

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Repotrectinib (AUGTYRO®)

Bristol-Myers Squibb GmbH & Co. KGaA

Modul 4B

Anhang 4-G

Fortgeschrittenes ROS1-positives NSCLC

Ergänzende Analysen

Stand: 28.04.2025

Modul 4B – Anhang 4-G - Ergänzende Analysen

Inhaltsverzeichnis Anhang 4-G

Modul 4B – Anhang 4-G - Ergänzende Analysen	2
Anhang 4-G: Ergänzende Analysen der Studie TRIDENT-1	4
Anhang 4-G 1 : Endpunkt Mortalität: Antineoplastische Folgetherapien.....	4
Anhang 4-G 2 : Endpunkte Morbidität und Lebensqualität gemäß EORTC QLQ-C30 und EORTC QLQ-LC13: Zusatzanalysen	7
Anhang 4-G 2.1 : EORTC QLQ-C30	7
Anhang 4-G 2.2 : EORTC QLQ-LC13.....	503
Anhang 4-G 3 : Endpunkte Verträglichkeit: Weitere Analysen.....	834
Anhang 4-G 3.1 : Unerwünschte Ereignisse von besonderem Interesse (UESI)	834
Anhang 4-G 3.1.1 : Jegliche UESI.....	834
Anhang 4-G 3.1.2 : Schwere UESI (UESI mit einem Schweregrad von ≥ 3 nach CTCAE)	836
Anhang 4-G 3.1.3 : Schwerwiegende UESI	838
Anhang 4-G 3.2 : UE auf SOC/PT-Ebene	840
Anhang 4-G 3.2.1 : Jegliche UE auf SOC/PT-Ebene	840
Anhang 4-G 3.2.2 : Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE) auf SOC/PT-Ebene	870
Anhang 4-G 3.2.3 : Schwerwiegende UE auf SOC/PT-Ebene	880
Anhang 4-G 3.2.4 : Zum Therapieabbruch führende UE auf SOC/PT-Ebene	888
Anhang 4-G 4 : Subgruppenanalysen.....	891
Anhang 4-G 4.1 : Endpunkt Mortalität – Gesamtüberleben (OS).....	891
Anhang 4-G 4.2 : Endpunkte Verträglichkeit.....	894
Anhang 4-G 4.2.1 : Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE)	894
Anhang 4-G 4.2.2 : Schwerwiegende UE	897
Anhang 4-G 4.2.3 : Zum Therapieabbruch führende UE	900
Anhang 4-G 4.2.4 : Jegliche UESI.....	903
Anhang 4-G 5 : Kaplan-Meier-Kurven	906
Anhang 4-G 5.1 : Kaplan-Meier-Kurven für den Endpunkt Dauer des Ansprechens (DOR) gemäß BICR.....	906
Anhang 4-G 5.2 : Kaplan-Meier-Kurven für den Endpunkt Dauer des intrakraniellen Ansprechens (IC-DOR) gemäß BICR	908
Anhang 4-G 5.3 : Kaplan-Meier-Kurven für den Endpunkt intrakranielles progressionsfreies Überleben (IC-PFS) gemäß BICR.....	910
Anhang 4-G 6 : Übersicht der den UESI zugrundeliegenden MedDRA-Terme.....	912
Anhang 4-G 7 : Indirekter Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA	923
Anhang 4-G 7.1 : Kaplan-Meier-Kurven für den Endpunkt Gesamtüberleben für den indirekten Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA.....	923
Anhang 4-G 7.2 : Kaplan-Meier-Kurven für den Endpunkt progressionsfreies Überleben für den indirekten Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA	925

Anhang 4-G: Ergänzende Analysen der Studie TRIDENT-1

Anhang 4-G 1: Endpunkt Mortalität: Antineoplastische Folgetherapien

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table B.9.1
Subsequent Anti-Cancer Therapies Summary
Safety Set for ROS1+

ATC Level 2 Generic Drug Names	TKI-naïve subjects N = 116	TKI-pretreated subjects N = 106
SUBJECTS WHO DISCONTINUED STUDY TREATMENT, N(%) (1)	61 (52.6)	77 (72.6)
SUBJECTS WITH ANY SUBSEQUENT ANTI-CANCER THERAPY, N(%) (2)	36 (59.0)	45 (58.4)
CHEMOTHERAPY	16 (13.8)	24 (22.6)
CARBOPLATIN	8 (6.9)	16 (15.1)
CISPLATIN	2 (1.7)	7 (6.6)
DOCETAXEL	1 (0.9)	0
GEMCITABINE	0	2 (1.9)
NEDAPLATIN	1 (0.9)	0
PACLITAXEL	2 (1.7)	1 (0.9)
PEMETREXED	11 (9.5)	15 (14.2)
IMMUNOTHERAPY	4 (3.4)	6 (5.7)
ATEZOLIZUMAB	1 (0.9)	2 (1.9)
PEMBROLIZUMAB	2 (1.7)	3 (2.8)
SUGEMALIMAB	0	1 (0.9)
TISLELIZUMAB INJECTION	1 (0.9)	0
OTHER TARGETED THERAPY	3 (2.6)	7 (6.6)
ANLOTINIB	1 (0.9)	0
BEVACIZUMAB	2 (1.7)	5 (4.7)
BINIMETINIB	0	1 (0.9)
CAPMATINIB	0	1 (0.9)
DS-1062A Q3W	0	1 (0.9)
OTHER THERAPY	0	1 (0.9)
ENDOSTATIN	0	1 (0.9)
TUMOR NECROSIS FACTOR	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

(1) Percentages are based on the total number of subjects in the corresponding cohort.

(2) Percentages are based on the total number of subjects who discontinued study treatment.

If a subject received one or more subsequent anti-cancer therapies, the subject is counted once at each level reported.

Categories are sorted alphabetically and within each Category generic drug names are also sorted alphabetically.

All subsequent anti-cancer therapies are included, not only the first one.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-dm-stsum-ebr2365.sas

24JUL2024:13:06:15

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table B.9.1
Subsequent Anti-Cancer Therapies Summary
Safety Set for ROS1+

ATC Level 2 Generic Drug Names	TKI-naïve subjects N = 116	TKI-pretreated subjects N = 106
TKI	20 (17.2)	22 (20.8)
CABOZANTINIB	0	1 (0.9)
CRIZOTINIB	9 (7.8)	2 (1.9)
ENTRECTINIB	5 (4.3)	4 (3.8)
LORLATINIB	3 (2.6)	11 (10.4)
NVL-520	2 (1.7)	5 (4.7)
TALETRECTINIB	1 (0.9)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

(1) Percentages are based on the total number of subjects in the corresponding cohort.

(2) Percentages are based on the total number of subjects who discontinued study treatment.

If a subject received one or more subsequent anti-cancer therapies, the subject is counted once at each level reported.

Categories are sorted alphabetically and within each Category generic drug names are also sorted alphabetically.

All subsequent anti-cancer therapies are included, not only the first one.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-dm-stsum-ebr2365.sas

24JUL2024:13:06:15

Anhang 4-G 2: Endpunkte Morbidität und Lebensqualität gemäß EORTC QLQ-C30 und EORTC QLQ-LC13: Zusatzanalysen

Anhang 4-G 2.1: EORTC QLQ-C30

Deskription der einzelnen Skalen des EORTC QLC-C30 sowie deren Veränderung gegenüber Baseline im Studienverlauf

