscale
Physical
Role
Emotional
Cognitive
Social
Symptom subscale
Fatigue
Nausea and vomiting
Pain
Dyspnea
Insomnia
Appetite loss
Constipation
Diarrhea
Financial difficulties

[a]Censoring for TUDD: patients without definitive deterioration before the end of the study or death or dropout are censored at the time of the last assessment for a respective score. Patients without baseline score are censored at baseline. EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaire-Core 30 items; MMRM, mixed model with repeated measures; PRO, patient-reported outcome; QoL, quality of life. 1. Musoro JZ, et al. *Eur J Cancer*. 2023.

Baseline EORTC QLQ-C30 Scores and Population Norms

- Patient compliance to questionnaire completion was high and similar for both arms and most scales throughout the study
  - GHS completion rates: induction cycle 1 (99.2%), consolidation cycle 1 (95.3%), and continuation cycle 1 (93.4%)

EORTC QLQ-C30, mean score (SD)		Quizartinib (n=254)	Placebo (n=255)	Total (N=509)	Ref, EU[a]	Ref, US[a]
Global QoL[a]	GHS/QoL	45.9 (24.4)	48.1 (24.9)	47.0 (24.6)	66.1 (21.7)	63.9 (22.9)
Functional subscale	Physical	68.5 (28.2)	68.9 (26.8)	68.7 (27.5)	85.1 (18.9)	80.8 (25.2)
	Role	52.2 (35.1)	49.9 (38.0)	51.1 (36.6)	84.3 (24.6)	81.7 (28.2)
	Social	53.5 (34.3)	53.4 (36.1)	53.4 (35.2)	86.2 (24.1)	81.6 (29.4)
Symptom subscale	Fatigue	51.0 (29.2)	48.0 (29.0)	49.5 (29.1)	29.5 (25.5)	31.9 (27.8)
	Nausea and vomiting	19.0 (23.7)	19.7 (24.7)	19.3 (24.2)	5.9 (16.0)	10.9 (22.6)
	Appetite loss	45.0 (34.4)	46.5 (35.7)	45.7 (35.0)	10.0 (21.6)	14.1 (25.3)
	Diarrhea	30.7 (35.2)	25.3 (30.5)	28.0 (33.0)	9.5 (20.9)	13.7 (27.1)
	Financial difficulties	27.2 (33.0)	25.0 (32.8)	26.1 (32.9)	10.6 (23.6)	17.5 (30.8)

- Higher scores on the Functional subscale are better, lower scores in the Symptom subscale are better
- Scores for all the other function and symptom subscale domains (not included in the table) were similar between QuANTUM-First data at baseline and the US or EU population norms

[a]The EU and US reference data are from other studies and are not adjusted for age and sex.

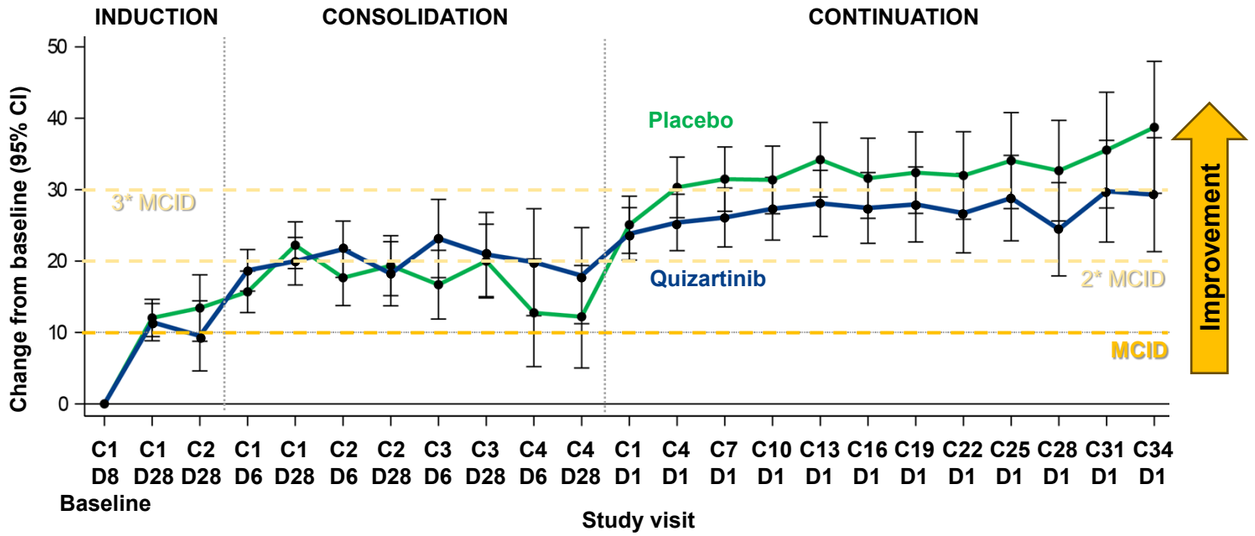
EU, European Union; GHS, global health status; NA, not applicable; QoL, quality of life; US, United States.

1. Nolte S, et al. *Eur J Cancer.* 2019.

EORTC QLQ-C30 Global Health Status/QoL Scale and Physical Functional Subscale MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

- Improvements in GHS/QoL were observed for both placebo and quizartinib arms and reached MCID

EORTC QLQ-C30 Global Health Status/QoL



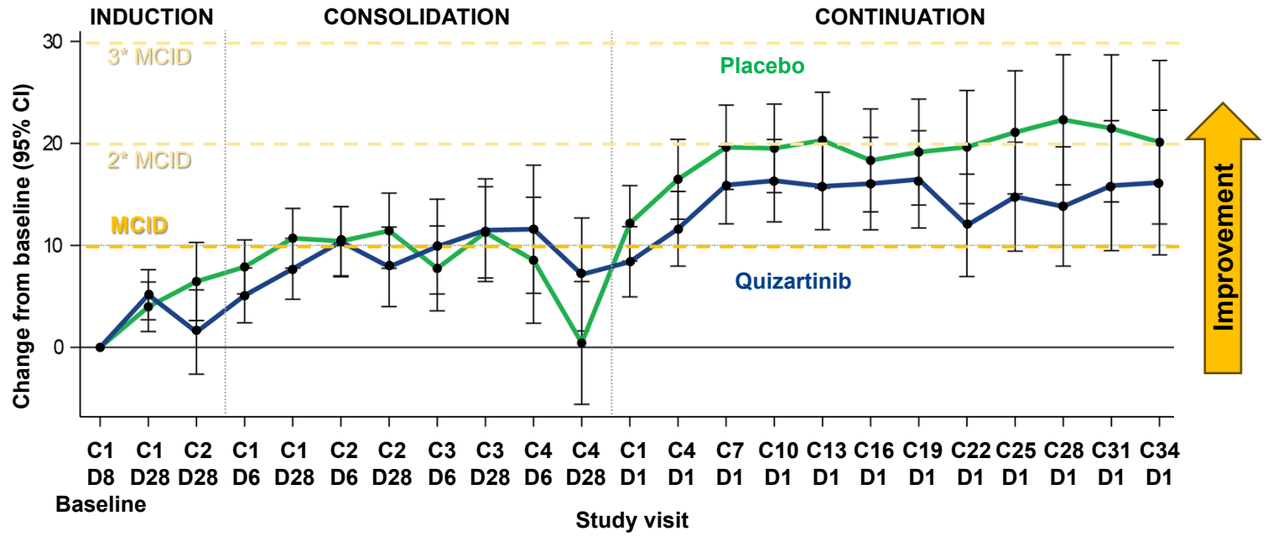
No. at risk

Quizartinib	252	199	36	153	103	71	55	35	32	18	20	100	79	74	64	59	51	45	40	35	29	24	19
Placebo	253	197	40	153	103	71	64	47	43	17	18	84	70	62	57	45	39	40	33	27	26	18	14

Quizartinib Placebo

Mean (±SD) at baseline: 45.9 (24.4) 48.1 (24.9)

EORTC QLQ-C30 Physical Functioning



No. at risk

Quizartinib	249	195	35	150	103	71	55	35	32	17	20	98	76	73	62	57	50	45	40	36	29	24	19
Placebo	252	197	40	152	106	71	63	47	43	17	17	84	69	61	56	45	39	40	33	27	26	18	15

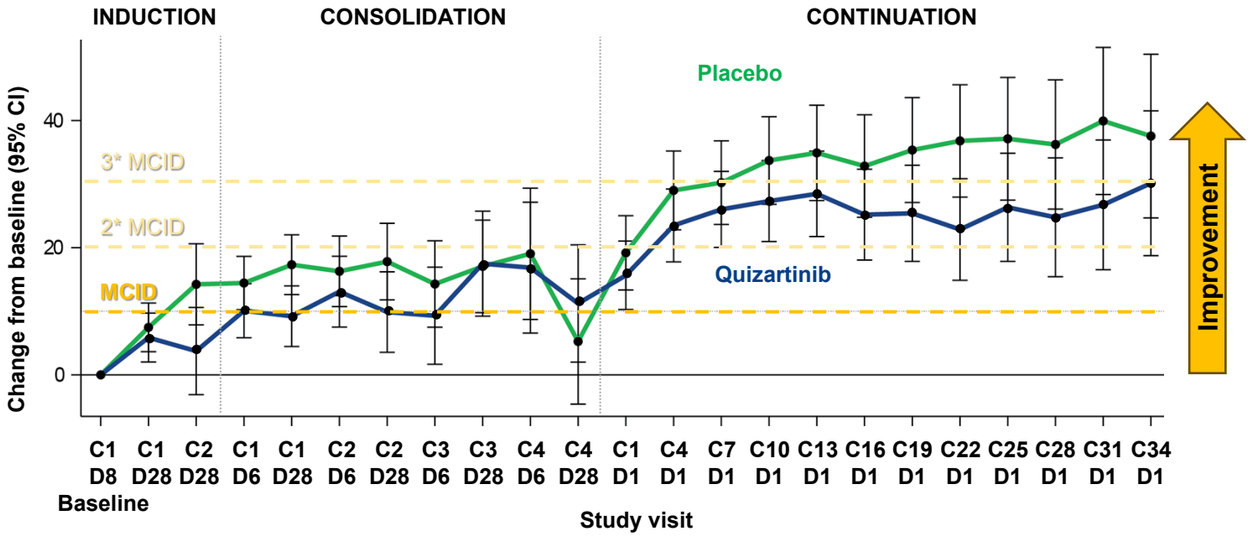
Quizartinib Placebo

Mean (±SD) at baseline: 68.5 (28.2) 68.9 (26.8)

C, cycle; D, day; GHS, global health status; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; QoL, quality of life.

EORTC QLQ-C30 Functional Subscales MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

EORTC QLQ-C30 Role Functioning



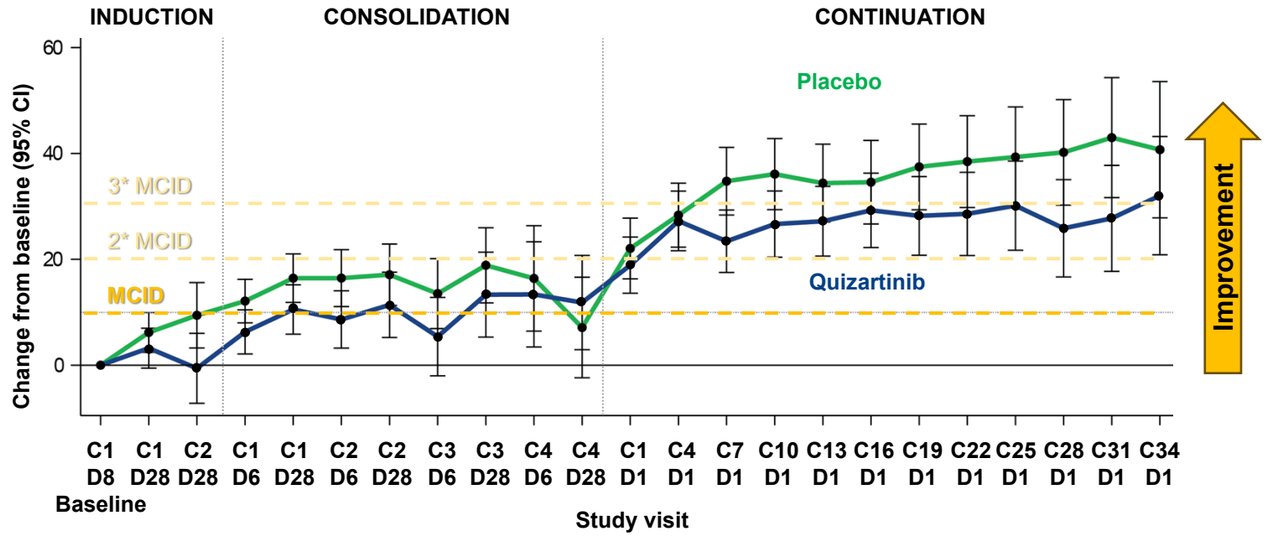
No. at risk

Quizartinib	251	195	35	150	103	71	55	35	32	18	20	99	78	73	63	58	51	45	40	36	29	24	19
Placebo	251	196	40	152	106	70	62	47	43	17	18	84	69	61	56	45	39	40	33	27	26	18	15

Quizartinib Placebo

Mean (±SD) at baseline: 52.2 (35.1) 49.9 (38.0)

EORTC QLQ-C30 Social Functioning



No. at risk

Quizartinib	251	198	35	151	103	72	55	35	32	18	20	99	78	73	63	58	51	45	40	35	29	24	19
Placebo	253	197	40	153	107	71	64	47	43	17	18	84	70	62	57	45	39	40	33	27	26	18	14

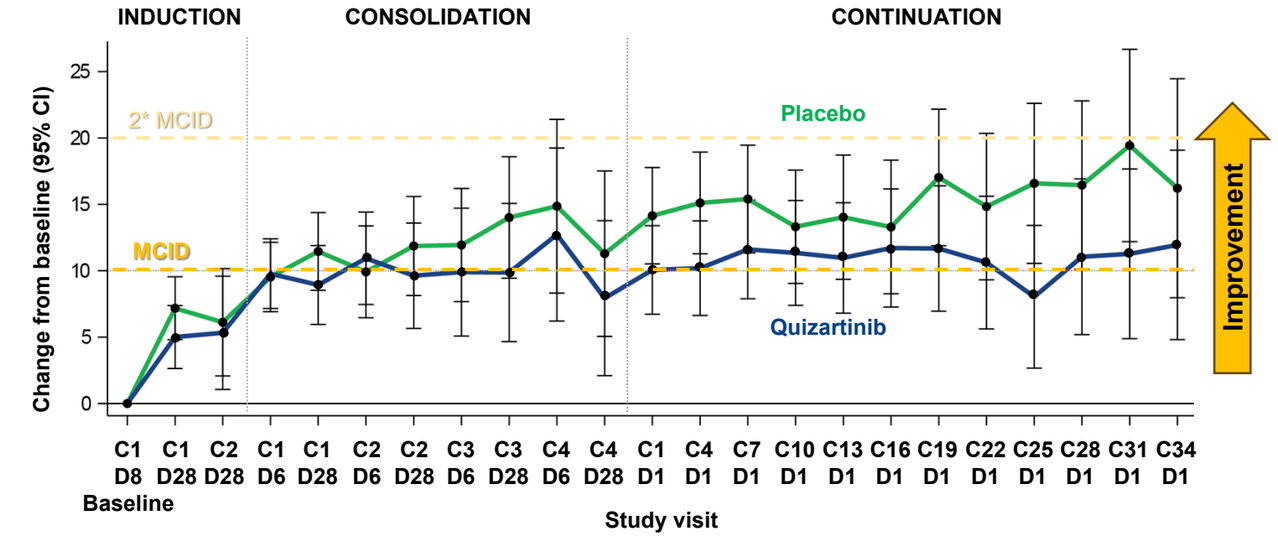
Quizartinib Placebo

Mean (±SD) at baseline: 53.5 (34.3) 53.4 (36.1)

C, cycle; D, day; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; SD, standard deviation.

EORTC QLQ-C30 Functional Subscales MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

EORTC QLQ-C30 Emotional Functioning

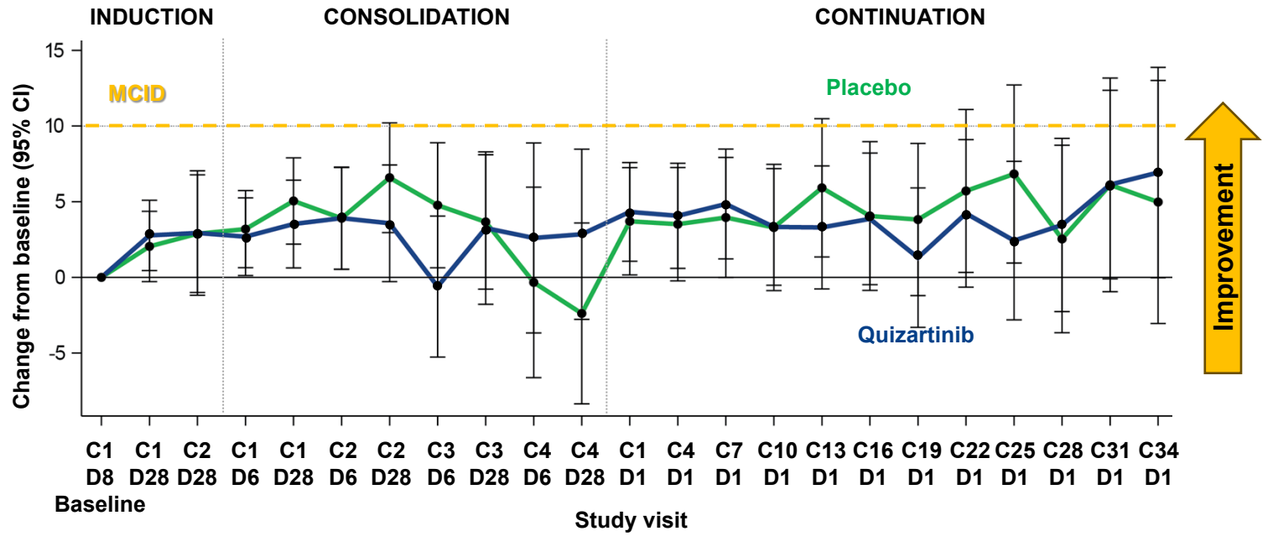


No. at risk																							
Quizartinib	252	199	36	153	103	72	55	35	32	18	20	100	79	74	64	59	51	45	40	35	29	24	19
Placebo	253	197	40	153	107	71	64	47	43	17	18	84	70	62	57	45	39	40	33	27	26	18	14