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
GLOBAL HEALTH STATUS		
BASELINE		
N	112	104
MEAN	66.22	58.49
SD	22.920	23.854
MEDIAN	66.67	58.33
Q1, Q3	50.00, 83.33	41.67, 83.33
MIN, MAX	8.3, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	61.78	63.70
SD	22.862	21.027
MEDIAN	66.67	66.67
Q1, Q3	45.83, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-4.41	3.80
SD	23.512	20.265
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 75.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;
QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2
portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	66.17	64.29
SD	20.337	20.395
MEDIAN	66.67	66.67
Q1, Q3	54.17, 83.33	50.00, 83.33
MIN, MAX	8.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	-1.00	1.79
SD	24.079	23.179
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-8.33, 16.67
MIN, MAX	-83.3, 66.7	-66.7, 58.3
CYCLE 4		
N	97	81
MEAN	65.21	65.64
SD	22.277	19.693
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	25.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-0.69	4.32
SD	25.151	23.315
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-75.0, 66.7	-58.3, 58.3
CYCLE 5		
N	93	73
MEAN	66.58	62.44
SD	19.640	21.612
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-0.82	0.91
SD	23.377	23.999
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-8.33, 8.33
MIN, MAX	-50.0, 66.7	-83.3, 58.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	65.31	61.59
SD	21.076	19.866
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-3.53	-0.12
SD	23.862	22.664
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-58.3, 58.3	-66.7, 58.3
CYCLE 7		
N	89	65
MEAN	66.76	62.31
SD	20.002	20.839
MEDIAN	66.67	66.67
Q1, Q3	58.33, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	16.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-1.99	1.15
SD	23.873	19.812
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 50.0	-50.0, 50.0
CYCLE 8		
N	82	57
MEAN	66.26	61.55
SD	20.450	19.905
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	0.0, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-2.98	1.02
SD	24.127	23.203
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-83.3, 50.0	-50.0, 58.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	64.88	60.82
SD	19.749	22.711
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	0.0, 100.0	8.3, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-4.32	-1.61
SD	22.480	26.514
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 58.3	-66.7, 50.0
CYCLE 10		
N	80	54
MEAN	65.42	56.79
SD	20.417	23.796
MEDIAN	66.67	54.17
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	-4.32	-4.78
SD	22.323	28.804
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 8.33
MIN, MAX	-66.7, 58.3	-100.0, 58.3
CYCLE 11		
N	72	47
MEAN	65.63	62.06
SD	22.593	19.721
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-4.05	-0.71
SD	23.151	22.241
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-66.7, 41.7	-66.7, 41.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 8 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	65.24	62.50
SD	22.876	19.413
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-5.19	0.00
SD	25.086	23.426
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-83.3, 50.0	-66.7, 50.0
CYCLE 13		
N	73	40
MEAN	64.38	61.25
SD	22.917	24.645
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	8.3, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 9 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-4.86	-2.50
SD	22.059	27.748
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 41.7	-83.3, 58.3
CYCLE 14		
N	55	27
MEAN	64.70	63.27
SD	22.565	21.590
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-4.32	4.01
SD	25.325	31.553
MEDIAN	0.00	8.33
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 50.0	-83.3, 58.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 10 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	66.41	63.02
SD	21.668	19.622
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 79.17
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-2.91	-0.52
SD	23.049	25.570
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-58.3, 50.0	-83.3, 50.0
CYCLE 16		
N	58	29
MEAN	61.49	63.22
SD	21.336	19.735
MEDIAN	58.33	66.67
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 11 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-7.31	0.29
SD	24.043	27.139
MEDIAN	0.00	0.00
Q1, Q3	-25.00, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 41.7	-83.3, 58.3
CYCLE 17		
N	56	31
MEAN	62.95	64.78
SD	21.957	21.700
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-7.29	-1.61
SD	21.026	25.947
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-83.3, 58.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 12 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	59.29	57.61
SD	24.065	25.240
MEDIAN	66.67	58.33
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-5.39	-2.54
SD	26.102	29.987
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-8.33, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 41.7
CYCLE 19		
N	45	28
MEAN	62.04	66.37
SD	21.213	19.041
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	54.17, 83.33
MIN, MAX	16.7, 100.0	16.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 13 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-7.04	-0.30
SD	24.487	23.840
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	-16.67, 12.50
MIN, MAX	-66.7, 50.0	-66.7, 41.7
CYCLE 20		
N	31	17
MEAN	60.75	64.71
SD	20.092	20.312
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	16.7, 100.0	25.0, 91.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-5.83	5.88
SD	23.484	29.428
MEDIAN	-4.17	8.33
Q1, Q3	-16.67, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-58.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 14 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	62.84	67.59
SD	18.901	22.120
MEDIAN	66.67	70.83
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	8.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-4.95	5.09
SD	22.945	26.062
MEDIAN	-8.33	8.33
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-50.0, 58.3	-50.0, 58.3
CYCLE 22		
N	44	13
MEAN	61.17	62.82
SD	21.786	28.181
MEDIAN	66.67	66.67
Q1, Q3	50.00, 79.17	41.67, 83.33
MIN, MAX	16.7, 100.0	16.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 15 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-7.75	-3.85
SD	25.026	30.735
MEDIAN	-8.33	-8.33
Q1, Q3	-25.00, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 50.0	-58.3, 58.3
CYCLE 23		
N	28	10
MEAN	58.93	65.83
SD	18.416	20.582
MEDIAN	50.00	66.67
Q1, Q3	50.00, 70.83	58.33, 83.33
MIN, MAX	16.7, 100.0	33.3, 91.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-6.85	-3.33
SD	19.779	33.380
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 4.17	-16.67, 8.33
MIN, MAX	-41.7, 50.0	-50.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 16 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	57.76	62.50
SD	21.003	26.425
MEDIAN	66.67	66.67
Q1, Q3	50.00, 66.67	33.33, 83.33
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-11.49	-1.67
SD	24.338	30.631
MEDIAN	-16.67	0.00
Q1, Q3	-25.00, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-50.0, 58.3
CYCLE 25		
N	35	13
MEAN	62.38	66.67
SD	21.425	18.942
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 17 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-7.86	0.00
SD	20.407	25.230
MEDIAN	-8.33	0.00
Q1, Q3	-25.00, 0.00	-16.67, 0.00
MIN, MAX	-41.7, 41.7	-50.0, 50.0
CYCLE 26		
N	20	9
MEAN	55.00	50.93
SD	24.543	18.840
MEDIAN	54.17	58.33
Q1, Q3	37.50, 70.83	33.33, 66.67
MIN, MAX	0.0, 100.0	16.7, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-11.25	-8.33
SD	22.503	25.000
MEDIAN	-8.33	-8.33
Q1, Q3	-33.33, 4.17	-16.67, 0.00
MIN, MAX	-41.7, 41.7	-50.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 18 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	53.67	61.81
SD	24.305	25.980
MEDIAN	58.33	62.50
Q1, Q3	33.33, 66.67	37.50, 83.33
MIN, MAX	0.0, 83.3	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-13.33	-7.64
SD	23.936	16.839
MEDIAN	-8.33	-4.17
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-58.3, 41.7	-50.0, 16.7
CYCLE 28		
N	30	9
MEAN	61.39	62.04
SD	22.899	19.145
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	50.00, 75.00
MIN, MAX	16.7, 100.0	33.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 19 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-11.67	-1.85
SD	17.589	28.191
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-50.0, 33.3	-50.0, 50.0
CYCLE 29		
N	18	7
MEAN	55.09	63.10
SD	25.905	21.440
MEDIAN	58.33	66.67
Q1, Q3	33.33, 83.33	33.33, 83.33
MIN, MAX	0.0, 83.3	33.3, 83.3
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-12.50	0.00
SD	24.959	35.026
MEDIAN	-16.67	0.00
Q1, Q3	-25.00, 8.33	-25.00, 16.67
MIN, MAX	-50.0, 41.7	-50.0, 58.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 20 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	60.71	59.52
SD	22.070	27.398
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	33.33, 75.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-11.51	-5.95
SD	20.995	29.936
MEDIAN	-8.33	-8.33
Q1, Q3	-25.00, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-50.0, 50.0
CYCLE 31		
N	23	6
MEAN	67.39	43.06
SD	22.178	13.351
MEDIAN	66.67	37.50
Q1, Q3	50.00, 83.33	33.33, 50.00
MIN, MAX	16.7, 100.0	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 21 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	-5.07	-20.83
SD	25.714	23.422
MEDIAN	0.00	-25.00
Q1, Q3	-16.67, 8.33	-33.33, -8.33
MIN, MAX	-50.0, 66.7	-50.0, 16.7
CYCLE 32		
N	16	4
MEAN	57.29	47.92
SD	24.128	14.232
MEDIAN	54.17	45.83
Q1, Q3	33.33, 83.33	37.50, 58.33
MIN, MAX	16.7, 83.3	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	-16.15	0.00
SD	19.595	35.355
MEDIAN	-16.67	12.50
Q1, Q3	-29.17, 0.00	-25.00, 25.00
MIN, MAX	-50.0, 16.7	-50.0, 25.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 22 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	61.46	61.67
SD	24.509	24.721
MEDIAN	66.67	58.33
Q1, Q3	50.00, 83.33	50.00, 66.67
MIN, MAX	16.7, 91.7	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-6.77	-10.00
SD	26.739	30.277
MEDIAN	-4.17	-16.67
Q1, Q3	-29.17, 12.50	-16.67, 0.00
MIN, MAX	-58.3, 41.7	-50.0, 33.3
CYCLE 34		
N	20	4
MEAN	61.25	56.25
SD	21.507	18.478
MEDIAN	66.67	58.33
Q1, Q3	50.00, 83.33	41.67, 70.83
MIN, MAX	16.7, 83.3	33.3, 75.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 23 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-10.83	-8.33
SD	21.477	37.884
MEDIAN	-12.50	-12.50
Q1, Q3	-20.83, 0.00	-33.33, 16.67
MIN, MAX	-50.0, 41.7	-50.0, 41.7
CYCLE 35		
N	13	4
MEAN	62.82	68.75
SD	26.487	25.797
MEDIAN	66.67	75.00
Q1, Q3	50.00, 83.33	50.00, 87.50
MIN, MAX	16.7, 100.0	33.3, 91.7
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-8.33	-4.17
SD	23.074	49.768
MEDIAN	-8.33	-16.67
Q1, Q3	-16.67, 8.33	-33.33, 25.00
MIN, MAX	-50.0, 25.0	-50.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 24 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	61.54	50.00
SD	22.958	23.570
MEDIAN	66.67	50.00
Q1, Q3	50.00, 83.33	33.33, 66.67
MIN, MAX	16.7, 83.3	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-13.46	-4.17
SD	18.490	64.818
MEDIAN	-8.33	-4.17
Q1, Q3	-16.67, 0.00	-50.00, 41.67
MIN, MAX	-50.0, 8.3	-50.0, 41.7
CYCLE 37		
N	14	2
MEAN	67.26	58.33
SD	19.738	35.355
MEDIAN	66.67	58.33
Q1, Q3	66.67, 83.33	33.33, 83.33
MIN, MAX	16.7, 83.3	33.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 25 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-5.95	-33.33
SD	25.409	23.570
MEDIAN	0.00	-33.33
Q1, Q3	-16.67, 8.33	-50.00, -16.67
MIN, MAX	-50.0, 50.0	-50.0, -16.7
CYCLE 38		
N	11	2
MEAN	63.64	45.83
SD	19.462	17.678
MEDIAN	66.67	45.83
Q1, Q3	50.00, 83.33	33.33, 58.33
MIN, MAX	16.7, 83.3	33.3, 58.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-5.30	-8.33
SD	26.686	58.926
MEDIAN	0.00	-8.33
Q1, Q3	-25.00, 8.33	-50.00, 33.33
MIN, MAX	-50.0, 50.0	-50.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 26 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	67.71	63.89
SD	19.127	26.788
MEDIAN	66.67	75.00
Q1, Q3	66.67, 83.33	33.33, 83.33
MIN, MAX	25.0, 83.3	33.3, 83.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-6.25	-5.56
SD	17.678	50.918
MEDIAN	-4.17	-16.67
Q1, Q3	-12.50, 4.17	-50.00, 50.00
MIN, MAX	-41.7, 16.7	-50.0, 50.0
CYCLE 40		
N	11	3
MEAN	65.91	61.11
SD	20.566	25.459
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	33.33, 83.33
MIN, MAX	16.7, 83.3	33.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 27 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-6.06	-8.33
SD	24.464	46.398
MEDIAN	-8.33	-16.67
Q1, Q3	-16.67, 0.00	-50.00, 41.67
MIN, MAX	-50.0, 50.0	-50.0, 41.7
CYCLE 41		
N	9	0
MEAN	62.04	
SD	21.695	
MEDIAN	66.67	
Q1, Q3	50.00, 83.33	
MIN, MAX	16.7, 83.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-7.41	
SD	28.700	
MEDIAN	0.00	
Q1, Q3	-25.00, 0.00	
MIN, MAX	-50.0, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 28 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	58.33	83.33
SD	25.276	N.A.
MEDIAN	58.33	83.33
Q1, Q3	50.00, 83.33	83.33, 83.33
MIN, MAX	16.7, 83.3	83.3, 83.3
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-12.50	-16.67
SD	25.139	N.A.
MEDIAN	-12.50	-16.67
Q1, Q3	-25.00, 8.33	-16.67, -16.67
MIN, MAX	-50.0, 16.7	-16.7, -16.7
CYCLE 43		
N	5	0
MEAN	68.33	
SD	12.360	
MEDIAN	66.67	
Q1, Q3	66.67, 75.00	
MIN, MAX	50.0, 83.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 29 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-15.00	
SD	16.029	
MEDIAN	-16.67	
Q1, Q3	-25.00, -8.33	
MIN, MAX	-33.3, 8.3	
CYCLE 44		
N	3	0
MEAN	72.22	
SD	19.245	
MEDIAN	83.33	
Q1, Q3	50.00, 83.33	
MIN, MAX	50.0, 83.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-5.56	
SD	17.347	
MEDIAN	0.00	
Q1, Q3	-25.00, 8.33	
MIN, MAX	-25.0, 8.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 30 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	71.67	
SD	17.280	
MEDIAN	75.00	
Q1, Q3	75.00, 83.33	
MIN, MAX	41.7, 83.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-11.67	
SD	13.944	
MEDIAN	-8.33	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	72.22	
SD	19.245	
MEDIAN	83.33	
Q1, Q3	50.00, 83.33	
MIN, MAX	50.0, 83.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 31 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	17.347	
MEDIAN	-16.67	
Q1, Q3	-25.00, 8.33	
MIN, MAX	-25.0, 8.3	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-41.67	
SD	N.A.	
MEDIAN	-41.67	
Q1, Q3	-41.67, -41.67	
MIN, MAX	-41.7, -41.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 32 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-25.00	
SD	N.A.	
MEDIAN	-25.00	
Q1, Q3	-25.00, -25.00	
MIN, MAX	-25.0, -25.0	
CYCLE 49		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 33 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-25.00	
SD	N.A.	
MEDIAN	-25.00	
Q1, Q3	-25.00, -25.00	
MIN, MAX	-25.0, -25.0	
END OF TREATMENT		
N	32	45
MEAN	46.88	46.67
SD	22.175	27.775
MEDIAN	50.00	50.00
Q1, Q3	33.33, 66.67	16.67, 66.67
MIN, MAX	0.0, 83.3	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-12.24	-11.67
SD	24.409	28.449
MEDIAN	-16.67	-8.33
Q1, Q3	-25.00, 8.33	-33.33, 8.33
MIN, MAX	-66.7, 33.3	-83.3, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 34 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PHYSICAL FUNCTIONING		
BASELINE		
N	112	104
MEAN	77.32	78.29
SD	22.487	21.701
MEDIAN	86.67	86.67
Q1, Q3	66.67, 93.33	66.67, 93.33
MIN, MAX	0.0, 100.0	6.7, 100.0
CYCLE 2		
N	104	91
MEAN	78.13	78.00
SD	20.998	22.065
MEDIAN	86.67	86.67
Q1, Q3	66.67, 93.33	66.67, 100.00
MIN, MAX	13.3, 100.0	13.3, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-0.21	-0.92
SD	23.238	14.968
MEDIAN	0.00	0.00
Q1, Q3	-7.50, 13.33	-6.67, 6.67
MIN, MAX	-66.7, 53.3	-40.0, 45.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 35 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	77.46	77.22
SD	23.763	22.031
MEDIAN	86.67	80.00
Q1, Q3	66.67, 93.33	60.00, 93.33
MIN, MAX	13.3, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-0.76	-4.54
SD	25.024	17.429
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 13.33	-13.33, 0.00
MIN, MAX	-80.0, 53.3	-46.7, 46.7
CYCLE 4		
N	97	81
MEAN	77.47	76.15
SD	22.238	21.998
MEDIAN	86.67	80.00
Q1, Q3	66.67, 93.33	60.00, 93.33
MIN, MAX	13.3, 100.0	13.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 36 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-1.30	-4.28
SD	21.482	18.727
MEDIAN	0.00	-5.00
Q1, Q3	-13.33, 6.67	-13.33, 6.67
MIN, MAX	-80.0, 53.3	-53.3, 46.7
CYCLE 5		
N	93	73
MEAN	80.65	78.36
SD	18.755	20.691
MEDIAN	86.67	86.67
Q1, Q3	66.67, 100.00	66.67, 93.33
MIN, MAX	26.7, 100.0	13.3, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	1.45	-4.09
SD	18.591	20.384
MEDIAN	0.00	0.00
Q1, Q3	-6.67, 13.33	-13.33, 6.67
MIN, MAX	-53.3, 53.3	-53.3, 60.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 37 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	78.01	75.24
SD	21.665	22.476
MEDIAN	86.67	80.00
Q1, Q3	66.67, 100.00	66.67, 93.33
MIN, MAX	6.7, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-1.47	-6.76
SD	20.050	23.265
MEDIAN	0.00	-6.67
Q1, Q3	-13.33, 6.67	-13.33, 0.00
MIN, MAX	-60.0, 60.0	-66.7, 46.7
CYCLE 7		
N	89	65
MEAN	80.90	73.03
SD	19.467	22.621
MEDIAN	86.67	73.33
Q1, Q3	73.33, 100.00	60.00, 86.67
MIN, MAX	26.7, 100.0	13.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 38 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	0.45	-7.97
SD	19.464	20.859
MEDIAN	0.00	-6.67
Q1, Q3	-13.33, 13.33	-20.00, 0.00
MIN, MAX	-53.3, 53.3	-66.7, 33.3
CYCLE 8		
N	82	57
MEAN	79.11	73.16
SD	20.575	22.629
MEDIAN	86.67	80.00
Q1, Q3	66.67, 100.00	60.00, 86.67
MIN, MAX	13.3, 100.0	13.3, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-2.80	-7.22
SD	21.522	22.426
MEDIAN	0.00	0.00
Q1, Q3	-13.33, 6.67	-20.00, 6.67
MIN, MAX	-60.0, 53.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 39 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	80.40	73.95
SD	18.666	22.442
MEDIAN	86.67	80.00
Q1, Q3	66.67, 100.00	60.00, 86.67
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-0.72	-7.19
SD	19.395	23.566
MEDIAN	0.00	-6.67
Q1, Q3	-13.33, 6.67	-13.33, 0.00
MIN, MAX	-46.7, 46.7	-93.3, 46.7
CYCLE 10		
N	81	54
MEAN	78.27	70.74
SD	19.742	25.025
MEDIAN	86.67	80.00
Q1, Q3	66.67, 93.33	53.33, 86.67
MIN, MAX	26.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 40 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-3.42	-10.62
SD	20.210	24.624
MEDIAN	-3.33	-6.67
Q1, Q3	-13.33, 6.67	-20.00, 0.00
MIN, MAX	-66.7, 53.3	-66.7, 60.0
CYCLE 11		
N	72	47
MEAN	77.20	76.31
SD	23.133	22.190
MEDIAN	80.00	80.00
Q1, Q3	66.67, 100.00	66.67, 93.33
MIN, MAX	13.3, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-4.47	-7.23
SD	22.472	22.961
MEDIAN	0.00	-6.67
Q1, Q3	-13.33, 6.67	-20.00, 0.00
MIN, MAX	-66.7, 40.0	-66.7, 60.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 41 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	78.10	72.70
SD	22.619	24.186
MEDIAN	86.67	80.00
Q1, Q3	66.67, 100.00	53.33, 93.33
MIN, MAX	13.3, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-4.83	-10.16
SD	23.870	23.246
MEDIAN	0.00	-6.67
Q1, Q3	-20.00, 6.67	-20.00, 0.00
MIN, MAX	-60.0, 60.0	-66.7, 66.7
CYCLE 13		
N	73	40
MEAN	76.80	73.33
SD	21.318	27.756
MEDIAN	80.00	80.00
Q1, Q3	60.00, 93.33	56.67, 100.00
MIN, MAX	20.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 42 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-4.54	-9.33
SD	22.317	24.752
MEDIAN	0.00	-6.67
Q1, Q3	-16.67, 6.67	-20.00, 0.00
MIN, MAX	-53.3, 40.0	-86.7, 73.3
CYCLE 14		
N	55	27
MEAN	75.76	72.65
SD	20.301	25.429
MEDIAN	80.00	80.00
Q1, Q3	66.67, 93.33	66.67, 93.33
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-3.70	-9.81
SD	22.306	23.932
MEDIAN	0.00	-6.67
Q1, Q3	-13.33, 6.67	-20.00, 0.00
MIN, MAX	-60.0, 53.3	-86.7, 40.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 43 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	75.38	65.63
SD	22.667	29.723
MEDIAN	80.00	70.00
Q1, Q3	60.00, 100.00	40.00, 93.33
MIN, MAX	13.3, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-5.83	-16.67
SD	21.789	24.944
MEDIAN	0.00	-13.33
Q1, Q3	-20.00, 6.67	-23.33, 0.00
MIN, MAX	-60.0, 46.7	-80.0, 26.7
CYCLE 16		
N	58	29
MEAN	75.86	73.56
SD	22.576	26.516
MEDIAN	80.00	80.00
Q1, Q3	60.00, 100.00	60.00, 93.33
MIN, MAX	20.0, 100.0	6.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 44 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-4.21	-11.03
SD	21.626	23.923
MEDIAN	0.00	-6.67
Q1, Q3	-20.00, 6.67	-13.33, 0.00
MIN, MAX	-60.0, 46.7	-80.0, 26.7
CYCLE 17		
N	56	31
MEAN	76.19	73.55
SD	23.159	25.150
MEDIAN	80.00	80.00
Q1, Q3	60.00, 100.00	53.33, 100.00
MIN, MAX	6.7, 100.0	13.3, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-6.79	-11.18
SD	22.256	21.388
MEDIAN	0.00	-6.67
Q1, Q3	-20.00, 6.67	-20.00, 0.00
MIN, MAX	-66.7, 40.0	-73.3, 26.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 45 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	70.67	68.12
SD	26.082	30.349
MEDIAN	73.33	80.00
Q1, Q3	60.00, 93.33	40.00, 100.00
MIN, MAX	0.0, 100.0	6.7, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-6.47	-14.78
SD	23.469	27.411
MEDIAN	-6.67	0.00
Q1, Q3	-20.00, 6.67	-20.00, 0.00
MIN, MAX	-66.7, 40.0	-80.0, 26.7
CYCLE 19		
N	45	28
MEAN	72.30	73.10
SD	24.698	27.246
MEDIAN	73.33	83.33
Q1, Q3	53.33, 100.00	56.67, 100.00
MIN, MAX	6.7, 100.0	13.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 46 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-10.37	-14.05
SD	26.306	23.750
MEDIAN	-6.67	-6.67
Q1, Q3	-26.67, 0.00	-23.33, 0.00
MIN, MAX	-73.3, 53.3	-73.3, 26.7
CYCLE 20		
N	31	17
MEAN	72.26	78.82
SD	23.795	20.444
MEDIAN	73.33	80.00
Q1, Q3	60.00, 93.33	66.67, 100.00
MIN, MAX	20.0, 100.0	40.0, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-6.89	-8.24