Quizartinib Placebo

Mean (±SD) at baseline: 71.7 (24.3) 72.3 (24.3)

EORTC QLQ-C30 Cognitive Functioning



No. at risk																							
Quizartinib	252	199	36	153	103	72	55	35	32	18	20	100	79	74	64	59	51	45	40	35	29	24	19
Placebo	253	197	40	153	107	71	64	47	43	17	18	85	70	62	57	45	39	40	33	27	26	18	14

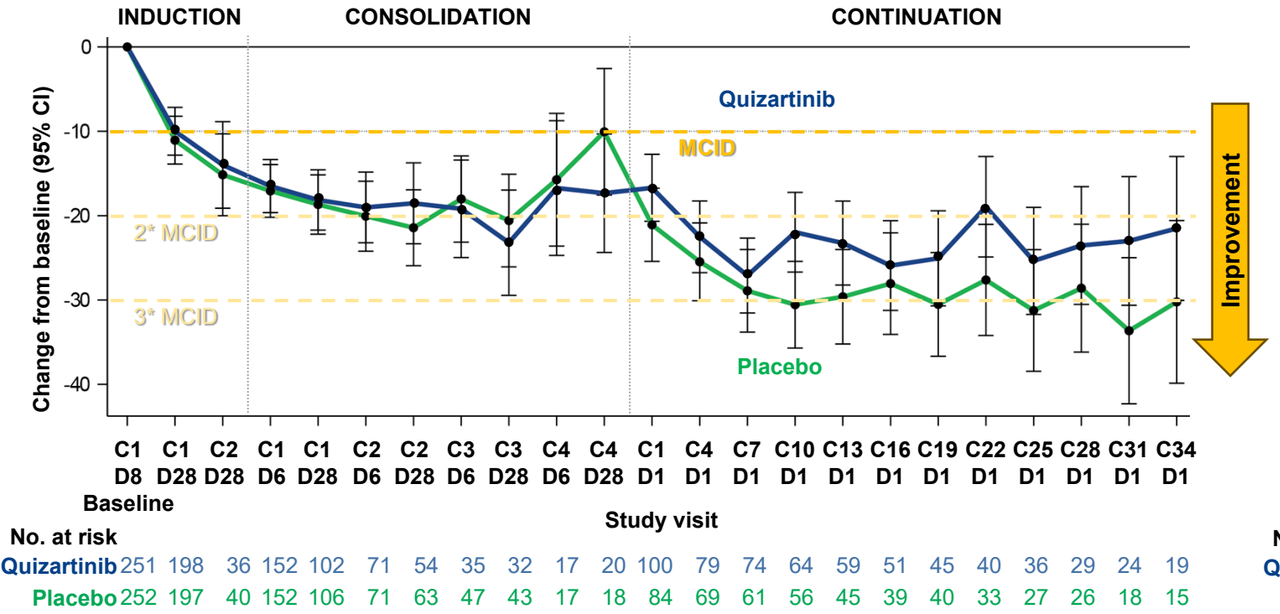
Quizartinib Placebo

Mean (±SD) at baseline: 80.4 (22.8) 81.9 (22.6)

C, cycle; D, day; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; SD, standard deviation.

EORTC QLQ-C30 Symptom Subscales MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

EORTC QLQ-C30 Fatigue



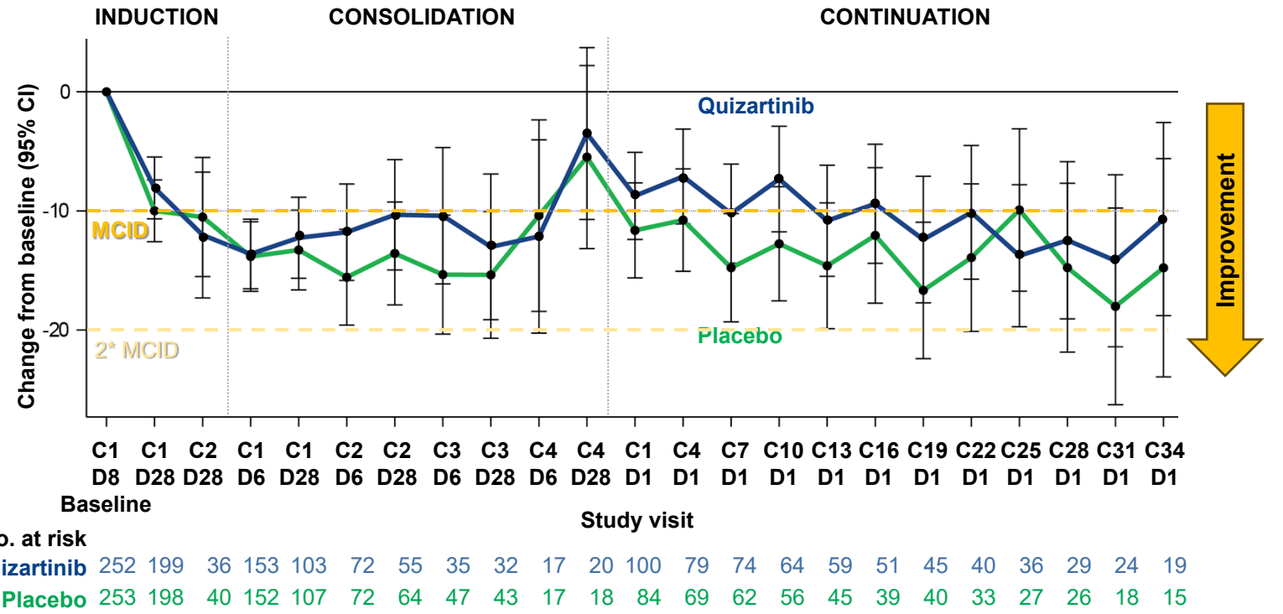
No. at risk

Quizartinib	251	198	36	152	102	71	54	35	32	17	20	100	79	74	64	59	51	45	40	36	29	24	19
Placebo	252	197	40	152	106	71	63	47	43	17	18	84	69	61	56	45	39	40	33	27	26	18	15

Quizartinib Placebo

Mean (±SD) at baseline: 51.0 (29.2) 48.0 (29.0)

EORTC QLQ-C30 Dyspnea



No. at risk

Quizartinib	252	199	36	153	103	72	55	35	32	17	20	100	79	74	64	59	51	45	40	36	29	24	19
Placebo	253	198	40	152	107	72	64	47	43	17	18	84	69	62	56	45	39	40	33	27	26	18	15

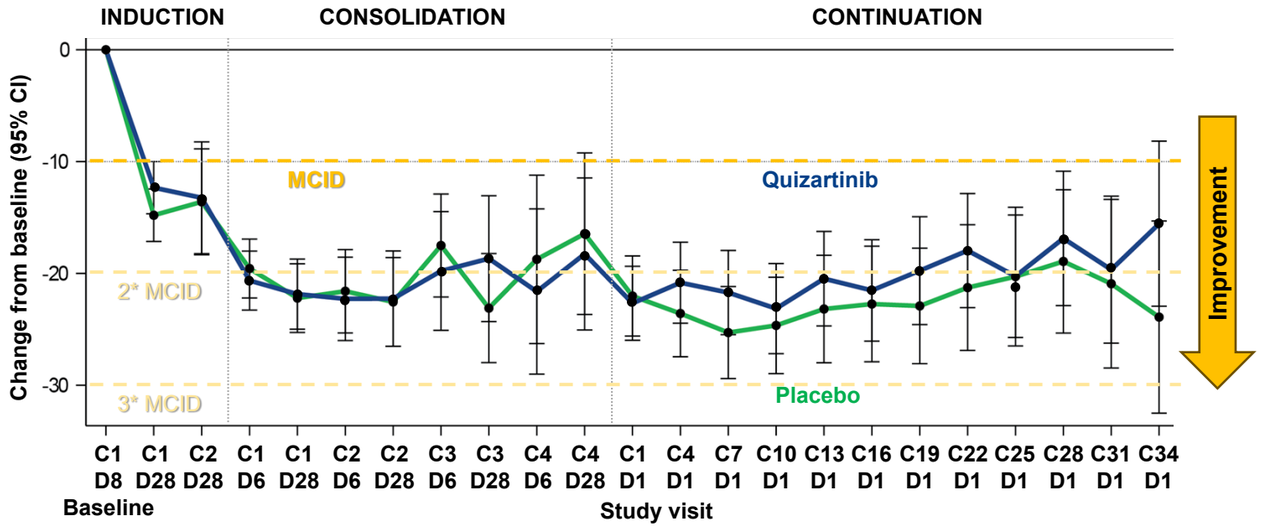
Quizartinib Placebo

Mean (±SD) at baseline: 23.4 (29.2) 23.8 (29.8)

C, cycle; D, day; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; SD, standard deviation.

EORTC QLQ-C30 Symptom Subscales MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

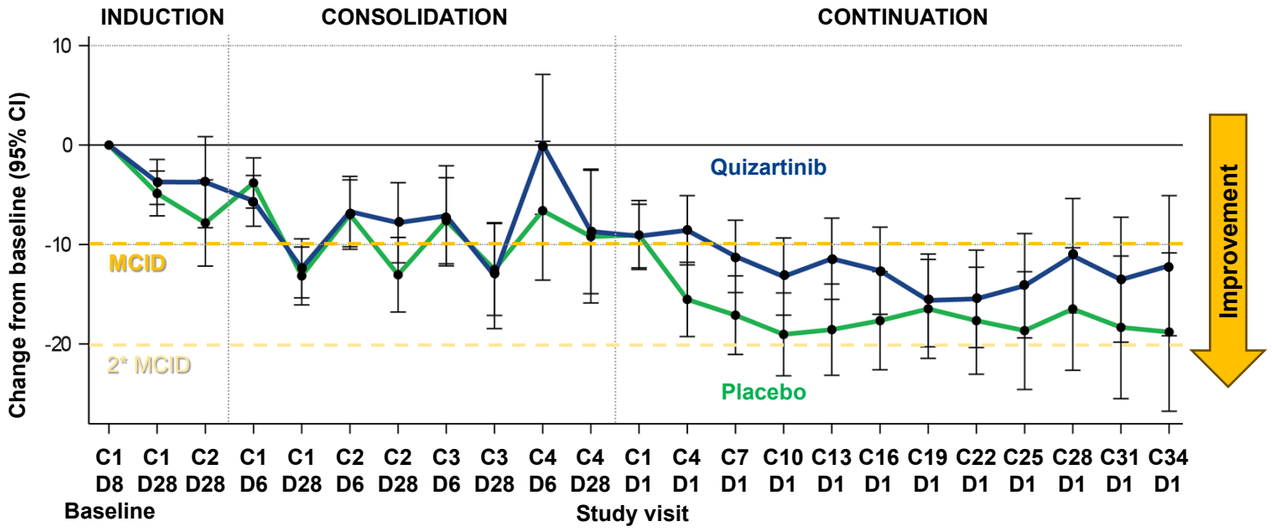
EORTC QLQ-C30 Diarrhea



No. at risk																							
Quizartinib	252	199	36	153	102	72	55	35	32	18	20	99	79	74	64	59	51	45	40	35	29	24	19
Placebo	253	197	40	153	107	71	64	47	43	17	18	84	70	62	57	45	39	40	33	27	26	18	14

Mean (±SD) at baseline:	Quizartinib	Placebo
	30.7 (35.2)	25.3 (30.5)

EORTC QLQ-C30 Nausea and vomiting



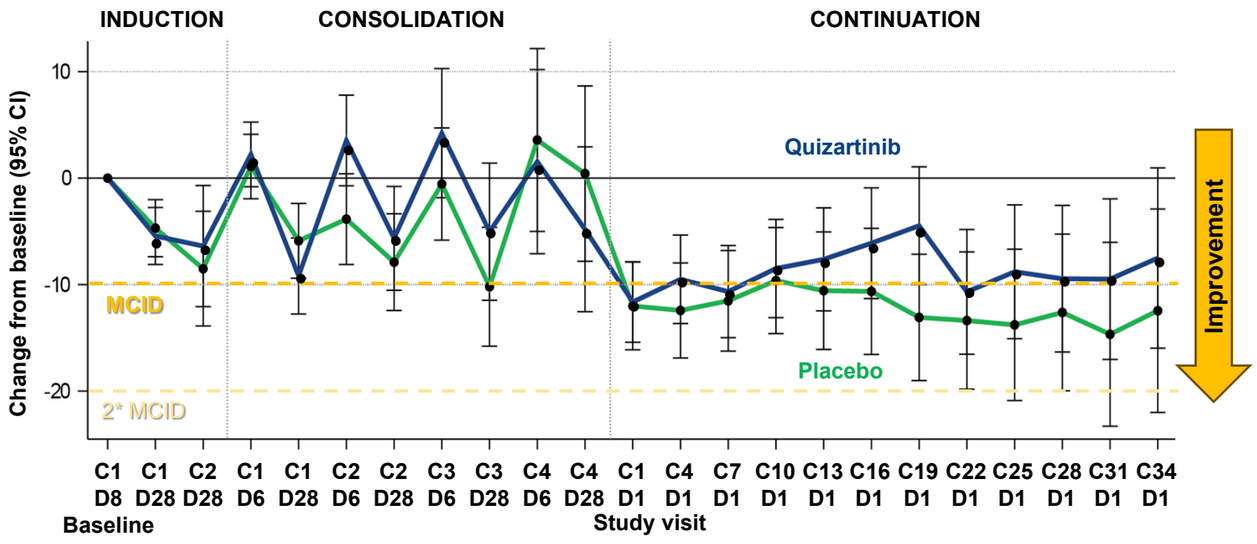
No. at risk																							
Quizartinib	251	198	36	152	102	71	55	34	32	17	20	99	78	73	63	58	50	44	40	35	29	24	19
Placebo	253	198	40	153	107	72	64	47	43	17	18	84	69	62	56	45	39	40	33	27	26	18	15

Mean (±SD) at baseline:	Quizartinib	Placebo
	19.0 (23.7)	19.7 (24.7)

C, cycle; D, day; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; SD, standard deviation.

EORTC QLQ-C30 Symptom Subscales MMRM for Change in Score From Baseline (Quizartinib vs Placebo)

EORTC QLQ-C30 Constipation

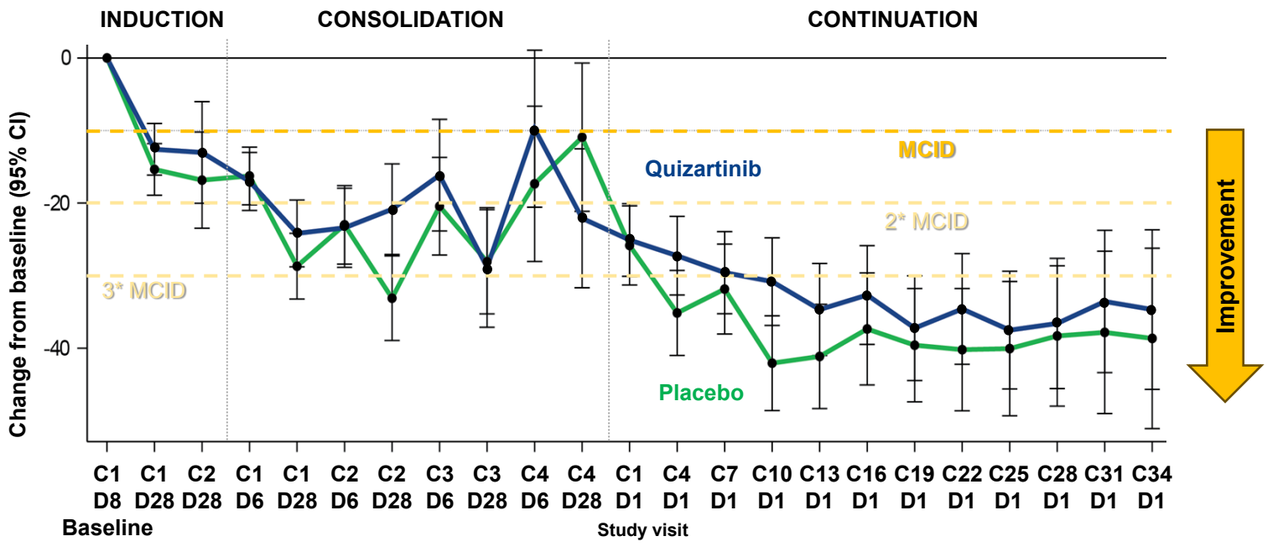


No. at risk

Quizartinib	252	199	36	153	103	72	55	35	32	17	20	100	79	74	64	59	51	45	40	35	29	24	19
Placebo	253	198	40	153	107	71	64	47	43	17	18	84	69	62	56	45	39	40	33	27	26	18	15