SD	25.340	18.489
MEDIAN	0.00	-6.67
Q1, Q3	-20.00, 6.67	-20.00, 0.00
MIN, MAX	-66.7, 53.3	-53.3, 26.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 47 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	73.87	78.52
SD	23.168	25.003
MEDIAN	73.33	90.00
Q1, Q3	60.00, 100.00	60.00, 100.00
MIN, MAX	13.3, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-7.21	-6.67
SD	26.123	17.564
MEDIAN	0.00	-3.33
Q1, Q3	-26.67, 6.67	-13.33, 0.00
MIN, MAX	-60.0, 53.3	-53.3, 26.7
CYCLE 22		
N	44	13
MEAN	73.79	73.85
SD	25.975	25.886
MEDIAN	76.67	80.00
Q1, Q3	56.67, 100.00	46.67, 100.00
MIN, MAX	6.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 48 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-8.22	-12.82
SD	26.180	23.007
MEDIAN	0.00	-6.67
Q1, Q3	-26.67, 6.67	-26.67, 0.00
MIN, MAX	-73.3, 53.3	-60.0, 13.3
CYCLE 23		
N	28	10
MEAN	69.05	66.00
SD	24.425	30.542
MEDIAN	73.33	80.00
Q1, Q3	53.33, 90.00	46.67, 86.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-10.00	-16.00
SD	25.756	19.676
MEDIAN	-6.67	-16.67
Q1, Q3	-26.67, 0.00	-20.00, 0.00
MIN, MAX	-73.3, 53.3	-60.0, 13.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 49 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	76.32	68.00
SD	20.593	27.720
MEDIAN	80.00	80.00
Q1, Q3	66.67, 93.33	46.67, 86.67
MIN, MAX	33.3, 100.0	20.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-5.75	-15.33
SD	21.729	17.512
MEDIAN	0.00	-13.33
Q1, Q3	-13.33, 0.00	-13.33, -6.67
MIN, MAX	-53.3, 40.0	-60.0, 0.0
CYCLE 25		
N	35	13
MEAN	75.24	69.74
SD	22.204	23.192
MEDIAN	73.33	73.33
Q1, Q3	60.00, 100.00	46.67, 86.67
MIN, MAX	26.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 50 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-8.76	-16.92
SD	25.451	22.871
MEDIAN	0.00	-13.33
Q1, Q3	-33.33, 6.67	-26.67, 0.00
MIN, MAX	-60.0, 40.0	-60.0, 20.0
CYCLE 26		
N	20	9
MEAN	72.33	62.96
SD	26.865	25.410
MEDIAN	76.67	60.00
Q1, Q3	60.00, 96.67	40.00, 86.67
MIN, MAX	6.7, 100.0	33.3, 93.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-8.00	-20.74
SD	29.940	26.341
MEDIAN	0.00	-13.33
Q1, Q3	-23.33, 6.67	-26.67, -6.67
MIN, MAX	-86.7, 40.0	-60.0, 20.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 51 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	67.73	65.56
SD	27.600	30.858
MEDIAN	73.33	76.67
Q1, Q3	46.67, 93.33	33.33, 93.33
MIN, MAX	13.3, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-13.33	-21.11
SD	32.660	27.973
MEDIAN	-6.67	-13.33
Q1, Q3	-40.00, 6.67	-46.67, 0.00
MIN, MAX	-73.3, 46.7	-66.7, 13.3
CYCLE 28		
N	30	9
MEAN	73.11	67.41
SD	25.460	25.043
MEDIAN	80.00	80.00
Q1, Q3	46.67, 100.00	40.00, 86.67
MIN, MAX	20.0, 100.0	40.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 52 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-11.78	-17.78
SD	25.949	21.858
MEDIAN	-3.33	-13.33
Q1, Q3	-33.33, 6.67	-26.67, 0.00
MIN, MAX	-66.7, 40.0	-53.3, 13.3
CYCLE 29		
N	18	7
MEAN	65.56	66.67
SD	22.434	21.430
MEDIAN	66.67	80.00
Q1, Q3	60.00, 80.00	40.00, 86.67
MIN, MAX	13.3, 100.0	40.0, 86.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-13.33	-16.19
SD	30.336	22.063
MEDIAN	-13.33	-13.33
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-80.0, 40.0	-53.3, 13.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 53 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	78.73	65.71
SD	19.278	21.919
MEDIAN	80.00	73.33
Q1, Q3	66.67, 93.33	40.00, 86.67
MIN, MAX	40.0, 100.0	33.3, 86.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-3.81	-19.05
SD	24.090	19.024
MEDIAN	0.00	-13.33
Q1, Q3	-20.00, 6.67	-26.67, -6.67
MIN, MAX	-40.0, 46.7	-53.3, 6.7
CYCLE 31		
N	23	7
MEAN	80.00	59.05
SD	20.597	27.333
MEDIAN	86.67	46.67
Q1, Q3	66.67, 100.00	33.33, 86.67
MIN, MAX	40.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 54 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-1.74	-23.81
SD	26.759	27.717
MEDIAN	0.00	-26.67
Q1, Q3	-20.00, 6.67	-53.33, 0.00
MIN, MAX	-53.3, 60.0	-53.3, 20.0
CYCLE 32		
N	17	4
MEAN	71.37	56.67
SD	22.702	17.638
MEDIAN	66.67	60.00
Q1, Q3	53.33, 93.33	43.33, 70.00
MIN, MAX	33.3, 100.0	33.3, 73.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-9.80	-20.00
SD	26.679	35.694
MEDIAN	-6.67	-23.33
Q1, Q3	-26.67, 0.00	-43.33, 3.33
MIN, MAX	-53.3, 40.0	-60.0, 26.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 55 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	72.08	64.00
SD	23.629	32.523
MEDIAN	73.33	73.33
Q1, Q3	56.67, 90.00	33.33, 86.67
MIN, MAX	20.0, 100.0	26.7, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-5.42	-29.33
SD	32.407	31.482
MEDIAN	0.00	-26.67
Q1, Q3	-23.33, 6.67	-60.00, -13.33
MIN, MAX	-73.3, 60.0	-60.0, 13.3
CYCLE 34		
N	20	4
MEAN	74.67	68.33
SD	22.952	23.960
MEDIAN	80.00	76.67
Q1, Q3	50.00, 93.33	53.33, 83.33
MIN, MAX	40.0, 100.0	33.3, 86.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 56 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-6.67	-26.67
SD	24.566	23.727
MEDIAN	0.00	-20.00
Q1, Q3	-20.00, 6.67	-43.33, -10.00
MIN, MAX	-53.3, 40.0	-60.0, -6.7
CYCLE 35		
N	13	4
MEAN	73.85	71.67
SD	20.810	25.748
MEDIAN	73.33	83.33
Q1, Q3	60.00, 93.33	56.67, 86.67
MIN, MAX	40.0, 100.0	33.3, 86.7
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-7.69	-20.00
SD	24.623	27.217
MEDIAN	0.00	-10.00
Q1, Q3	-33.33, 6.67	-36.67, -3.33
MIN, MAX	-46.7, 40.0	-60.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 57 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	76.92	46.67
SD	18.582	9.428
MEDIAN	80.00	46.67
Q1, Q3	66.67, 93.33	40.00, 53.33
MIN, MAX	46.7, 100.0	40.0, 53.3
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-5.64	-43.33
SD	23.229	14.142
MEDIAN	0.00	-43.33
Q1, Q3	-13.33, 6.67	-53.33, -33.33
MIN, MAX	-46.7, 40.0	-53.3, -33.3
CYCLE 37		
N	14	2
MEAN	79.52	60.00
SD	17.239	28.284
MEDIAN	83.33	60.00
Q1, Q3	66.67, 93.33	40.00, 80.00
MIN, MAX	46.7, 100.0	40.0, 80.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 58 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-2.86	-30.00
SD	22.451	32.998
MEDIAN	0.00	-30.00
Q1, Q3	-20.00, 6.67	-53.33, -6.67
MIN, MAX	-40.0, 40.0	-53.3, -6.7
CYCLE 38		
N	11	2
MEAN	77.58	33.33
SD	19.612	9.428
MEDIAN	80.00	33.33
Q1, Q3	66.67, 93.33	26.67, 40.00
MIN, MAX	40.0, 100.0	26.7, 40.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-1.82	-56.67
SD	27.823	4.714
MEDIAN	0.00	-56.67
Q1, Q3	-26.67, 6.67	-60.00, -53.33
MIN, MAX	-40.0, 46.7	-60.0, -53.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 59 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	79.17	60.00
SD	19.980	17.638
MEDIAN	80.00	66.67
Q1, Q3	70.00, 96.67	40.00, 73.33
MIN, MAX	40.0, 100.0	40.0, 73.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-10.00	-28.89
SD	14.693	21.430
MEDIAN	-6.67	-20.00
Q1, Q3	-16.67, 0.00	-53.33, -13.33
MIN, MAX	-40.0, 6.7	-53.3, -13.3
CYCLE 40		
N	11	3
MEAN	80.61	57.78
SD	17.500	19.245
MEDIAN	80.00	46.67
Q1, Q3	73.33, 100.00	46.67, 80.00
MIN, MAX	46.7, 100.0	46.7, 80.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 60 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-4.24	-31.11
SD	18.202	21.430
MEDIAN	0.00	-40.00
Q1, Q3	-20.00, 6.67	-46.67, -6.67
MIN, MAX	-33.3, 33.3	-46.7, -6.7
CYCLE 41		
N	9	0
MEAN	80.00	
SD	13.744	
MEDIAN	80.00	
Q1, Q3	73.33, 86.67	
MIN, MAX	60.0, 100.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-2.22	
SD	15.635	
MEDIAN	-6.67	
Q1, Q3	-13.33, 0.00	
MIN, MAX	-20.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 61 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	75.56	80.00
SD	16.689	N.A.
MEDIAN	73.33	80.00
Q1, Q3	66.67, 86.67	80.00, 80.00
MIN, MAX	53.3, 100.0	80.0, 80.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-12.22	-6.67
SD	12.939	N.A.
MEDIAN	-10.00	-6.67
Q1, Q3	-26.67, -6.67	-6.67, -6.67
MIN, MAX	-26.7, 6.7	-6.7, -6.7
CYCLE 43		
N	5	0
MEAN	85.33	
SD	16.600	
MEDIAN	86.67	
Q1, Q3	80.00, 100.00	
MIN, MAX	60.0, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 62 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-8.00	
SD	15.202	
MEDIAN	-6.67	
Q1, Q3	-6.67, 0.00	
MIN, MAX	-33.3, 6.7	
CYCLE 44		
N	3	0
MEAN	84.44	
SD	13.878	
MEDIAN	80.00	
Q1, Q3	73.33, 100.00	
MIN, MAX	73.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-6.67	
SD	13.333	
MEDIAN	-6.67	
Q1, Q3	-20.00, 6.67	
MIN, MAX	-20.0, 6.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 63 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	89.33	
SD	12.111	
MEDIAN	93.33	
Q1, Q3	80.00, 100.00	
MIN, MAX	73.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-4.00	
SD	10.111	
MEDIAN	0.00	
Q1, Q3	-6.67, 0.00	
MIN, MAX	-20.0, 6.7	
CYCLE 46		
N	3	0
MEAN	84.44	
SD	16.777	
MEDIAN	86.67	
Q1, Q3	66.67, 100.00	
MIN, MAX	66.7, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 64 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	16.777	
MEDIAN	-13.33	
Q1, Q3	-26.67, 6.67	
MIN, MAX	-26.7, 6.7	
CYCLE 47		
N	1	0
MEAN	46.67	
SD	N.A.	
MEDIAN	46.67	
Q1, Q3	46.67, 46.67	
MIN, MAX	46.7, 46.7	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-46.67	
SD	N.A.	
MEDIAN	-46.67	
Q1, Q3	-46.67, -46.67	
MIN, MAX	-46.7, -46.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 65 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-26.67	
SD	N.A.	
MEDIAN	-26.67	
Q1, Q3	-26.67, -26.67	
MIN, MAX	-26.7, -26.7	
CYCLE 49		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 66 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-26.67	
SD	N.A.	
MEDIAN	-26.67	
Q1, Q3	-26.67, -26.67	
MIN, MAX	-26.7, -26.7	
END OF TREATMENT		
N	32	45
MEAN	61.88	60.00
SD	25.072	32.443
MEDIAN	63.33	60.00
Q1, Q3	43.33, 83.33	40.00, 86.67
MIN, MAX	6.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-11.88	-17.30
SD	29.316	29.893
MEDIAN	-10.00	-13.33
Q1, Q3	-33.33, 6.67	-33.33, 0.00
MIN, MAX	-80.0, 60.0	-73.3, 53.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 67 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
ROLE FUNCTIONING		
BASELINE		
N	112	104
MEAN	71.88	68.27
SD	29.172	33.132
MEDIAN	75.00	83.33
Q1, Q3	58.33, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	70.67	71.79
SD	26.326	31.397
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-1.44	3.11
SD	32.106	26.047
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-100.0, 83.3	-66.7, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 68 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	70.63	72.02
SD	30.925	28.242
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-1.65	-1.79
SD	34.921	29.726
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-100.0, 100.0	-66.7, 83.3
CYCLE 4		
N	97	81
MEAN	70.96	71.19
SD	28.390	30.506
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 69 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-2.43	-1.65
SD	31.713	32.124
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-100.0, 83.3	-83.3, 83.3
CYCLE 5		
N	93	73
MEAN	75.63	71.23
SD	25.955	29.300
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	1.27	-3.42
SD	28.413	31.422
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 83.3	-83.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 70 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	75.48	69.32
SD	25.012	28.672
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-0.39	-5.07
SD	28.003	35.735
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 83.3	-100.0, 83.3
CYCLE 7		
N	89	65
MEAN	75.28	66.15
SD	26.246	29.311
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 71 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-0.38	-8.21
SD	29.467	35.737
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-83.3, 66.7	-100.0, 66.7
CYCLE 8		
N	82	57
MEAN	73.98	70.47
SD	26.332	26.914
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-3.09	-2.63
SD	30.289	33.893
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-83.3, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 72 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	73.41	68.13
SD	25.232	27.328
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-3.41	-5.56
SD	26.257	30.592
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 50.0	-100.0, 50.0
CYCLE 10		
N	81	54
MEAN	73.87	65.43
SD	24.712	30.689
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 73 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-3.75	-9.26
SD	25.014	37.150
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 50.0	-100.0, 66.7
CYCLE 11		
N	72	47
MEAN	72.69	71.99
SD	29.907	27.388
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-3.94	-5.32
SD	29.931	32.805
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-83.3, 50.0	-83.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 74 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	72.86	68.25
SD	29.238	29.634
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-3.86	-9.13
SD	30.804	34.571
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-83.3, 83.3
CYCLE 13		
N	73	40
MEAN	70.78	71.67
SD	28.704	31.169
MEDIAN	66.67	75.00
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 75 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-5.79	-5.83
SD	32.036	39.504
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-33.33, 16.67
MIN, MAX	-83.3, 66.7	-83.3, 83.3
CYCLE 14		
N	55	27
MEAN	71.82	69.14
SD	25.025	28.005
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-2.47	-6.17
SD	29.568	34.328
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 76 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	70.00	60.42
SD	29.196	33.534
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 91.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-7.03	-15.63
SD	32.774	34.114
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-83.3, 66.7
CYCLE 16		
N	58	29
MEAN	70.69	67.24
SD	29.338	30.041
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 77 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-5.85	-9.77
SD	31.731	31.026
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-83.3, 50.0	-83.3, 50.0
CYCLE 17		
N	56	31
MEAN	71.43	66.67
SD	27.287	31.032
MEDIAN	66.67	66.67
Q1, Q3	58.33, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-9.52	-12.90
SD	27.681	40.072
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 50.0	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 78 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	68.10	62.32
SD	29.806	32.651
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-1.47	-13.77
SD	30.805	41.939
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 66.7
CYCLE 19		
N	45	28
MEAN	67.78	69.05
SD	30.855	32.620
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 79 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-11.48	-14.88
SD	36.380	37.499
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-83.3, 83.3
CYCLE 20		
N	31	17
MEAN	65.05	74.51
SD	26.996	27.712
MEDIAN	66.67	66.67
Q1, Q3	50.00, 83.33	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-11.67	-2.94
SD	34.227	34.478
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 80 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	68.92	71.30
SD	31.221	32.240
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-9.46	-4.63
SD	36.333	31.210
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-16.67, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 50.0
CYCLE 22		
N	44	13
MEAN	66.67	69.23
SD	31.745	32.522
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 81 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-12.40	-10.26
SD	35.091	33.705
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 66.7	-66.7, 66.7
CYCLE 23		
N	28	10
MEAN	60.12	60.00
SD	28.810	28.545
MEDIAN	66.67	66.67
Q1, Q3	41.67, 83.33	50.00, 83.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-16.07	-26.67
SD	34.984	21.082
MEDIAN	-16.67	-25.00
Q1, Q3	-50.00, 8.33	-33.33, -16.67
MIN, MAX	-66.7, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 82 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	69.54	63.33
SD	27.120	29.187
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-10.92	-11.67
SD	30.301	27.273
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 50.0	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	68.57	65.38
SD	31.512	30.017
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	50.00, 83.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 83 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-12.86	-14.10
SD	33.354	35.905
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 50.0	-100.0, 33.3
CYCLE 26		
N	20	9
MEAN	63.33	50.00
SD	31.807	31.180
MEDIAN	66.67	66.67
Q1, Q3	41.67, 100.00	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-14.17	-27.78
SD	40.923	36.324
MEDIAN	-8.33	-33.33
Q1, Q3	-41.67, 8.33	-50.00, 0.00
MIN, MAX	-100.0, 66.7	-83.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 84 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	60.00	59.72
SD	36.641	29.694
MEDIAN	66.67	50.00
Q1, Q3	33.33, 100.00	33.33, 91.67
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-17.33	-23.61
SD	47.502	27.941
MEDIAN	-16.67	-16.67
Q1, Q3	-50.00, 0.00	-50.00, 0.00
MIN, MAX	-100.0, 83.3	-66.7, 0.0
CYCLE 28		
N	30	9
MEAN	71.67	68.52
SD	33.088	24.216
MEDIAN	83.33	66.67
Q1, Q3	33.33, 100.00	66.67, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 85 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-13.33	-7.41
SD	35.124	32.394
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-66.7, 50.0	-66.7, 33.3
CYCLE 29		
N	18	7
MEAN	55.56	66.67
SD	31.829	21.517
MEDIAN	66.67	66.67
Q1, Q3	33.33, 66.67	50.00, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-21.30	-14.29
SD	43.086	39.002
MEDIAN	-16.67	-16.67
Q1, Q3	-66.67, 0.00	-50.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 86 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	71.43	66.67
SD	26.427	25.459
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 83.33
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-9.52	-11.90
SD	30.538	36.911
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 50.0	-66.7, 50.0
CYCLE 31		
N	23	7
MEAN	72.46	52.38
SD	29.133	17.817
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	33.33, 66.67
MIN, MAX	16.7, 100.0	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 87 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-6.52	-19.05
SD	36.146	32.530
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-66.7, 33.3
CYCLE 32		
N	17	4
MEAN	60.78	50.00
SD	28.224	19.245
MEDIAN	66.67	50.00
Q1, Q3	33.33, 66.67	33.33, 66.67
MIN, MAX	16.7, 100.0	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-17.65	-16.67
SD	37.947	43.033
MEDIAN	-16.67	-16.67
Q1, Q3	-33.33, 0.00	-50.00, 16.67
MIN, MAX	-83.3, 50.0	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 88 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	68.75	70.00
SD	28.464	29.814
MEDIAN	66.67	66.67
Q1, Q3	41.67, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-4.17	-16.67
SD	35.746	33.333
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 16.7
CYCLE 34		
N	20	4
MEAN	65.00	58.33
SD	31.484	16.667
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	50.00, 66.67
MIN, MAX	16.7, 100.0	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 89 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-13.33	-25.00
SD	37.307	41.944
MEDIAN	-8.33	-33.33
Q1, Q3	-33.33, 16.67	-50.00, 0.00
MIN, MAX	-83.3, 50.0	-66.7, 33.3
CYCLE 35		
N	13	4
MEAN	70.51	70.83
SD	29.778	28.464
MEDIAN	66.67	75.00
Q1, Q3	50.00, 100.00	50.00, 91.67
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-7.69	-12.50
SD	33.065	41.667
MEDIAN	0.00	-8.33
Q1, Q3	-33.33, 16.67	-41.67, 16.67
MIN, MAX	-83.3, 50.0	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 90 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	70.51	41.67
SD	21.681	11.785
MEDIAN	66.67	41.67
Q1, Q3	66.67, 83.33	33.33, 50.00
MIN, MAX	33.3, 100.0	33.3, 50.0
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-8.97	-25.00
SD	29.357	58.926
MEDIAN	-16.67	-25.00
Q1, Q3	-16.67, 16.67	-66.67, 16.67
MIN, MAX	-66.7, 50.0	-66.7, 16.7
CYCLE 37		
N	14	2
MEAN	70.24	66.67
SD	26.294	47.140
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 91 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-4.76	-33.33
SD	38.911	47.140
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 16.67	-66.67, 0.00
MIN, MAX	-83.3, 66.7	-66.7, 0.0
CYCLE 38		
N	11	2
MEAN	66.67	33.33
SD	32.489	0.000
MEDIAN	66.67	33.33
Q1, Q3	33.33, 100.00	33.33, 33.33
MIN, MAX	16.7, 100.0	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-3.03	-33.33
SD	40.013	47.140
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 33.33	-66.67, 0.00
MIN, MAX	-83.3, 50.0	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 92 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	70.83	66.67
SD	27.817	33.333
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-8.33	-11.11
SD	34.503	50.918
MEDIAN	-8.33	0.00
Q1, Q3	-25.00, 8.33	-66.67, 33.33
MIN, MAX	-66.7, 50.0	-66.7, 33.3
CYCLE 40		
N	11	3
MEAN	74.24	66.67
SD	22.808	33.333
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 93 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-1.52	-11.11
SD	33.710	50.918
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-66.67, 33.33
MIN, MAX	-66.7, 50.0	-66.7, 33.3
CYCLE 41		
N	9	0
MEAN	66.67	
SD	18.634	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	32.035	
MEDIAN	-16.67	
Q1, Q3	-16.67, 16.67	
MIN, MAX	-50.0, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 94 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	72.22	100.00
SD	32.773	N.A.
MEDIAN	83.33	100.00
Q1, Q3	33.33, 100.00	100.00, 100.00
MIN, MAX	33.3, 100.0	100.0, 100.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-2.78	0.00
SD	41.388	N.A.
MEDIAN	8.33	0.00
Q1, Q3	-33.33, 16.67	0.00, 0.00
MIN, MAX	-66.7, 50.0	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	83.33	
SD	28.868	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	33.3, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 95 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-3.33	
SD	41.500	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-66.7, 50.0	