Mean (±SD) at baseline:	Quizartinib	Placebo
	18.7 (28.4)	15.8 (25.3)

EORTC QLQ-C30 Appetite loss



No. at risk

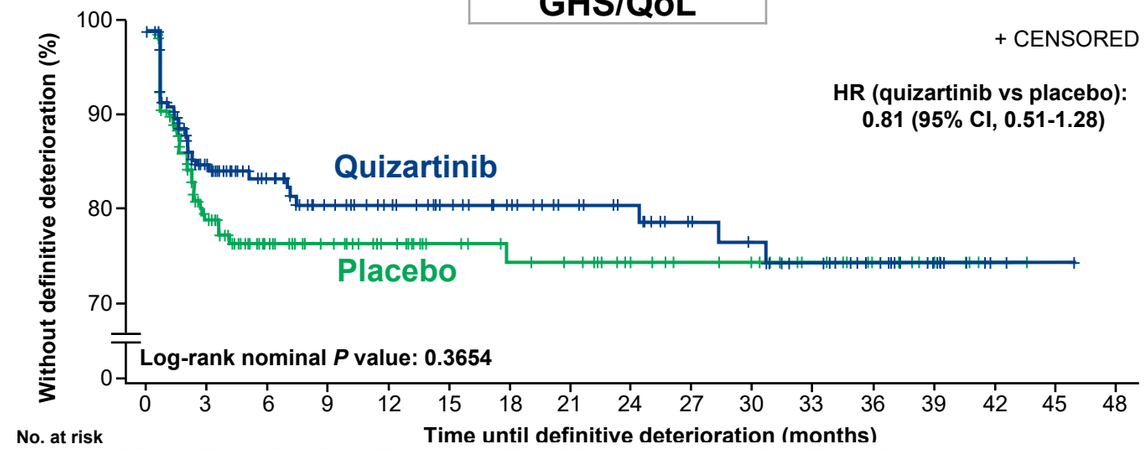
Quizartinib	252	198	36	153	103	72	55	35	32	17	20	100	79	74	64	59	51	45	40	36	29	24	19
Placebo	253	198	40	152	107	72	64	47	43	17	18	84	69	62	56	45	39	40	33	27	26	18	15

Mean (±SD) at baseline:	Quizartinib	Placebo
	45.0 (34.4)	46.5 (35.7)

C, cycle; D, day; MCID, minimal clinically important difference; MMRM, mixed model with repeated measures; SD, standard deviation.

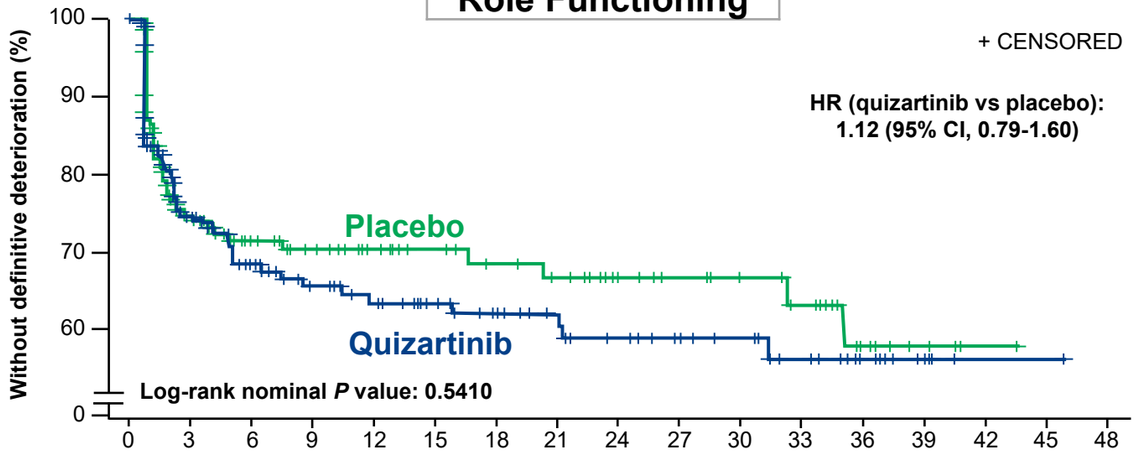
Time Until Definitive Deterioration (TUDD) of EORTC QLQ-C30

GHS/QoL



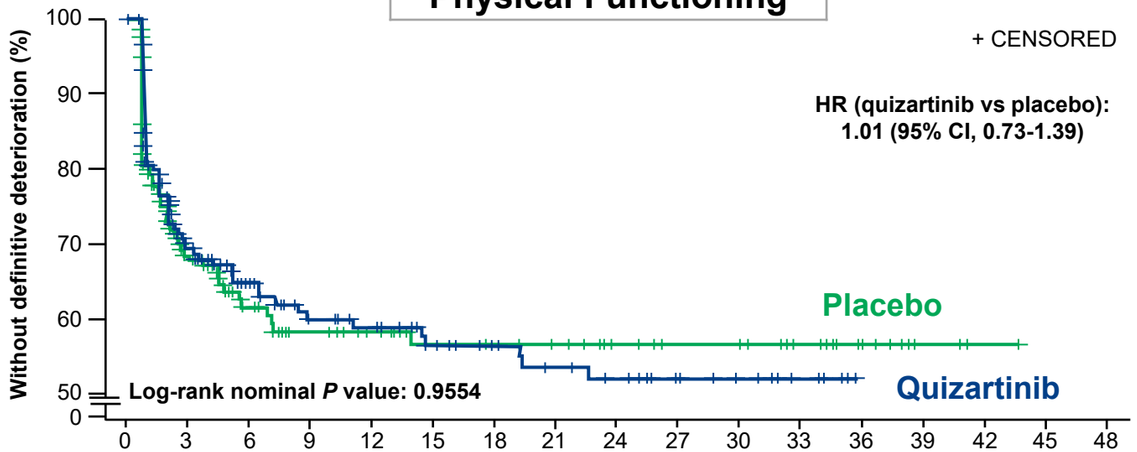
No. at risk																	
Quizartinib	252	122	95	79	70	62	56	50	46	38	35	28	18	8	2	1	0
Placebo	253	112	73	64	53	44	40	38	31	27	24	19	12	5	1	0	

Role Functioning



No. at risk																	
Quizartinib	251	108	81	66	59	51	43	38	33	27	24	18	10	4	1	1	0
Placebo	251	103	67	59	49	42	38	35	28	24	20	17	9	4	1	0	

Physical Functioning

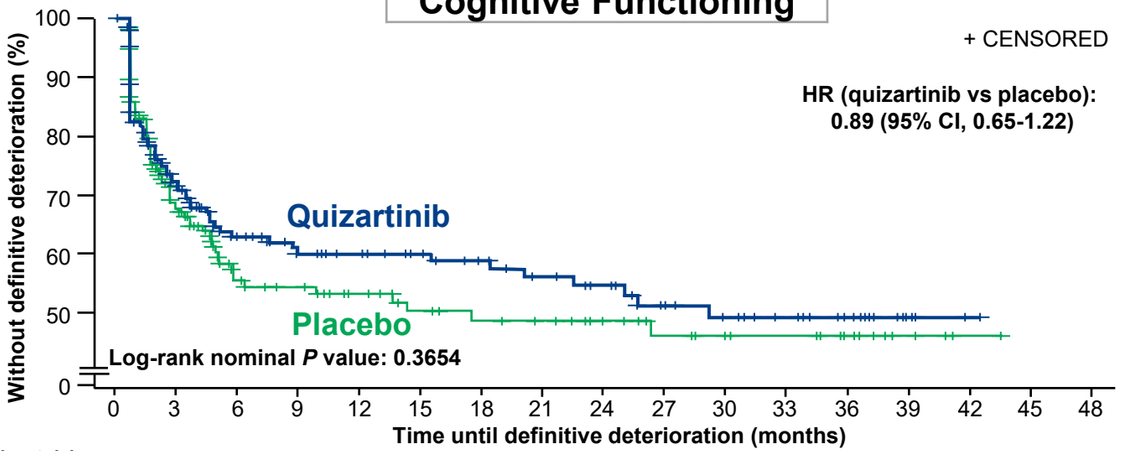


No. at risk																	
Quizartinib	249	101	71	59	54	46	40	36	33	27	24	20	13	5	1	0	
Placebo	252	95	58	48	42	34	33	31	26	22	20	16	9	3	1	0	

GHS, global health status; HR, hazard ratio; QoL, quality of life.

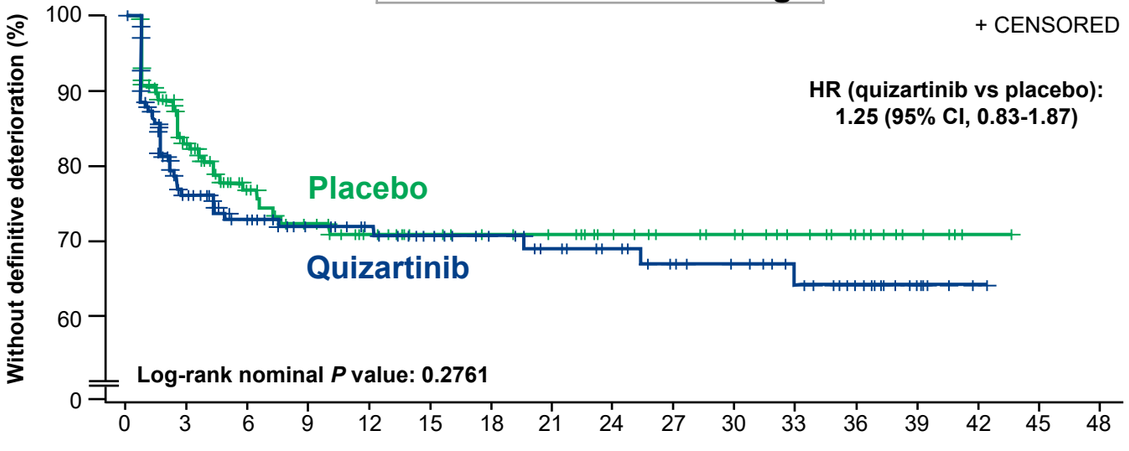
Time Until Definitive Deterioration (TUDD) of EORTC QLQ-C30

Cognitive Functioning



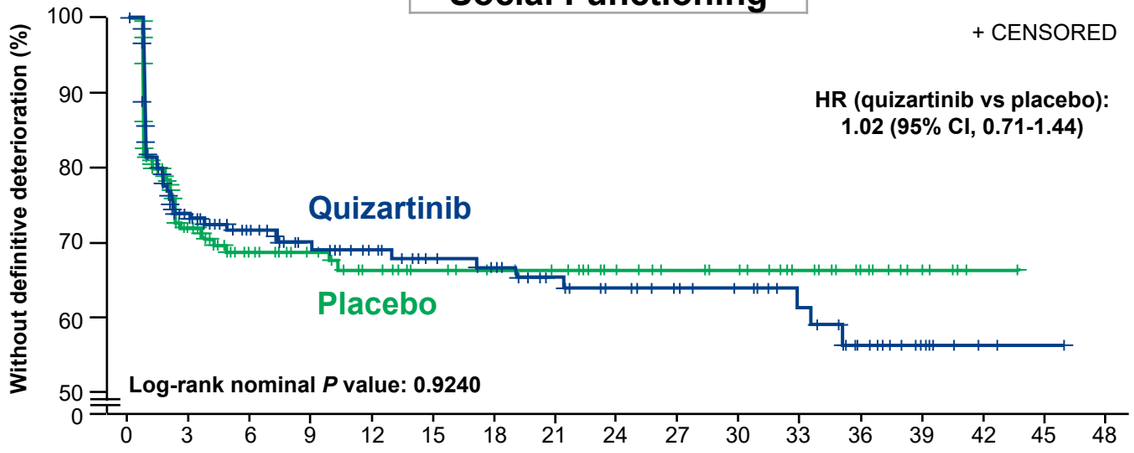
No. at risk																
Quizartinib	252	104	71	60	55	50	45	40	36	27	23	18	12	4	1	0
Placebo	253	93	54	48	40	33	30	28	23	18	14	13	9	4	1	0

Emotional Functioning



No. at risk																
Quizartinib	252	108	82	68	60	52	46	41	37	30	27	22	15	6	1	0
Placebo	253	111	70	58	49	40	37	35	29	25	22	18	12	5	1	0

Social Functioning

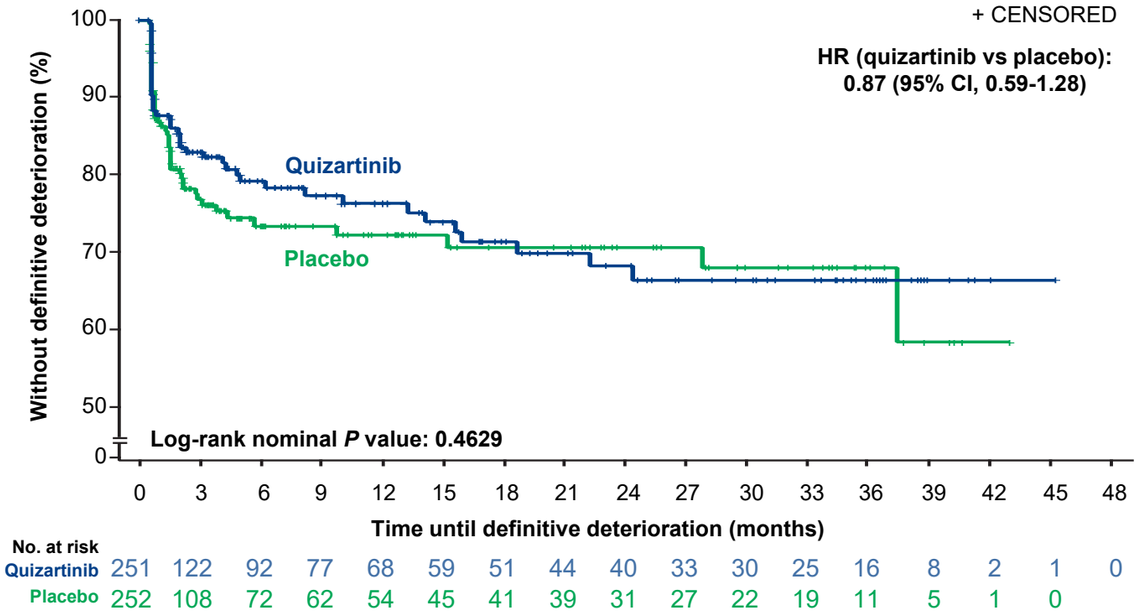


No. at risk																
Quizartinib	251	109	85	73	65	57	52	45	40	35	32	25	17	7	2	1	0
Placebo	253	101	69	61	52	45	42	40	33	29	25	19	12	5	1	0	

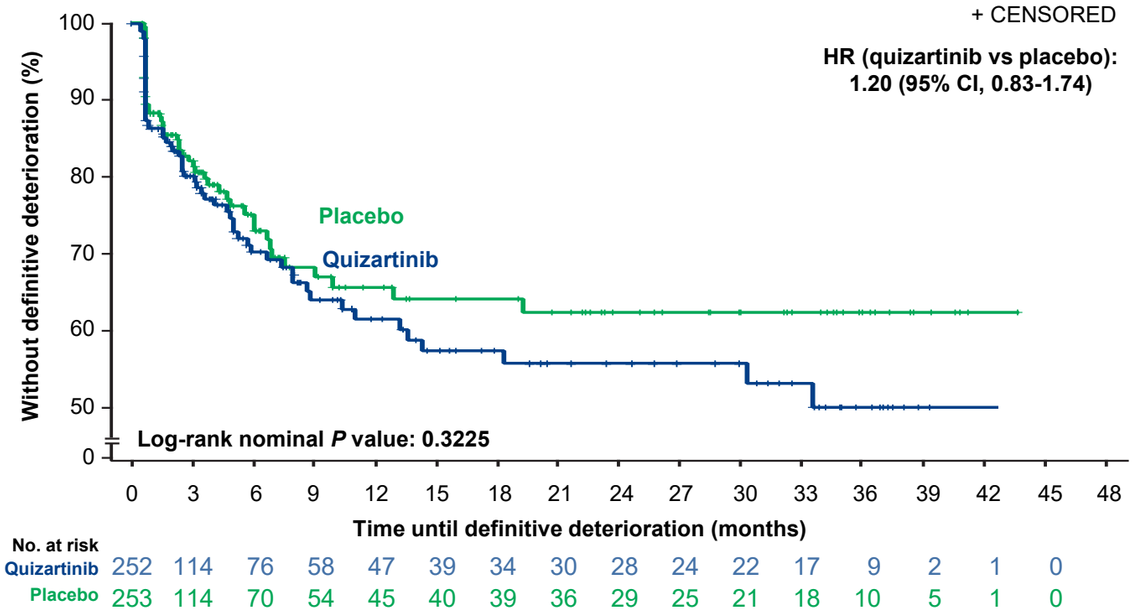
HR, hazard ratio.