CYCLE 44		
N	3	0
MEAN	66.67	
SD	33.333	
MEDIAN	66.67	
Q1, Q3	33.33, 100.00	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-11.11	
SD	58.531	
MEDIAN	-16.67	
Q1, Q3	-66.67, 50.00	
MIN, MAX	-66.7, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 96 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	83.33	
SD	28.868	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-3.33	
SD	41.500	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-66.7, 50.0	
CYCLE 46		
N	3	0
MEAN	77.78	
SD	38.490	
MEDIAN	100.00	
Q1, Q3	33.33, 100.00	
MIN, MAX	33.3, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 97 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-5.56	
SD	58.531	
MEDIAN	0.00	
Q1, Q3	-66.67, 50.00	
MIN, MAX	-66.7, 50.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 98 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 99 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	
END OF TREATMENT		
N	32	45
MEAN	51.04	52.59
SD	29.916	36.920
MEDIAN	50.00	50.00
Q1, Q3	33.33, 66.67	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-13.54	-14.07
SD	37.968	40.351
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 100 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
EMOTIONAL FUNCTIONING		
BASELINE		
N	112	104
MEAN	77.60	75.80
SD	21.488	24.565
MEDIAN	83.33	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	81.44	82.96
SD	19.639	16.616
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	8.3, 100.0	41.7, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	4.51	6.39
SD	16.096	19.595
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 16.67
MIN, MAX	-33.3, 50.0	-50.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 101 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	81.19	77.48
SD	24.200	20.526
MEDIAN	91.67	83.33
Q1, Q3	75.00, 100.00	66.67, 95.83
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	2.78	1.29
SD	18.388	20.392
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-75.0, 50.0	-50.0, 58.3
CYCLE 4		
N	97	81
MEAN	82.56	77.47
SD	22.018	19.915
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 102 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	4.60	2.16
SD	18.451	21.802
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 8.33
MIN, MAX	-58.3, 58.3	-58.3, 66.7
CYCLE 5		
N	93	73
MEAN	84.23	80.14
SD	19.013	19.722
MEDIAN	91.67	83.33
Q1, Q3	75.00, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	6.79	6.28
SD	17.642	24.603
MEDIAN	0.00	0.00
Q1, Q3	0.00, 20.83	0.00, 16.67
MIN, MAX	-50.0, 58.3	-58.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 103 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	84.40	78.50
SD	18.821	21.824
MEDIAN	91.67	83.33
Q1, Q3	75.00, 100.00	66.67, 100.00
MIN, MAX	25.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	6.96	4.11
SD	15.845	22.051
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	-25.0, 41.7	-58.3, 66.7
CYCLE 7		
N	89	65
MEAN	84.08	75.98
SD	20.858	22.208
MEDIAN	91.67	75.00
Q1, Q3	75.00, 100.00	58.33, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 104 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	6.63	3.29
SD	17.876	24.056
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-41.7, 50.0	-50.0, 66.7
CYCLE 8		
N	82	57
MEAN	83.77	79.48
SD	19.257	21.303
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	5.49	6.53
SD	14.672	23.956
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	-33.3, 33.3	-41.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 105 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	83.93	77.63
SD	20.198	23.047
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	8.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	6.33	4.53
SD	17.778	26.167
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-58.3, 50.0	-50.0, 100.0
CYCLE 10		
N	80	54
MEAN	84.27	77.78
SD	19.666	21.899
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	25.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 106 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	6.33	3.55
SD	15.517	26.923
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-33.3, 50.0	-91.7, 66.7
CYCLE 11		
N	72	47
MEAN	80.44	76.77
SD	23.618	22.112
MEDIAN	87.50	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	3.24	2.84
SD	18.050	23.843
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 8.33
MIN, MAX	-66.7, 41.7	-50.0, 75.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 107 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	82.78	76.59
SD	22.703	21.796
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	8.3, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	5.11	3.77
SD	19.858	28.996
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 16.67
MIN, MAX	-41.7, 41.7	-58.3, 83.3
CYCLE 13		
N	73	40
MEAN	81.74	76.11
SD	22.509	25.121
MEDIAN	91.67	80.56
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	25.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 108 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	5.09	2.78
SD	18.846	27.563
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-33.3, 41.7	-66.7, 83.3
CYCLE 14		
N	55	27
MEAN	80.00	73.77
SD	24.248	26.725
MEDIAN	91.67	75.00
Q1, Q3	75.00, 100.00	58.33, 100.00
MIN, MAX	16.7, 100.0	8.3, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	4.01	4.01
SD	18.224	35.534
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-16.67, 25.00
MIN, MAX	-58.3, 41.7	-91.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 109 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	81.12	75.26
SD	24.678	25.266
MEDIAN	91.67	79.17
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	4.76	2.60
SD	18.677	27.225
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 8.33
MIN, MAX	-50.0, 50.0	-66.7, 100.0
CYCLE 16		
N	58	29
MEAN	81.32	75.57
SD	23.586	20.646
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	25.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 110 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	5.56	2.01
SD	18.388	26.508
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 16.67
MIN, MAX	-33.3, 50.0	-66.7, 66.7
CYCLE 17		
N	56	31
MEAN	81.10	78.76
SD	23.110	20.843
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	8.3, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	3.13	2.42
SD	18.158	25.476
MEDIAN	0.00	0.00
Q1, Q3	-4.17, 16.67	-8.33, 8.33
MIN, MAX	-66.7, 33.3	-91.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 111 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	78.57	73.91
SD	24.942	24.657
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	8.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	5.15	-1.09
SD	19.892	30.804
MEDIAN	4.17	0.00
Q1, Q3	-8.33, 16.67	-8.33, 8.33
MIN, MAX	-33.3, 50.0	-100.0, 66.7
CYCLE 19		
N	45	28
MEAN	80.93	77.98
SD	25.290	23.594
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	25.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 112 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	3.70	0.60
SD	19.749	22.786
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 8.33
MIN, MAX	-66.7, 33.3	-58.3, 50.0
CYCLE 20		
N	31	17
MEAN	76.34	77.45
SD	27.563	20.992
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-0.56	5.88
SD	20.405	23.893
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-8.33, 16.67
MIN, MAX	-50.0, 25.0	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 113 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	77.70	80.09
SD	25.839	17.419
MEDIAN	83.33	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	58.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	1.80	5.09
SD	20.519	21.606
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 8.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 22		
N	44	13
MEAN	80.87	80.77
SD	23.678	19.657
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 114 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	2.91	0.64
SD	18.624	29.357
MEDIAN	8.33	0.00
Q1, Q3	-8.33, 16.67	-8.33, 0.00
MIN, MAX	-50.0, 41.7	-58.3, 66.7
CYCLE 23		
N	28	10
MEAN	74.70	71.67
SD	25.908	26.701
MEDIAN	83.33	75.00
Q1, Q3	66.67, 100.00	58.33, 91.67
MIN, MAX	8.3, 100.0	25.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-0.60	-9.17
SD	18.276	25.292
MEDIAN	0.00	-4.17
Q1, Q3	-8.33, 12.50	-16.67, 0.00
MIN, MAX	-41.7, 25.0	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 115 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	77.87	77.50
SD	27.573	15.240
MEDIAN	91.67	70.83
Q1, Q3	66.67, 100.00	66.67, 91.67
MIN, MAX	0.0, 100.0	58.3, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	2.87	0.83
SD	21.161	29.253
MEDIAN	0.00	-4.17
Q1, Q3	0.00, 16.67	-16.67, 0.00
MIN, MAX	-50.0, 41.7	-33.3, 66.7
CYCLE 25		
N	35	13
MEAN	81.67	86.54
SD	24.571	15.418
MEDIAN	91.67	91.67
Q1, Q3	66.67, 100.00	75.00, 100.00
MIN, MAX	0.0, 100.0	58.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 116 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	3.57	6.41
SD	18.665	23.852
MEDIAN	8.33	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 26		
N	20	9
MEAN	80.83	75.93
SD	22.798	17.895
MEDIAN	91.67	66.67
Q1, Q3	66.67, 100.00	66.67, 91.67
MIN, MAX	25.0, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	2.92	-1.85
SD	17.990	30.556
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-8.33, 0.00
MIN, MAX	-41.7, 25.0	-41.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 117 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	74.67	86.81
SD	25.513	20.859
MEDIAN	83.33	95.83
Q1, Q3	58.33, 100.00	79.17, 100.00
MIN, MAX	25.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	0.67	1.39
SD	22.684	13.685
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	0.00, 0.00
MIN, MAX	-66.7, 33.3	-25.0, 33.3
CYCLE 28		
N	30	9
MEAN	79.72	81.48
SD	26.685	18.056
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	50.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 118 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	1.94	7.41
SD	20.139	29.885
MEDIAN	8.33	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	-66.7, 33.3	-41.7, 66.7
CYCLE 29		
N	18	7
MEAN	79.63	83.33
SD	26.231	15.957
MEDIAN	91.67	75.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	25.0, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	2.78	3.57
SD	22.506	30.753
MEDIAN	8.33	0.00
Q1, Q3	-8.33, 16.67	-25.00, 8.33
MIN, MAX	-41.7, 50.0	-25.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 119 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	84.52	78.57
SD	25.992	12.599
MEDIAN	100.00	75.00
Q1, Q3	75.00, 100.00	66.67, 91.67
MIN, MAX	33.3, 100.0	66.7, 91.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	8.33	3.57
SD	19.543	29.603
MEDIAN	16.67	-8.33
Q1, Q3	0.00, 25.00	-8.33, 8.33
MIN, MAX	-33.3, 33.3	-25.0, 66.7
CYCLE 31		
N	23	6
MEAN	81.16	63.89
SD	25.527	28.219
MEDIAN	91.67	62.50
Q1, Q3	66.67, 100.00	33.33, 91.67
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 120 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	5.43	-4.17
SD	16.969	21.570
MEDIAN	8.33	-8.33
Q1, Q3	0.00, 16.67	-8.33, 0.00
MIN, MAX	-33.3, 25.0	-33.3, 33.3
CYCLE 32		
N	16	4
MEAN	76.04	75.00
SD	27.534	11.785
MEDIAN	87.50	70.83
Q1, Q3	58.33, 100.00	66.67, 83.33
MIN, MAX	16.7, 100.0	66.7, 91.7
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	1.04	10.42
SD	17.710	39.893
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 16.67	-16.67, 37.50
MIN, MAX	-33.3, 25.0	-25.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 121 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	78.13	83.33
SD	24.697	19.543
MEDIAN	87.50	91.67
Q1, Q3	62.50, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	58.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	1.56	-8.33
SD	17.272	14.434
MEDIAN	4.17	0.00
Q1, Q3	-8.33, 12.50	-8.33, 0.00
MIN, MAX	-33.3, 25.0	-33.3, 0.0
CYCLE 34		
N	20	4
MEAN	79.58	72.92
SD	27.369	20.833
MEDIAN	91.67	70.83
Q1, Q3	58.33, 100.00	58.33, 87.50
MIN, MAX	16.7, 100.0	50.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 122 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	4.58	-10.42
SD	18.629	21.916
MEDIAN	4.17	-4.17
Q1, Q3	-8.33, 16.67	-25.00, 4.17
MIN, MAX	-33.3, 33.3	-41.7, 8.3
CYCLE 35		
N	13	4
MEAN	84.62	77.08
SD	20.651	29.950
MEDIAN	91.67	87.50
Q1, Q3	66.67, 100.00	58.33, 95.83
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	5.13	-12.50
SD	14.648	32.275
MEDIAN	8.33	-4.17
Q1, Q3	0.00, 16.67	-33.33, 8.33
MIN, MAX	-33.3, 25.0	-58.3, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 123 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	85.90	62.50
SD	20.521	5.893
MEDIAN	100.00	62.50
Q1, Q3	75.00, 100.00	58.33, 66.67
MIN, MAX	33.3, 100.0	58.3, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	5.77	-16.67
SD	14.979	11.785
MEDIAN	8.33	-16.67
Q1, Q3	0.00, 16.67	-25.00, -8.33
MIN, MAX	-33.3, 25.0	-25.0, -8.3
CYCLE 37		
N	14	2
MEAN	85.12	83.33
SD	17.956	23.570
MEDIAN	91.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	50.0, 100.0	66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 124 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	7.74	-12.50
SD	12.431	17.678
MEDIAN	8.33	-12.50
Q1, Q3	0.00, 16.67	-25.00, 0.00
MIN, MAX	-16.7, 25.0	-25.0, 0.0
CYCLE 38		
N	11	2
MEAN	82.58	62.50
SD	21.875	5.893
MEDIAN	91.67	62.50
Q1, Q3	66.67, 100.00	58.33, 66.67
MIN, MAX	33.3, 100.0	58.3, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	4.55	-16.67
SD	16.817	11.785
MEDIAN	8.33	-16.67
Q1, Q3	-8.33, 16.67	-25.00, -8.33
MIN, MAX	-33.3, 25.0	-25.0, -8.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 125 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	81.25	69.44
SD	23.038	20.972
MEDIAN	87.50	66.67
Q1, Q3	70.83, 100.00	50.00, 91.67
MIN, MAX	33.3, 100.0	50.0, 91.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	5.21	-16.67
SD	19.384	22.048
MEDIAN	8.33	-8.33
Q1, Q3	-4.17, 20.83	-41.67, 0.00
MIN, MAX	-33.3, 25.0	-41.7, 0.0
CYCLE 40		
N	11	3
MEAN	83.33	72.22
SD	15.811	17.347
MEDIAN	91.67	66.67
Q1, Q3	66.67, 100.00	58.33, 91.67
MIN, MAX	58.3, 100.0	58.3, 91.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 126 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	9.85	-13.89
SD	11.067	9.623
MEDIAN	8.33	-8.33
Q1, Q3	0.00, 16.67	-25.00, -8.33
MIN, MAX	-8.3, 25.0	-25.0, -8.3
CYCLE 41		
N	9	0
MEAN	82.41	
SD	17.403	
MEDIAN	91.67	
Q1, Q3	66.67, 100.00	
MIN, MAX	58.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	12.04	
SD	11.111	
MEDIAN	16.67	
Q1, Q3	8.33, 16.67	
MIN, MAX	-8.3, 25.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 127 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	86.11	91.67
SD	15.516	N.A.
MEDIAN	91.67	91.67
Q1, Q3	66.67, 100.00	91.67, 91.67
MIN, MAX	66.7, 100.0	91.7, 91.7
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	13.89	-8.33
SD	8.607	N.A.
MEDIAN	16.67	-8.33
Q1, Q3	8.33, 16.67	-8.33, -8.33
MIN, MAX	0.0, 25.0	-8.3, -8.3
CYCLE 43		
N	5	0
MEAN	86.67	
SD	12.638	
MEDIAN	83.33	
Q1, Q3	75.00, 100.00	
MIN, MAX	75.0, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 128 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	8.33	
SD	10.206	
MEDIAN	8.33	
Q1, Q3	0.00, 8.33	
MIN, MAX	0.0, 25.0	
CYCLE 44		
N	3	0
MEAN	94.44	
SD	9.623	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	13.89	
SD	9.623	
MEDIAN	8.33	
Q1, Q3	8.33, 25.00	
MIN, MAX	8.3, 25.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 129 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	93.33	
SD	9.129	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	15.00	
SD	9.129	
MEDIAN	8.33	
Q1, Q3	8.33, 25.00	
MIN, MAX	8.3, 25.0	
CYCLE 46		
N	3	0
MEAN	100.00	
SD	0.000	
MEDIAN	100.00	
Q1, Q3	100.00, 100.00	
MIN, MAX	100.0, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 130 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	19.44	
SD	9.623	
MEDIAN	25.00	
Q1, Q3	8.33, 25.00	
MIN, MAX	8.3, 25.0	
CYCLE 47		
N	1	0
MEAN	91.67	
SD	N.A.	
MEDIAN	91.67	
Q1, Q3	91.67, 91.67	
MIN, MAX	91.7, 91.7	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 131 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	100.00	
SD	N.A.	
MEDIAN	100.00	
Q1, Q3	100.00, 100.00	
MIN, MAX	100.0, 100.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	25.00	
SD	N.A.	
MEDIAN	25.00	
Q1, Q3	25.00, 25.00	
MIN, MAX	25.0, 25.0	
CYCLE 49		
N	1	0
MEAN	75.00	
SD	N.A.	
MEDIAN	75.00	
Q1, Q3	75.00, 75.00	
MIN, MAX	75.0, 75.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 132 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	71.88	67.22
SD	25.378	29.751
MEDIAN	75.00	66.67
Q1, Q3	54.17, 100.00	50.00, 91.67
MIN, MAX	25.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-1.82	-6.85
SD	19.713	26.844
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 8.33
MIN, MAX	-50.0, 41.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 133 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
COGNITIVE FUNCTIONING		
BASELINE		
N	112	104
MEAN	90.77	86.86
SD	15.311	20.860
MEDIAN	100.00	100.00
Q1, Q3	83.33, 100.00	83.33, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	83.81	82.78
SD	18.790	20.971
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-6.89	-4.63
SD	16.358	19.835
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-66.7, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 134 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	82.00	81.15
SD	20.056	23.396
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	-8.83	-7.34
SD	16.319	20.915
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 33.3	-66.7, 33.3
CYCLE 4		
N	97	81
MEAN	83.51	81.07
SD	20.623	25.652
MEDIAN	83.33	100.00
Q1, Q3	83.33, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 135 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-6.77	-5.76
SD	16.680	21.756
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 33.3	-66.7, 66.7
CYCLE 5		
N	93	73
MEAN	85.13	81.28
SD	18.628	21.145
MEDIAN	83.33	83.33
Q1, Q3	83.33, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-4.89	-5.94
SD	16.490	19.319
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-50.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 136 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	84.11	79.47
SD	16.746	23.070
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-6.27	-7.97
SD	14.768	18.875
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-66.7, 33.3
CYCLE 7		
N	89	65
MEAN	84.27	80.00
SD	18.354	22.087
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 137 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-5.87	-6.41
SD	16.959	17.602
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 50.0	-66.7, 33.3
CYCLE 8		
N	82	57
MEAN	83.54	78.36
SD	17.857	25.966
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-7.20	-8.48
SD	16.016	22.299
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 138 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	84.13	79.82
SD	16.547	21.533
MEDIAN	83.33	83.33
Q1, Q3	83.33, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-6.02	-7.02
SD	16.375	20.641
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-66.7, 50.0
CYCLE 10		
N	80	54
MEAN	83.33	77.78
SD	18.373	22.431
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 139 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	-7.38	-8.33
SD	16.178	17.953
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-50.0, 50.0
CYCLE 11		
N	72	47
MEAN	80.09	77.30
SD	21.602	23.679
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-9.72	-8.51
SD	17.857	21.387
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 16.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 140 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	83.10	75.79
SD	19.348	22.148
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-7.97	-9.13
SD	16.322	23.048
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-66.7, 50.0
CYCLE 13		
N	72	40
MEAN	81.71	78.75
SD	20.395	22.325
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 141 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	40
MEAN	-8.45	-5.42
SD	16.396	20.460
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-66.7, 66.7
CYCLE 14		
N	55	27
MEAN	80.91	80.86
SD	20.138	21.535
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-8.33	-4.32
SD	13.640	24.281
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 142 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	82.03	78.65
SD	19.315	22.889
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-7.67	-5.21
SD	15.504	22.175
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-50.0, 50.0
CYCLE 16		
N	58	29
MEAN	82.18	75.29
SD	19.462	25.828
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 143 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-6.73	-10.34
SD	16.324	24.565
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-66.7, 33.3
CYCLE 17		
N	56	31
MEAN	81.25	74.19
SD	19.608	28.166
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-8.63	-11.83
SD	17.113	23.646
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 16.7	-66.7, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 144 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	80.00	73.19
SD	23.151	21.165
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-6.86	-10.87
SD	16.976	17.844
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 33.3	-33.3, 33.3
CYCLE 19		
N	45	28
MEAN	78.52	79.17
SD	25.282	25.509
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 145 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-10.37	-6.55
SD	20.191	19.426
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 16.7	-83.3, 16.7
CYCLE 20		
N	31	17
MEAN	76.88	79.41
SD	21.377	21.674
MEDIAN	83.33	83.33
Q1, Q3	66.67, 83.33	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-11.11	-2.94
SD	15.982	13.483
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-33.3, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 146 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	77.48	82.41
SD	26.122	23.895
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-10.36	-2.78
SD	23.357	18.302