Time Until Definitive Deterioration (TUDD) of EORTC QLQ-C30 Symptom Subscales

Fatigue



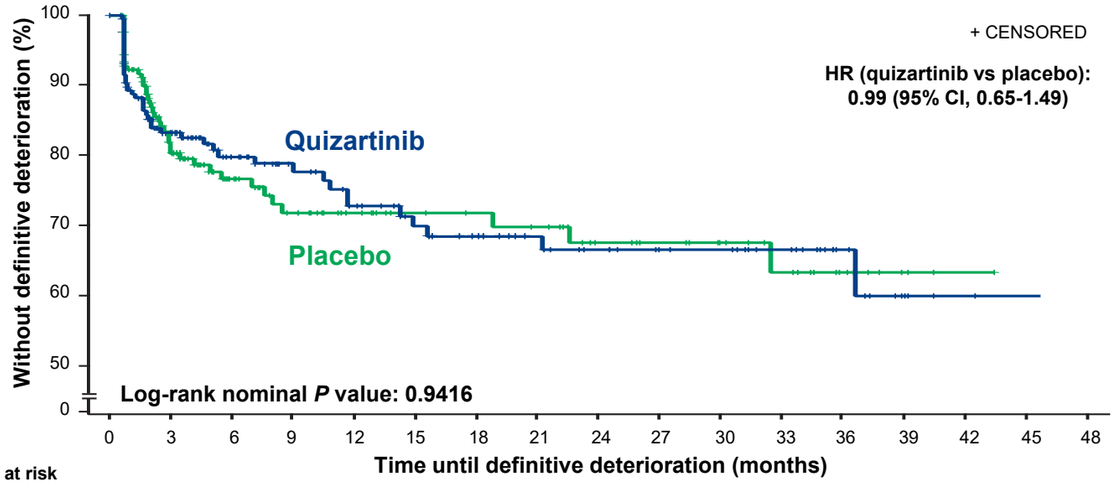
Dyspnea



HR, hazard ratio.

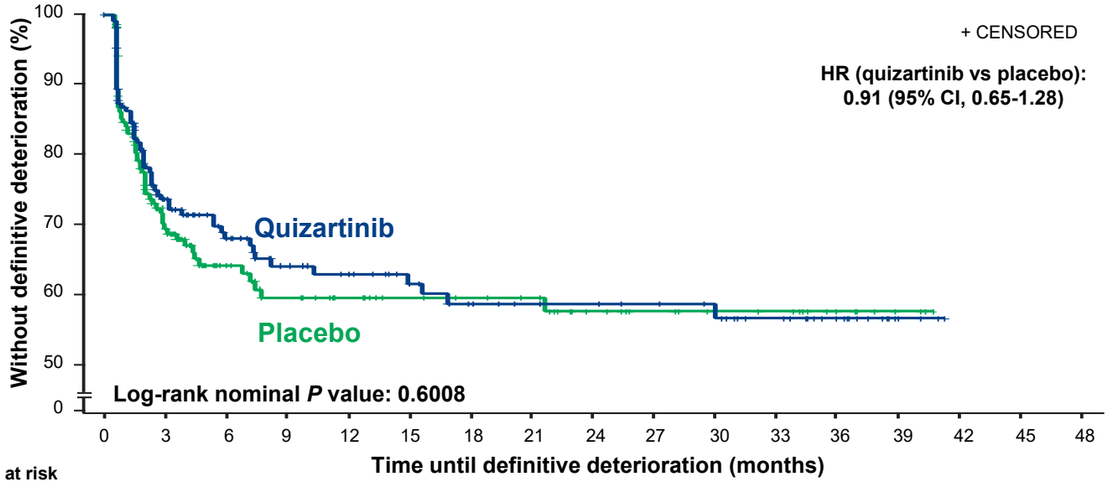
Time Until Definitive Deterioration (TUDD) of EORTC QLQ-C30 Symptom Subscales

Diarrhea



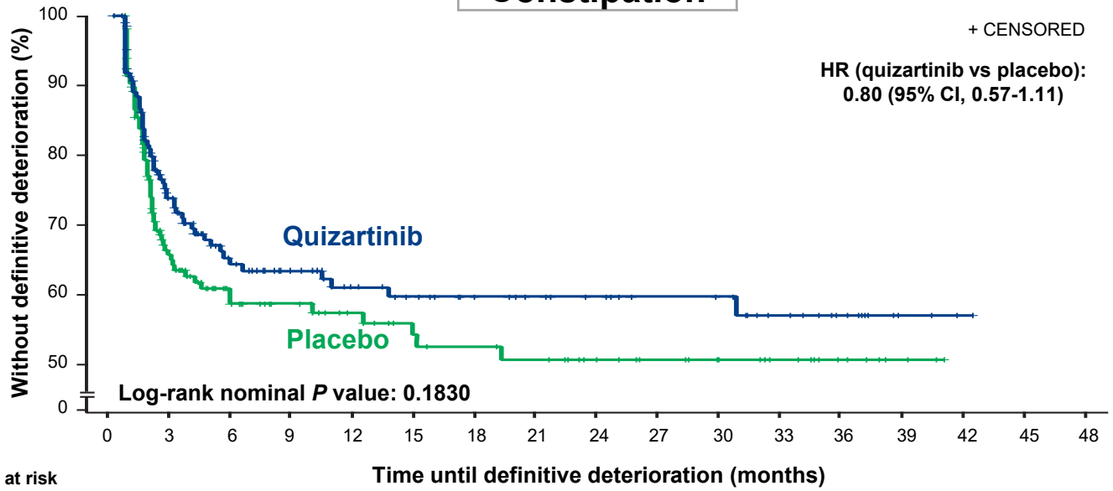
No. at risk																
Quizartinib	252	117	82	69	58	49	43	37	32	28	26	20	11	5	2	1	0
Placebo	253	107	70	57	46	39	37	35	27	23	19	15	8	3	1	0	

Nausea and Vomiting



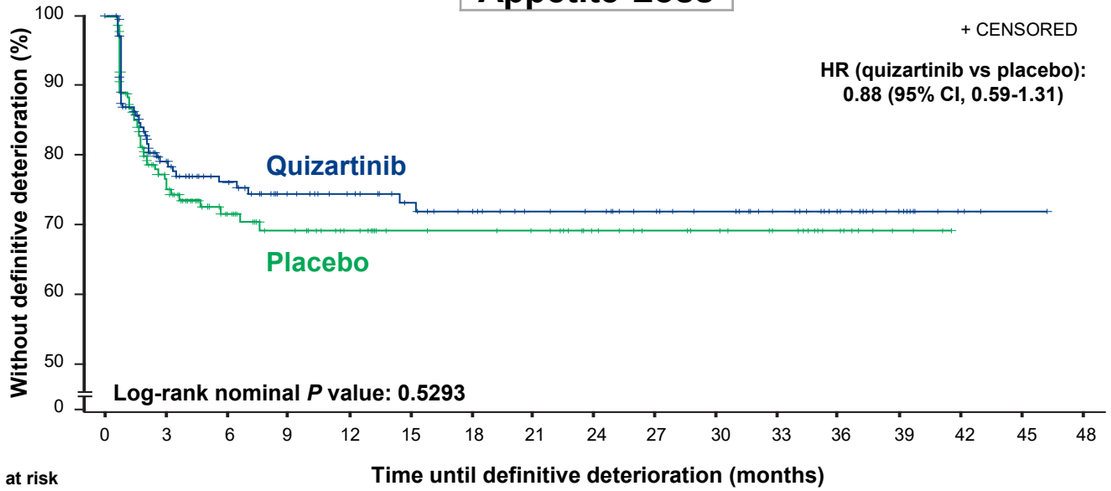
No. at risk																
Quizartinib	251	106	79	60	53	46	39	35	34	31	29	23	15	5	0	
Placebo	253	97	59	48	41	36	34	32	24	19	16	14	8	4	0	

Constipation



No. at risk																
Quizartinib	252	104	71	58	48	42	35	32	29	24	23	16	10	3	1	0
Placebo	253	87	54	47	39	32	30	28	22	19	15	12	7	3	0	

Appetite Loss



No. at risk																	
Quizartinib	252	115	90	75	67	59	53	48	45	38	35	28	17	8	2	1	0
Placebo	253	105	66	55	45	38	37	35	27	23	19	16	8	3	0		

HR, hazard ratio.

Analysis During Treatment Continuation Phase

- Propensity score weighting leads to sufficient balance/overlap to conduct further analysis in the continuation PRO ITT analysis set

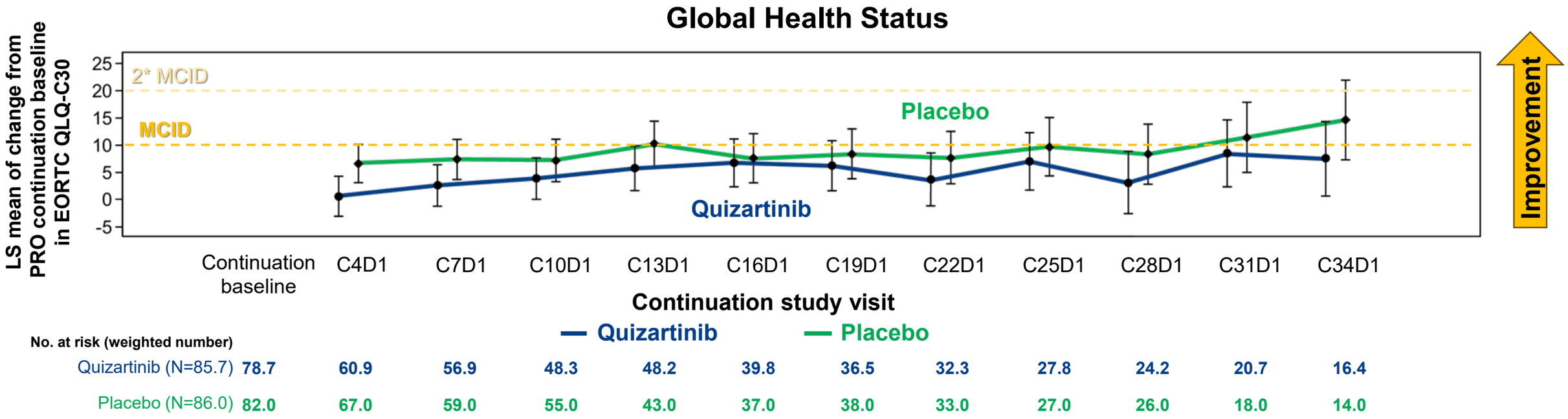
Patient Characteristics After Propensity Score Weighting: Descriptive Summary (Continuation PRO ITT Analysis Set)[a]

	Quizartinib		Placebo	
	Before weighting (N=109)	After propensity score weighting (N=85.7)	Before weighting (N=88)	After propensity score weighting (N=86.0)[b]
Median age at study baseline, years	53.0	**58.0**	57.0	**57.0**
Male sex, n (%)	52 (47.7)	**33.3 (38.8)**	35 (39.8)	**35.0 (40.7)**
WBC count at initial diagnosis <40×10^{-9}/L, n (%)	53 (48.6)	**50.9 (59.4)**	53 (60.2)	**52.0 (60.5)**
Unfavorable AML cytogenetic risk score at study baseline, n (%)	8 (7.3)	**8.0 (9.3)**	9 (10.2)	**8.0 (9.3)**
ECOG PS of 0 at study baseline	38 (34.9)	**31.0 (36.1)**	34 (38.6)	**32.0 (37.2)**
***FLT3*-ITD VAF ≥3 to ≤25%, by central laboratory testing, n (%)[c]**	41 (37.6)	**37.4 (43.6)**	41 (46.6)	**40.0 (46.5)**
***NPM1* mutational status positive at study baseline, n (%)**	64 (58.7)	**56.8 (66.2)**	57 (64.8)	**57.0 (66.3)**
Median rederived allelic ratio at study baseline	0.5	**0.4**	0.4	**0.4**
Median platelet count at study baseline	22.0	**22.0**	25.0	**25.0**

[a]Propensity score weighting conducted based on a logistic regression model with treatment as dependent variable and the variables listed in the table as independent variables. Covariance balance was assessed based on a prespecified SMD criterion of 0.1. [b]Due to missing data for some variables included in the propensity score weighting, 2 patients were removed from the placebo group to estimate the propensity scores. [c]*FLT3*-ITD VAF refers to the allelic ratio of *FLT3*-ITD/total *FLT3*. AML, acute myeloid leukemia; ECOG PS, Eastern Cooperative Oncology Group performance status; *FLT3*-ITD, FMS-like tyrosine kinase 3–internal tandem duplication; ITT, intent-to-treat; *NPM1*, nucleophosmin 1; PRO, patient reported outcome; SMD, standardized mean difference; VAF, variant allele frequency; WBC, white blood cell.

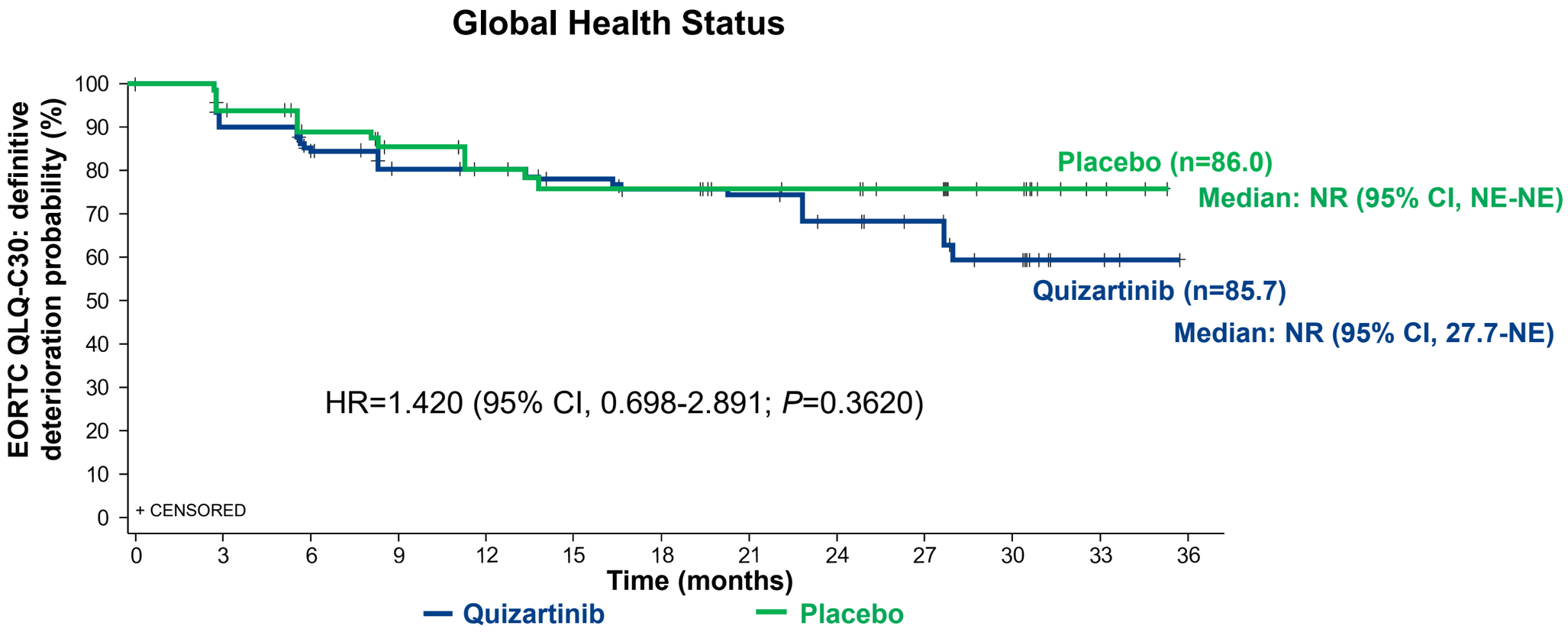
MMRM Analysis During Treatment Continuation Phase

- Plot of LS mean estimate by treatment over time (propensity score weighted) showing the change from baseline of continuation up to the end of the study
  - Baseline scores are high (mean [±SD] of 67.5 [±22.7] with quizartinib and 71.0 [±17.3] with placebo) relative to the normal population
  - There is no difference between quizartinib and placebo over time
  - QoL is maintained in both arms



C, cycle; D, day; LS, least squares; MMRM, mixed model with repeated measures; QoL, quality of life.

Time Until Definitive Deterioration (TUDD) Analysis of GHS During Treatment Continuation Phase



No. at risk (weighted number)													
Quizartinib (N=85.7)	78.7	54.1	49.3	42.2	40.6	35.8	30.0	24.7	20.5	16.9	12.4	3.6	0
Placebo (N=86.0)	82.0	58.0	51.0	39.0	34.0	31.0	28.0	23.0	22.0	18.0	13.0	3.0	0

GHS, global health status; HR, hazard ratio; ITT, intent-to-treat; NE, not estimable; NR, not reached; OS, overall survival.

Conclusions

- QuANTUM-First is the first study to explore the impact on PROs of a FLT3 inhibitor as first-line therapy that has shown a significant advantage in OS
- The EORTC QLQ-C30 has shown improvement in the QoL for all patients in the study during induction, consolidation, and maintained during continuation irrespective of the treatment arm. Patients who received quizartinib did not show negative impact in their QoL compared with the patients who received placebo
- TUDD showed that for most PRO scales, there was no consistent longitudinal difference between treatment arms
- Quizartinib showed no consistent short- or long-term deterioration of QoL and symptoms while providing a significant OS benefit in comparison with placebo

FLT3, FMS-like tyrosine kinase 3; MMRM, mixed model with repeated measures; PRO, patient-reported outcome; QoL, quality of life; TUDD, time until definitive deterioration.

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