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-83.3, 16.7	-50.0, 33.3
CYCLE 22		
N	44	13
MEAN	80.68	75.64
SD	21.550	22.169
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 147 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-9.30	-10.26
SD	17.557	24.093
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 16.7	-50.0, 33.3
CYCLE 23		
N	28	10
MEAN	76.19	68.33
SD	23.319	28.814
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-10.71	-10.00
SD	20.893	16.102
MEDIAN	-16.67	-8.33
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 148 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	78.74	83.33
SD	19.869	15.713
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-10.34	1.67
SD	19.114	18.342
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-50.0, 16.7	-33.3, 33.3
CYCLE 25		
N	35	13
MEAN	79.52	78.21
SD	23.944	21.926
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 149 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-11.43	-7.69
SD	20.915	14.618
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 0.00
MIN, MAX	-83.3, 16.7	-33.3, 0.0
CYCLE 26		
N	20	9
MEAN	78.33	66.67
SD	20.305	25.000
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	50.00, 83.33
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-10.83	-14.81
SD	18.945	17.568
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 16.7	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 150 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	78.00	77.78
SD	21.900	21.711
MEDIAN	83.33	75.00
Q1, Q3	66.67, 100.00	58.33, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-10.00	-11.11
SD	25.000	17.885
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 50.0	-33.3, 16.7
CYCLE 28		
N	30	9
MEAN	80.00	83.33
SD	21.620	22.048
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 151 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-12.22	0.00
SD	19.541	14.434
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-50.0, 16.7	-33.3, 16.7
CYCLE 29		
N	18	7
MEAN	75.00	83.33
SD	26.352	13.608
MEDIAN	83.33	83.33
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	16.7, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-12.04	-2.38
SD	26.075	17.817
MEDIAN	-8.33	0.00
Q1, Q3	-33.33, 16.67	-16.67, 0.00
MIN, MAX	-66.7, 16.7	-16.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 152 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	80.16	76.19
SD	27.192	23.288
MEDIAN	83.33	66.67
Q1, Q3	83.33, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-9.52	-7.14
SD	24.479	18.898
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 16.7	-33.3, 16.7
CYCLE 31		
N	23	6
MEAN	78.26	61.11
SD	23.802	22.771
MEDIAN	83.33	58.33
Q1, Q3	66.67, 100.00	50.00, 66.67
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 153 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	-10.87	-16.67
SD	21.678	25.820
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 16.7	-50.0, 16.7
CYCLE 32		
N	16	4
MEAN	68.75	75.00
SD	26.440	16.667
MEDIAN	83.33	66.67
Q1, Q3	58.33, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	66.7, 100.0
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	-19.79	-4.17
SD	25.253	28.464
MEDIAN	-16.67	-8.33
Q1, Q3	-33.33, 0.00	-25.00, 16.67
MIN, MAX	-66.7, 16.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 154 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	73.96	70.00
SD	23.546	24.721
MEDIAN	83.33	66.67
Q1, Q3	66.67, 83.33	66.67, 83.33
MIN, MAX	16.7, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-12.50	-26.67
SD	23.960	19.003
MEDIAN	-16.67	-33.33
Q1, Q3	-16.67, 0.00	-33.33, -16.67
MIN, MAX	-66.7, 33.3	-50.0, 0.0
CYCLE 34		
N	20	4
MEAN	79.17	75.00
SD	25.862	21.517
MEDIAN	83.33	75.00
Q1, Q3	75.00, 100.00	58.33, 91.67
MIN, MAX	0.0, 100.0	50.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 155 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-8.33	-12.50
SD	23.258	15.957
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-25.00, 0.00
MIN, MAX	-83.3, 16.7	-33.3, 0.0
CYCLE 35		
N	13	4
MEAN	78.21	83.33
SD	19.702	33.333
MEDIAN	83.33	100.00
Q1, Q3	66.67, 83.33	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-11.54	-12.50
SD	18.490	25.000
MEDIAN	-16.67	0.00
Q1, Q3	-16.67, 0.00	-25.00, 0.00
MIN, MAX	-50.0, 16.7	-50.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 156 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	79.49	75.00
SD	19.429	35.355
MEDIAN	83.33	75.00
Q1, Q3	83.33, 83.33	50.00, 100.00
MIN, MAX	33.3, 100.0	50.0, 100.0
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-12.82	-16.67
SD	18.199	23.570
MEDIAN	-16.67	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 16.7	-33.3, 0.0
CYCLE 37		
N	14	2
MEAN	79.76	66.67
SD	19.805	47.140
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 157 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-8.33	-25.00
SD	19.337	35.355
MEDIAN	-8.33	-25.00
Q1, Q3	-16.67, 0.00	-50.00, 0.00
MIN, MAX	-50.0, 16.7	-50.0, 0.0
CYCLE 38		
N	11	2
MEAN	75.76	66.67
SD	20.226	47.140
MEDIAN	83.33	66.67
Q1, Q3	66.67, 83.33	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-10.61	-25.00
SD	20.101	35.355
MEDIAN	-16.67	-25.00
Q1, Q3	-16.67, 0.00	-50.00, 0.00
MIN, MAX	-50.0, 16.7	-50.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 158 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	75.00	66.67
SD	19.920	33.333
MEDIAN	83.33	66.67
Q1, Q3	66.67, 83.33	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-18.75	-27.78
SD	18.767	25.459
MEDIAN	-16.67	-33.33
Q1, Q3	-33.33, 0.00	-50.00, 0.00
MIN, MAX	-50.0, 0.0	-50.0, 0.0
CYCLE 40		
N	11	3
MEAN	84.85	77.78
SD	17.408	25.459
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	50.0, 100.0	50.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 159 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-3.03	-16.67
SD	14.564	16.667
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 16.7	-33.3, 0.0
CYCLE 41		
N	9	0
MEAN	81.48	
SD	17.568	
MEDIAN	83.33	
Q1, Q3	66.67, 100.00	
MIN, MAX	50.0, 100.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	21.695	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 160 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	83.33	83.33
SD	14.907	N.A.
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	83.33, 83.33
MIN, MAX	66.7, 100.0	83.3, 83.3
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-8.33	-16.67
SD	13.944	N.A.
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-16.67, -16.67
MIN, MAX	-33.3, 0.0	-16.7, -16.7
CYCLE 43		
N	5	0
MEAN	93.33	
SD	9.129	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 161 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	11.785	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-16.7, 16.7	
CYCLE 44		
N	3	0
MEAN	94.44	
SD	9.623	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 162 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	90.00	
SD	9.129	
MEDIAN	83.33	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-3.33	
SD	13.944	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 16.7	
CYCLE 46		
N	3	0
MEAN	88.89	
SD	19.245	
MEDIAN	100.00	
Q1, Q3	66.67, 100.00	
MIN, MAX	66.7, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 163 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	0.00	
SD	16.667	
MEDIAN	0.00	
Q1, Q3	-16.67, 16.67	
MIN, MAX	-16.7, 16.7	
CYCLE 47		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 164 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
CYCLE 49		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 165 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-16.67	
SD	N.A.	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, -16.7	
END OF TREATMENT		
N	32	45
MEAN	76.04	74.44
SD	19.828	27.661
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	33.3, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-16.15	-13.70
SD	19.622	26.659
MEDIAN	-16.67	0.00
Q1, Q3	-25.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 16.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 166 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
SOCIAL FUNCTIONING		
BASELINE		
N	112	104
MEAN	76.49	74.20
SD	26.523	30.002
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	75.00	76.85
SD	27.283	25.319
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-1.28	0.00
SD	25.830	24.733
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-100.0, 83.3	-83.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 167 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	75.33	77.18
SD	26.641	26.483
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	58.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	-2.17	-1.98
SD	30.946	26.562
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 4		
N	97	81
MEAN	74.23	76.54
SD	26.898	25.655
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 168 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-2.08	-1.23
SD	30.325	27.985
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 66.7
CYCLE 5		
N	93	73
MEAN	80.11	78.54
SD	23.858	27.000
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	3.62	0.68
SD	28.044	27.700
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 16.67
MIN, MAX	-66.7, 83.3	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 169 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	77.33	75.36
SD	25.554	26.754
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-2.35	-1.93
SD	27.235	30.187
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-16.67, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 66.7
CYCLE 7		
N	89	65
MEAN	76.40	71.28
SD	28.847	29.830
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 170 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-1.33	-5.38
SD	29.494	31.610
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-83.3, 66.7	-66.7, 83.3
CYCLE 8		
N	82	57
MEAN	76.63	74.85
SD	28.311	27.661
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-2.88	-0.88
SD	28.479	30.767
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-83.3, 66.7	-100.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 171 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	76.98	76.02
SD	25.599	25.976
MEDIAN	83.33	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-0.60	0.29
SD	27.106	29.962
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-83.3, 66.7	-83.3, 83.3
CYCLE 10		
N	80	54
MEAN	78.33	69.75
SD	26.966	29.152
MEDIAN	91.67	66.67
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 172 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	-1.05	-5.86
SD	30.116	30.399
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-83.3, 83.3
CYCLE 11		
N	72	47
MEAN	75.69	74.82
SD	28.518	23.280
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-3.01	-2.48
SD	29.778	26.689
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 8.33	-16.67, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 173 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	74.76	71.43
SD	30.659	29.051
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-3.86	-5.16
SD	30.936	35.209
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-83.3, 83.3
CYCLE 13		
N	73	40
MEAN	74.66	71.25
SD	27.793	34.175
MEDIAN	83.33	91.67
Q1, Q3	66.67, 100.00	41.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 174 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-3.24	-5.83
SD	29.290	35.716
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-83.3, 100.0
CYCLE 14		
N	55	27
MEAN	73.94	75.93
SD	26.011	27.477
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-4.63	-0.62
SD	28.487	35.949
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 175 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	72.40	65.10
SD	28.977	31.498
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-6.08	-11.46
SD	26.824	29.157
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 50.0	-83.3, 66.7
CYCLE 16		
N	58	29
MEAN	73.28	68.97
SD	27.562	31.093
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 176 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-6.14	-10.92
SD	28.458	29.639
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-83.3, 50.0
CYCLE 17		
N	56	31
MEAN	70.83	74.19
SD	29.345	25.762
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	16.7, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-11.61	-6.99
SD	27.692	24.636
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 50.0	-66.7, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 177 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	73.81	77.54
SD	29.507	30.817
MEDIAN	83.33	100.00
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-4.90	-4.35
SD	25.468	28.523
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-83.3, 50.0
CYCLE 19		
N	45	28
MEAN	72.96	72.02
SD	31.036	29.064
MEDIAN	83.33	75.00
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 178 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-7.04	-10.12
SD	29.191	28.810
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-83.3, 50.0
CYCLE 20		
N	31	17
MEAN	71.51	79.41
SD	28.282	23.957
MEDIAN	66.67	83.33
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-4.44	1.96
SD	31.542	27.565
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 179 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	73.87	69.44
SD	27.650	28.726
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-5.86	-6.48
SD	22.297	22.966
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 22		
N	44	13
MEAN	73.86	69.23
SD	28.393	29.538
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	33.33, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 180 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-6.98	-2.56
SD	23.069	31.802
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-83.3, 33.3	-66.7, 50.0
CYCLE 23		
N	28	10
MEAN	63.69	50.00
SD	33.961	29.397
MEDIAN	66.67	41.67
Q1, Q3	33.33, 100.00	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-11.90	-18.33
SD	26.394	14.593
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 8.33	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 181 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	74.14	68.33
SD	27.309	32.820
MEDIAN	83.33	75.00
Q1, Q3	66.67, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-7.47	1.67
SD	23.816	35.530
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 25		
N	35	13
MEAN	73.33	65.38
SD	31.102	33.652
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 182 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-7.62	-6.41
SD	22.989	40.562
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 16.67
MIN, MAX	-50.0, 33.3	-83.3, 66.7
CYCLE 26		
N	20	9
MEAN	65.83	61.11
SD	33.102	35.355
MEDIAN	66.67	66.67
Q1, Q3	41.67, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-10.83	-5.56
SD	30.720	43.301
MEDIAN	0.00	-16.67
Q1, Q3	-41.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 33.3	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 183 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	70.00	66.67
SD	32.275	32.567
MEDIAN	83.33	66.67
Q1, Q3	50.00, 100.00	41.67, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-8.00	-2.78
SD	33.375	41.337
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 50.0	-100.0, 66.7
CYCLE 28		
N	30	9
MEAN	76.11	70.37
SD	28.595	23.241
MEDIAN	91.67	66.67
Q1, Q3	66.67, 100.00	50.00, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 184 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-7.22	3.70
SD	20.381	38.889
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 29		
N	18	7
MEAN	70.37	64.29
SD	29.459	24.398
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	33.33, 83.33
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-7.41	-4.76
SD	26.948	36.911
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 185 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	77.78	73.81
SD	24.907	23.288
MEDIAN	83.33	66.67
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-7.14	11.90
SD	25.588	36.911
MEDIAN	0.00	16.67
Q1, Q3	-16.67, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 31		
N	23	6
MEAN	78.26	69.44
SD	26.796	26.701
MEDIAN	100.00	66.67
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 186 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	-5.80	-2.78
SD	26.878	40.023
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 32		
N	16	4
MEAN	68.75	58.33
SD	27.806	16.667
MEDIAN	66.67	66.67
Q1, Q3	50.00, 100.00	50.00, 66.67
MIN, MAX	16.7, 100.0	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	-14.58	4.17
SD	30.353	47.871
MEDIAN	-8.33	-8.33
Q1, Q3	-33.33, 0.00	-33.33, 41.67
MIN, MAX	-83.3, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 187 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	75.00	73.33
SD	26.527	27.889
MEDIAN	75.00	66.67
Q1, Q3	58.33, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-4.17	-3.33
SD	23.174	29.814
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-50.0, 50.0	-33.3, 33.3
CYCLE 34		
N	20	4
MEAN	72.50	75.00
SD	28.753	31.914
MEDIAN	66.67	83.33
Q1, Q3	50.00, 100.00	50.00, 100.00
MIN, MAX	16.7, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 188 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-10.83	0.00
SD	28.753	40.825
MEDIAN	0.00	-8.33
Q1, Q3	-25.00, 0.00	-33.33, 33.33
MIN, MAX	-83.3, 33.3	-33.3, 50.0
CYCLE 35		
N	13	4
MEAN	78.21	83.33
SD	20.844	33.333
MEDIAN	66.67	100.00
Q1, Q3	66.67, 100.00	66.67, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-5.13	12.50
SD	18.490	36.956
MEDIAN	0.00	16.67
Q1, Q3	-16.67, 0.00	-16.67, 41.67
MIN, MAX	-33.3, 16.7	-33.3, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 189 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	80.77	58.33
SD	19.059	35.355
MEDIAN	66.67	58.33
Q1, Q3	66.67, 100.00	33.33, 83.33
MIN, MAX	50.0, 100.0	33.3, 83.3
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-5.13	0.00
SD	18.490	47.140
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-50.0, 16.7	-33.3, 33.3
CYCLE 37		
N	14	2
MEAN	73.81	66.67
SD	24.209	47.140
MEDIAN	66.67	66.67
Q1, Q3	66.67, 100.00	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 190 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-8.33	0.00
SD	25.107	47.140
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 16.7	-33.3, 33.3
CYCLE 38		
N	11	2
MEAN	69.70	50.00
SD	23.355	23.570
MEDIAN	66.67	50.00
Q1, Q3	66.67, 100.00	33.33, 66.67
MIN, MAX	33.3, 100.0	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-7.58	-8.33
SD	23.995	35.355
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 16.7	-33.3, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 191 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	72.92	77.78
SD	21.708	38.490
MEDIAN	66.67	100.00
Q1, Q3	66.67, 91.67	33.33, 100.00
MIN, MAX	33.3, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-12.50	16.67
SD	29.209	44.096
MEDIAN	0.00	33.33
Q1, Q3	-33.33, 8.33	-33.33, 50.00
MIN, MAX	-66.7, 16.7	-33.3, 50.0
CYCLE 40		
N	11	3
MEAN	72.73	44.44
SD	21.438	19.245
MEDIAN	83.33	33.33
Q1, Q3	50.00, 83.33	33.33, 66.67
MIN, MAX	33.3, 100.0	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 192 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-10.61	-16.67
SD	22.697	28.868
MEDIAN	0.00	-33.33
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-50.0, 16.7	-33.3, 16.7
CYCLE 41		
N	9	0
MEAN	75.93	
SD	23.733	
MEDIAN	83.33	
Q1, Q3	66.67, 100.00	
MIN, MAX	33.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-7.41	
SD	25.154	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-50.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 193 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	83.33	33.33
SD	21.082	N.A.
MEDIAN	91.67	33.33
Q1, Q3	66.67, 100.00	33.33, 33.33
MIN, MAX	50.0, 100.0	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-8.33	-33.33
SD	22.973	N.A.
MEDIAN	0.00	-33.33
Q1, Q3	-16.67, 0.00	-33.33, -33.33
MIN, MAX	-50.0, 16.7	-33.3, -33.3
CYCLE 43		
N	5	0
MEAN	93.33	
SD	14.907	
MEDIAN	100.00	
Q1, Q3	100.00, 100.00	
MIN, MAX	66.7, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 194 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	94.44	
SD	9.623	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-5.56	
SD	9.623	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 195 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	93.33	
SD	9.129	
MEDIAN	100.00	
Q1, Q3	83.33, 100.00	
MIN, MAX	83.3, 100.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	9.129	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	
CYCLE 46		
N	3	0
MEAN	83.33	
SD	28.868	
MEDIAN	100.00	
Q1, Q3	50.00, 100.00	
MIN, MAX	50.0, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 196 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-16.67	
SD	28.868	
MEDIAN	0.00	
Q1, Q3	-50.00, 0.00	
MIN, MAX	-50.0, 0.0	
CYCLE 47		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-50.00	
SD	N.A.	
MEDIAN	-50.00	
Q1, Q3	-50.00, -50.00	
MIN, MAX	-50.0, -50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 197 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-50.00	
SD	N.A.	
MEDIAN	-50.00	
Q1, Q3	-50.00, -50.00	
MIN, MAX	-50.0, -50.0	
CYCLE 49		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 198 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-50.00	
SD	N.A.	
MEDIAN	-50.00	
Q1, Q3	-50.00, -50.00	
MIN, MAX	-50.0, -50.0	
END OF TREATMENT		
N	32	45
MEAN	58.85	58.15
SD	35.161	34.382
MEDIAN	66.67	66.67
Q1, Q3	33.33, 100.00	33.33, 100.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-16.15	-15.19
SD	37.504	40.016
MEDIAN	0.00	0.00
Q1, Q3	-50.00, 8.33	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 199 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
FATIGUE		
BASELINE		
N	112	104
MEAN	31.45	35.15
SD	25.262	27.745
MEDIAN	33.33	33.33
Q1, Q3	11.11, 44.44	11.11, 55.56
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	31.52	29.85
SD	22.389	24.239
MEDIAN	33.33	33.33
Q1, Q3	11.11, 44.44	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	0.43	-4.70
SD	27.169	20.520
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	-22.22, 11.11
MIN, MAX	-88.9, 66.7	-77.8, 44.4

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 200 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	27.89	27.12
SD	24.695	21.359
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-3.36	-3.97
SD	29.628	21.587
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-77.8, 77.8	-66.7, 44.4
CYCLE 4		
N	97	81
MEAN	26.92	27.43
SD	25.094	24.158
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 201 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-4.51	-5.35
SD	28.685	24.031
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-100.0, 77.8	-66.7, 44.4
CYCLE 5		
N	93	73
MEAN	23.89	28.31
SD	21.669	23.790
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-6.64	-3.35
SD	27.566	26.816
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-100.0, 55.6	-66.7, 44.4

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 202 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	23.05	29.31
SD	20.289	24.326
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-7.43	-3.54
SD	24.693	26.092
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-88.9, 33.3	-66.7, 66.7
CYCLE 7		
N	89	65
MEAN	23.10	34.19
SD	22.797	25.177
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 55.56
MIN, MAX	0.0, 88.9	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 203 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-6.82	-0.68
SD	28.760	26.994
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-77.8, 88.9	-55.6, 66.7
CYCLE 8		
N	82	57
MEAN	22.63	31.38
SD	22.321	22.135
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-5.21	-3.90
SD	27.949	24.977
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-100.0, 88.9	-66.7, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 204 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	22.62	29.24
SD	21.435	24.000
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-5.89	-5.26
SD	26.789	26.486
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-66.7, 77.8	-66.7, 55.6
CYCLE 10		
N	80	54
MEAN	25.49	34.98
SD	20.968	26.646
MEDIAN	22.22	33.33
Q1, Q3	5.56, 33.33	11.11, 55.56
MIN, MAX	0.0, 83.3	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 205 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	-2.74	1.03
SD	25.735	27.495
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 22.22
MIN, MAX	-66.7, 83.3	-55.6, 55.6
CYCLE 11		
N	72	47
MEAN	26.39	29.79
SD	24.203	25.072
MEDIAN	22.22	22.22
Q1, Q3	5.56, 33.33	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-2.47	-2.60
SD	28.172	31.188
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 11.11	-22.22, 11.11
MIN, MAX	-66.7, 88.9	-77.8, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 206 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	25.08	32.28
SD	20.953	24.761
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 55.56
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-2.58	-0.26
SD	26.276	30.502
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-22.22, 22.22
MIN, MAX	-66.7, 77.8	-88.9, 66.7
CYCLE 13		
N	73	40
MEAN	24.66	31.67
SD	21.931	31.583
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	0.00, 38.89
MIN, MAX	0.0, 88.9	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 207 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-5.25	-1.39
SD	27.215	29.038
MEDIAN	-11.11	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-66.7, 55.6	-66.7, 77.8
CYCLE 14		
N	55	27
MEAN	26.06	30.04
SD	22.142	25.190
MEDIAN	22.22	33.33
Q1, Q3	0.00, 44.44	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-5.56	-5.35
SD	27.704	31.483
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-33.33, 11.11
MIN, MAX	-66.7, 44.4	-66.7, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 208 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	24.62	34.38
SD	23.529	27.847
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	11.11, 44.44
MIN, MAX	0.0, 88.9	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-4.69	-0.69
SD	26.472	28.213
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 55.6	-66.7, 77.8
CYCLE 16		
N	58	29
MEAN	25.29	31.80
SD	20.895	28.749
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	0.00, 44.44
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 209 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-5.07	-2.68
SD	26.148	27.483
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-66.7, 44.4	-44.4, 77.8
CYCLE 17		
N	56	31
MEAN	25.20	27.60
SD	22.572	27.796
MEDIAN	22.22	22.22
Q1, Q3	0.00, 33.33	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-2.38	-4.30
SD	26.777	27.767
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 16.67	-33.33, 11.11
MIN, MAX	-77.8, 66.7	-44.4, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 210 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	29.84	34.30
SD	24.369	31.590
MEDIAN	22.22	33.33
Q1, Q3	11.11, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-2.94	-3.38
SD	31.105	31.505
MEDIAN	0.00	-11.11
Q1, Q3	-22.22, 11.11	-33.33, 11.11
MIN, MAX	-88.9, 66.7	-44.4, 66.7
CYCLE 19		
N	45	28
MEAN	27.65	32.54
SD	23.285	29.308
MEDIAN	22.22	33.33
Q1, Q3	11.11, 44.44	5.56, 55.56
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 211 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-0.25	3.17
SD	28.866	29.453
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	-16.67, 16.67
MIN, MAX	-77.8, 66.7	-44.4, 66.7
CYCLE 20		
N	31	17
MEAN	27.60	26.80
SD	21.057	22.243
MEDIAN	22.22	33.33
Q1, Q3	11.11, 33.33	0.00, 44.44
MIN, MAX	0.0, 77.8	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-1.48	-10.46
SD	28.994	22.385
MEDIAN	0.00	-11.11
Q1, Q3	-22.22, 22.22	-33.33, 0.00
MIN, MAX	-66.7, 77.8	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 212 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	28.23	24.69
SD	24.229	28.149
MEDIAN	22.22	16.67
Q1, Q3	11.11, 33.33	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-0.60	-8.02
SD	28.442	22.484
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-55.6, 33.3
CYCLE 22		
N	44	13
MEAN	27.78	29.06
SD	22.543	31.927
MEDIAN	27.78	22.22
Q1, Q3	11.11, 44.44	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 213 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-0.78	-2.56
SD	26.824	29.451
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 0.00
MIN, MAX	-66.7, 66.7	-55.6, 66.7
CYCLE 23		
N	28	10
MEAN	31.75	34.44
SD	23.563	34.921
MEDIAN	33.33	27.78
Q1, Q3	16.67, 44.44	0.00, 55.56
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	2.78	2.22
SD	31.079	13.659
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	0.00, 11.11
MIN, MAX	-66.7, 66.7	-22.2, 22.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 214 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	25.67	30.00
SD	20.163	24.031
MEDIAN	33.33	33.33
Q1, Q3	11.11, 33.33	0.00, 44.44
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-2.68	-6.67
SD	30.087	19.738
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	-22.22, 11.11
MIN, MAX	-66.7, 55.6	-44.4, 11.1
CYCLE 25		
N	35	13
MEAN	27.62	35.04
SD	25.476	28.991
MEDIAN	22.22	33.33
Q1, Q3	0.00, 44.44	11.11, 55.56
MIN, MAX	0.0, 100.0	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 215 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	1.27	3.42
SD	31.516	24.589
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	0.00, 22.22
MIN, MAX	-66.7, 66.7	-33.3, 55.6
CYCLE 26		
N	20	9
MEAN	28.89	44.44
SD	21.143	29.397
MEDIAN	22.22	44.44
Q1, Q3	16.67, 44.44	33.33, 66.67
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	2.22	2.47
SD	27.596	27.090
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 11.11
MIN, MAX	-44.4, 55.6	-33.3, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 216 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	33.33	37.04
SD	24.428	39.164
MEDIAN	33.33	22.22
Q1, Q3	11.11, 55.56	0.00, 72.22
MIN, MAX	0.0, 77.8	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	5.33	7.41
SD	31.447	23.371
MEDIAN	11.11	5.56
Q1, Q3	-11.11, 22.22	-11.11, 16.67
MIN, MAX	-66.7, 77.8	-22.2, 66.7
CYCLE 28		
N	30	9
MEAN	30.74	30.86
SD	29.568	33.230
MEDIAN	27.78	33.33
Q1, Q3	0.00, 55.56	0.00, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 217 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	4.81	-2.47
SD	32.320	18.239
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 33.33	-11.11, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3
CYCLE 29		
N	18	7
MEAN	31.48	28.57
SD	20.612	26.338
MEDIAN	27.78	33.33
Q1, Q3	22.22, 44.44	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	5.56	-4.76
SD	27.016	23.880
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 33.33	-22.22, 22.22
MIN, MAX	-44.4, 55.6	-44.4, 22.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 218 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	23.28	33.33
SD	18.561	24.845
MEDIAN	22.22	33.33
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 66.7	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-2.65	-6.35
SD	28.307	22.090
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-22.22, 11.11
MIN, MAX	-66.7, 33.3	-44.4, 22.2
CYCLE 31		
N	23	7
MEAN	23.67	42.06
SD	19.906	23.972
MEDIAN	22.22	44.44
Q1, Q3	0.00, 33.33	33.33, 55.56
MIN, MAX	0.0, 66.7	0.0, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 219 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-3.86	0.79
SD	27.546	29.819
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 22.22	-27.78, 22.22
MIN, MAX	-66.7, 33.3	-44.4, 44.4
CYCLE 32		
N	17	4
MEAN	31.37	41.67
SD	22.985	10.638
MEDIAN	33.33	38.89
Q1, Q3	11.11, 44.44	33.33, 50.00
MIN, MAX	0.0, 88.9	33.3, 55.6
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	5.88	-13.89
SD	26.093	43.862
MEDIAN	11.11	-5.56
Q1, Q3	-11.11, 11.11	-50.00, 22.22
MIN, MAX	-44.4, 55.6	-66.7, 22.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 220 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	27.78	28.89
SD	17.213	25.580
MEDIAN	33.33	22.22
Q1, Q3	11.11, 44.44	11.11, 55.56
MIN, MAX	0.0, 55.6	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	1.39	2.22
SD	24.301	18.257
MEDIAN	11.11	11.11
Q1, Q3	-16.67, 16.67	-11.11, 11.11
MIN, MAX	-44.4, 33.3	-22.2, 22.2
CYCLE 34		
N	20	4
MEAN	26.67	30.56
SD	19.876	13.981
MEDIAN	22.22	33.33
Q1, Q3	11.11, 44.44	22.22, 38.89
MIN, MAX	0.0, 66.7	11.1, 44.4

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 221 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	0.56	-8.33
SD	23.216	24.637
MEDIAN	5.56	0.00
Q1, Q3	-16.67, 16.67	-22.22, 5.56
MIN, MAX	-44.4, 44.4	-44.4, 11.1
CYCLE 35		
N	13	4
MEAN	21.37	19.44
SD	15.357	26.255
MEDIAN	22.22	11.11
Q1, Q3	11.11, 33.33	0.00, 38.89
MIN, MAX	0.0, 44.4	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	0.85	-11.11
SD	21.014	32.710
MEDIAN	11.11	-5.56
Q1, Q3	-11.11, 11.11	-33.33, 11.11
MIN, MAX	-44.4, 33.3	-55.6, 22.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 222 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	25.64	61.11
SD	18.361	7.857
MEDIAN	22.22	61.11
Q1, Q3	22.22, 44.44	55.56, 66.67
MIN, MAX	0.0, 55.6	55.6, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	5.13	5.56
SD	28.188	23.570
MEDIAN	11.11	5.56
Q1, Q3	-11.11, 22.22	-11.11, 22.22
MIN, MAX	-44.4, 55.6	-11.1, 22.2
CYCLE 37		
N	14	2
MEAN	25.40	22.22
SD	17.118	31.427
MEDIAN	33.33	22.22
Q1, Q3	11.11, 33.33	0.00, 44.44
MIN, MAX	0.0, 55.6	0.0, 44.4

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 223 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	0.79	0.00
SD	29.061	15.713
MEDIAN	5.56	0.00
Q1, Q3	-22.22, 22.22	-11.11, 11.11
MIN, MAX	-55.6, 33.3	-11.1, 11.1
CYCLE 38		
N	11	2
MEAN	23.23	50.00
SD	18.227	7.857
MEDIAN	22.22	50.00
Q1, Q3	11.11, 33.33	44.44, 55.56
MIN, MAX	0.0, 55.6	44.4, 55.6
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-2.02	-5.56
SD	28.029	23.570
MEDIAN	11.11	-5.56
Q1, Q3	-33.33, 22.22	-22.22, 11.11
MIN, MAX	-55.6, 33.3	-22.2, 11.1

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 224 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	26.39	29.63
SD	16.733	27.962
MEDIAN	33.33	33.33
Q1, Q3	11.11, 38.89	0.00, 55.56
MIN, MAX	0.0, 44.4	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	4.17	-11.11
SD	16.733	33.333
MEDIAN	5.56	-11.11
Q1, Q3	-5.56, 11.11	-44.44, 22.22
MIN, MAX	-22.2, 33.3	-44.4, 22.2
CYCLE 40		
N	11	3
MEAN	23.23	37.04
SD	17.536	32.075
MEDIAN	22.22	55.56
Q1, Q3	11.11, 33.33	0.00, 55.56
MIN, MAX	0.0, 55.6	0.0, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 225 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-2.02	-3.70
SD	15.570	23.130
MEDIAN	-11.11	-11.11
Q1, Q3	-11.11, 11.11	-22.22, 22.22
MIN, MAX	-22.2, 33.3	-22.2, 22.2
CYCLE 41		
N	9	0
MEAN	25.93	
SD	17.568	
MEDIAN	22.22	
Q1, Q3	11.11, 33.33	
MIN, MAX	0.0, 55.6	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-1.23	
SD	17.954	
MEDIAN	0.00	
Q1, Q3	-11.11, 11.11	
MIN, MAX	-33.3, 22.2	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 226 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	20.37	0.00
SD	21.564	N.A.
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 55.6	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-1.85	-11.11
SD	25.740	N.A.
MEDIAN	-5.56	-11.11
Q1, Q3	-22.22, 22.22	-11.11, -11.11
MIN, MAX	-33.3, 33.3	-11.1, -11.1
CYCLE 43		
N	5	0
MEAN	17.78	
SD	12.669	
MEDIAN	22.22	
Q1, Q3	11.11, 22.22	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 227 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-8.89	
SD	16.480	
MEDIAN	-11.11	
Q1, Q3	-11.11, 0.00	
MIN, MAX	-33.3, 11.1	
CYCLE 44		
N	3	0
MEAN	18.52	
SD	16.973	
MEDIAN	22.22	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-14.81	
SD	16.973	
MEDIAN	-11.11	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 228 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	20.00	
SD	12.172	
MEDIAN	22.22	
Q1, Q3	22.22, 22.22	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	18.592	
MEDIAN	-11.11	
Q1, Q3	-11.11, 11.11	
MIN, MAX	-33.3, 11.1	
CYCLE 46		
N	3	0
MEAN	7.41	
SD	12.830	
MEDIAN	0.00	
Q1, Q3	0.00, 22.22	
MIN, MAX	0.0, 22.2	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 229 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-18.52	
SD	12.830	
MEDIAN	-11.11	
Q1, Q3	-33.33, -11.11	
MIN, MAX	-33.3, -11.1	
CYCLE 47		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 230 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	22.22	
SD	N.A.	
MEDIAN	22.22	
Q1, Q3	22.22, 22.22	
MIN, MAX	22.2, 22.2	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-11.11	
SD	N.A.	
MEDIAN	-11.11	
Q1, Q3	-11.11, -11.11	
MIN, MAX	-11.1, -11.1	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 231 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	41.67	46.42
SD	31.172	29.991
MEDIAN	38.89	44.44
Q1, Q3	16.67, 66.67	22.22, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	4.51	9.38
SD	36.127	29.393
MEDIAN	11.11	11.11
Q1, Q3	-27.78, 33.33	-11.11, 22.22
MIN, MAX	-77.8, 66.7	-55.6, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 232 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
NAUSEA AND VOMITING		
BASELINE		
N	112	104
MEAN	7.89	8.17
SD	17.610	16.421
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	4.17	3.30
SD	9.217	7.943
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-3.53	-4.21
SD	17.790	15.633
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 33.3	-83.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 233 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	2.31	3.37
SD	6.679	8.091
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-6.27	-4.17
SD	17.297	16.742
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 16.7	-100.0, 33.3
CYCLE 4		
N	97	81
MEAN	3.95	4.94
SD	10.964	14.299
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 234 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-4.34	-2.88
SD	14.758	20.546
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-83.3, 16.7	-100.0, 83.3
CYCLE 5		
N	93	73
MEAN	3.58	2.97
SD	9.469	8.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-4.53	-4.79
SD	16.958	17.454
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-83.3, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 235 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	2.87	2.90
SD	9.911	8.554
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-4.65	-5.31
SD	14.608	18.632
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 16.7	-100.0, 50.0
CYCLE 7		
N	89	65
MEAN	3.00	3.33
SD	8.905	7.906
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 236 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-4.73	-5.38
SD	19.237	15.896
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 8		
N	82	57
MEAN	2.85	2.05
SD	8.609	6.354
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-5.14	-7.02
SD	19.301	19.145
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 237 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	2.58	2.92
SD	8.381	7.794
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-4.62	-5.56
SD	17.714	17.631
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 33.3	-83.3, 33.3
CYCLE 10		
N	81	54
MEAN	1.65	6.79
SD	5.003	17.886
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 238 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-5.63	-1.54
SD	17.778	23.407
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-83.3, 16.7	-66.7, 100.0
CYCLE 11		
N	72	47
MEAN	2.31	2.13
SD	6.443	5.622
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-5.09	-7.09
SD	18.897	17.633
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 16.7	-83.3, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 239 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	2.38	8.73
SD	7.114	20.242
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-3.86	-1.59
SD	15.952	25.979
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 33.3	-83.3, 100.0
CYCLE 13		
N	73	40
MEAN	4.11	5.83
SD	13.828	16.256
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 240 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-3.47	-4.17
SD	13.969	14.495
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 50.0	-66.7, 33.3
CYCLE 14		
N	55	27
MEAN	2.73	4.94
SD	8.342	12.067
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-4.94	-6.79
SD	18.494	26.255
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-83.3, 33.3	-100.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 241 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	4.10	4.69
SD	11.423	9.685
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-3.91	-4.69
SD	15.067	20.406
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 16.7
CYCLE 16		
N	58	29
MEAN	3.74	2.30
SD	11.275	5.849
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 242 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-3.80	-7.47
SD	18.903	18.680
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 50.0	-83.3, 16.7
CYCLE 17		
N	56	31
MEAN	3.87	4.84
SD	11.006	15.027
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-4.46	-3.76
SD	14.031	18.110
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 16.7	-50.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 243 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	5.71	5.07
SD	18.052	11.715
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-4.41	-5.80
SD	23.680	13.861
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 66.7	-50.0, 16.7
CYCLE 19		
N	45	28
MEAN	3.70	5.36
SD	7.857	11.161
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 244 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-3.70	-3.57
SD	16.240	17.776
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-8.33, 0.00
MIN, MAX	-83.3, 16.7	-66.7, 33.3
CYCLE 20		
N	31	17
MEAN	5.91	1.96
SD	11.012	5.535
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-2.22	-10.78
SD	16.800	25.645
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 245 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	4.50	2.78
SD	10.129	8.575
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-4.05	-9.26
SD	20.186	17.360
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-83.3, 33.3	-66.7, 0.0
CYCLE 22		
N	44	13
MEAN	3.79	3.85
SD	9.417	9.986
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 246 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-3.49	-11.54
SD	14.799	19.702
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 0.0
CYCLE 23		
N	28	10
MEAN	5.36	5.00
SD	14.383	11.249
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-6.55	-13.33
SD	16.567	21.943
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 247 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	9.20	5.00
SD	19.713	8.051
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	1.15	-13.33
SD	21.330	25.820
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 50.0	-83.3, 0.0
CYCLE 25		
N	35	13
MEAN	3.81	6.41
SD	10.760	10.841
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 50.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 248 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-1.90	-8.97
SD	13.869	28.557
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 50.0	-100.0, 16.7
CYCLE 26		
N	20	9
MEAN	4.17	7.41
SD	7.404	8.784
MEDIAN	0.00	0.00
Q1, Q3	0.00, 8.33	0.00, 16.67
MIN, MAX	0.0, 16.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-2.50	-14.81
SD	11.180	34.805
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 16.7	-100.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 249 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	10.00	5.56
SD	18.002	14.794
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	5.33	-9.72
SD	18.459	29.694
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-8.33, 0.00
MIN, MAX	-16.7, 50.0	-100.0, 16.7
CYCLE 28		
N	30	9
MEAN	5.00	3.70
SD	10.854	7.349
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 250 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-0.56	-12.96
SD	10.249	34.134
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 16.7
CYCLE 29		
N	18	7
MEAN	3.70	0.00
SD	7.130	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-1.85	-19.05
SD	11.273	36.551
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 16.7	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 251 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	3.97	2.38
SD	8.983	6.299
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	1.59	-16.67
SD	10.415	37.268
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-16.7, 33.3	-100.0, 0.0
CYCLE 31		
N	23	7
MEAN	5.07	7.14
SD	14.595	13.113
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 252 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	2.90	-11.90
SD	15.612	41.627
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-16.7, 66.7	-100.0, 33.3
CYCLE 32		
N	17	4
MEAN	4.90	4.17
SD	16.420	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 8.33
MIN, MAX	0.0, 66.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	2.94	-25.00
SD	17.907	39.675
MEDIAN	0.00	-8.33
Q1, Q3	0.00, 0.00	-50.00, 0.00
MIN, MAX	-16.7, 66.7	-83.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 253 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	2.08	0.00
SD	5.693	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-1.04	-3.33
SD	7.376	7.454
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-16.7, 16.7	-16.7, 0.0
CYCLE 34		
N	20	4
MEAN	5.83	4.17
SD	11.180	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 8.33	0.00, 8.33
MIN, MAX	0.0, 33.3	0.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 254 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	3.33	-4.17
SD	11.598	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-8.33, 0.00
MIN, MAX	-16.7, 33.3	-16.7, 0.0
CYCLE 35		
N	13	4
MEAN	1.28	0.00
SD	4.623	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 16.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-1.28	-4.17
SD	4.623	8.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-8.33, 0.00
MIN, MAX	-16.7, 0.0	-16.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 255 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-1.28	-8.33
SD	4.623	11.785
MEDIAN	0.00	-8.33
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-16.7, 0.0	-16.7, 0.0
CYCLE 37		
N	14	2
MEAN	7.14	8.33
SD	14.194	11.785
MEDIAN	0.00	8.33
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 256 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	4.76	8.33
SD	13.757	11.785
MEDIAN	0.00	8.33
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-16.7, 33.3	0.0, 16.7
CYCLE 38		
N	11	2
MEAN	1.52	8.33
SD	5.025	11.785
MEDIAN	0.00	8.33
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 16.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-1.52	0.00
SD	5.025	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-16.7, 0.0	-16.7, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 257 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	2.08	5.56
SD	5.893	9.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 16.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	0.00
SD	8.909	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-16.7, 16.7	-16.7, 16.7
CYCLE 40		
N	11	3
MEAN	1.52	5.56
SD	5.025	9.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 16.7	0.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 258 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-1.52	0.00
SD	5.025	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-16.7, 0.0	-16.7, 16.7
CYCLE 41		
N	9	0
MEAN	7.41	
SD	12.108	
MEDIAN	0.00	
Q1, Q3	0.00, 16.67	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	3.70	
SD	13.889	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-16.7, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 259 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-2.78	0.00
SD	6.804	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-16.7, 0.0	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 260 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 261 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 262 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 263 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 264 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	9.38	14.07
SD	16.361	27.051
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-6.25	5.93
SD	21.061	29.119
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-66.7, 33.3	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 265 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PAIN		
BASELINE		
N	112	104
MEAN	22.92	28.69
SD	25.909	29.510
MEDIAN	16.67	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	12.66	14.65
SD	20.707	21.493
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 83.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-10.42	-13.55
SD	25.985	25.929
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-83.3, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 266 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	12.54	13.29
SD	19.636	19.666
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-10.23	-11.31
SD	26.454	29.516
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 83.3
CYCLE 4		
N	97	81
MEAN	14.95	18.11
SD	21.039	21.602
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 267 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-7.64	-8.23
SD	25.468	26.500
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 50.0
CYCLE 5		
N	93	73
MEAN	11.47	16.67
SD	19.031	21.337
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-10.33	-8.68
SD	23.158	27.090
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 50.0	-100.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 268 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	11.49	20.53
SD	18.383	26.529
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 83.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-8.53	-6.52
SD	19.761	33.846
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-100.0, 83.3
CYCLE 7		
N	89	65
MEAN	12.55	18.46
SD	21.064	23.958
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 269 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-8.33	-10.00
SD	26.017	30.162
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-83.3, 100.0
CYCLE 8		
N	82	57
MEAN	11.38	18.42
SD	21.095	25.913
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-7.41	-9.94
SD	25.550	32.253
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 270 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	10.52	18.13
SD	16.318	27.146
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 50.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-9.84	-10.23
SD	22.846	34.897
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 33.3	-100.0, 83.3
CYCLE 10		
N	81	54
MEAN	12.55	21.60
SD	21.495	27.592
MEDIAN	0.00	8.33
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 271 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-7.71	-6.17
SD	22.336	33.380
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-100.0, 83.3
CYCLE 11		
N	72	47
MEAN	14.12	17.02
SD	22.319	22.918
MEDIAN	0.00	0.00
Q1, Q3	0.00, 25.00	0.00, 33.33
MIN, MAX	0.0, 83.3	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-5.56	-9.22
SD	25.175	26.876
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 66.7	-83.3, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 272 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	11.43	23.02
SD	19.149	27.038
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-7.49	-4.76
SD	24.677	33.188
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-83.3, 83.3
CYCLE 13		
N	73	40
MEAN	12.79	25.83
SD	21.788	32.456
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 273 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-6.71	-1.67
SD	25.278	33.291
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-25.00, 16.67
MIN, MAX	-83.3, 66.7	-100.0, 66.7
CYCLE 14		
N	55	27
MEAN	13.94	15.43
SD	23.519	25.287
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-7.41	-13.58
SD	27.976	35.817
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 274 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	15.38	21.35
SD	24.528	29.095
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-4.43	-5.73
SD	25.240	35.572
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 16		
N	58	29
MEAN	14.08	16.09
SD	22.686	24.186
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 83.3	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 275 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-6.73	-10.34
SD	26.700	30.672
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 83.3
CYCLE 17		
N	56	31
MEAN	13.99	19.89
SD	21.267	27.359
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-2.68	-4.84
SD	20.787	29.248
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-83.3, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 276 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	16.67	21.01
SD	26.813	32.262
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-6.86	-7.97
SD	26.628	37.896
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-100.0, 66.7	-100.0, 83.3
CYCLE 19		
N	45	28
MEAN	17.78	20.24
SD	25.475	28.093
MEDIAN	0.00	8.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 277 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-1.11	-5.36
SD	32.255	30.107
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-25.00, 0.00
MIN, MAX	-100.0, 83.3	-83.3, 66.7
CYCLE 20		
N	31	17
MEAN	15.59	14.71
SD	21.489	19.439
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-6.11	-14.71
SD	30.476	31.115
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 50.0	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 278 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	15.77	11.11
SD	24.828	17.150
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-3.60	-14.81
SD	31.460	29.643
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 83.3	-100.0, 16.7
CYCLE 22		
N	44	13
MEAN	17.42	10.26
SD	23.003	17.398
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 279 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-1.16	-15.38
SD	25.561	24.019
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-50.0, 33.3
CYCLE 23		
N	28	10
MEAN	21.43	23.33
SD	26.394	25.092
MEDIAN	16.67	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-1.19	0.00
SD	30.065	27.217
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 16.67
MIN, MAX	-83.3, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 280 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	16.67	13.33
SD	26.352	23.307
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-1.72	-15.00
SD	33.138	28.814
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-83.3, 83.3	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	20.48	8.97
SD	28.031	12.938
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 281 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	4.76	-15.38
SD	27.880	30.017
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 0.00
MIN, MAX	-50.0, 66.7	-100.0, 16.7
CYCLE 26		
N	20	9
MEAN	20.00	14.81
SD	24.543	28.191
MEDIAN	8.33	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 83.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	2.50	-16.67
SD	24.941	41.667
MEDIAN	0.00	0.00
Q1, Q3	-8.33, 8.33	-33.33, 0.00
MIN, MAX	-50.0, 50.0	-100.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 282 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	17.33	9.72
SD	27.420	20.669
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 8.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-2.00	-11.11
SD	35.132	26.905
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-25.00, 0.00
MIN, MAX	-83.3, 83.3	-66.7, 33.3
CYCLE 28		
N	30	9
MEAN	21.67	12.96
SD	28.077	18.215
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 283 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	7.78	-14.81
SD	29.599	34.805
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 33.33	-16.67, 0.00
MIN, MAX	-50.0, 66.7	-100.0, 16.7
CYCLE 29		
N	18	7
MEAN	22.22	19.05
SD	24.918	36.551
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	2.78	-7.14
SD	32.964	54.311
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-33.33, 0.00
MIN, MAX	-50.0, 66.7	-100.0, 83.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 284 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	12.70	11.90
SD	22.916	15.853
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-1.59	-19.05
SD	28.822	27.936
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-50.00, 0.00
MIN, MAX	-50.0, 66.7	-66.7, 0.0
CYCLE 31		
N	23	7
MEAN	14.49	19.05
SD	25.773	37.796
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 83.3	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 285 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-2.17	-14.29
SD	35.285	51.306
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-50.00, 0.00
MIN, MAX	-83.3, 83.3	-100.0, 66.7
CYCLE 32		
N	17	4
MEAN	14.71	16.67
SD	23.483	23.570
MEDIAN	0.00	8.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-0.98	-20.83
SD	29.739	34.359
MEDIAN	0.00	-25.00
Q1, Q3	-16.67, 0.00	-50.00, 8.33
MIN, MAX	-50.0, 66.7	-50.0, 16.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 286 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	13.54	10.00
SD	19.454	9.129
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 50.0	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-7.29	-3.33
SD	25.069	18.257
MEDIAN	-8.33	0.00
Q1, Q3	-16.67, 8.33	0.00, 0.00
MIN, MAX	-50.0, 33.3	-33.3, 16.7
CYCLE 34		
N	20	4
MEAN	15.00	29.17
SD	23.508	20.972
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	16.67, 41.67
MIN, MAX	0.0, 66.7	0.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 287 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-2.50	4.17
SD	30.240	20.972
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-8.33, 16.67
MIN, MAX	-50.0, 66.7	-16.7, 33.3
CYCLE 35		
N	13	4
MEAN	11.54	12.50
SD	22.958	25.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 25.00
MIN, MAX	0.0, 66.7	0.0, 50.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-3.85	-4.17
SD	28.991	41.667
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-33.33, 25.00
MIN, MAX	-50.0, 66.7	-50.0, 50.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 288 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	10.26	16.67
SD	22.088	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-5.13	-8.33
SD	27.542	11.785
MEDIAN	0.00	-8.33
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 66.7	-16.7, 0.0
CYCLE 37		
N	14	2
MEAN	10.71	0.00
SD	22.272	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 289 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-7.14	-8.33
SD	28.280	11.785
MEDIAN	-8.33	-8.33
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 66.7	-16.7, 0.0
CYCLE 38		
N	11	2
MEAN	18.18	8.33
SD	22.918	11.785
MEDIAN	0.00	8.33
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 16.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-1.52	-16.67
SD	30.235	23.570
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-50.0, 66.7	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 290 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	18.75	0.00
SD	24.296	0.000
MEDIAN	8.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	2.08	-22.22
SD	32.657	25.459
MEDIAN	0.00	-16.67
Q1, Q3	-8.33, 8.33	-50.00, 0.00
MIN, MAX	-50.0, 66.7	-50.0, 0.0
CYCLE 40		
N	11	3
MEAN	10.61	11.11
SD	15.407	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 291 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-10.61	-11.11
SD	25.025	9.623
MEDIAN	-16.67	-16.67
Q1, Q3	-16.67, 0.00	-16.67, 0.00
MIN, MAX	-50.0, 33.3	-16.7, 0.0
CYCLE 41		
N	9	0
MEAN	20.37	
SD	26.058	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	1.85	
SD	24.216	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 50.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 292 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	19.44	0.00
SD	19.484	N.A.
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 50.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	-16.67
SD	22.771	N.A.
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-16.67, -16.67
MIN, MAX	-16.7, 50.0	-16.7, -16.7
CYCLE 43		
N	5	0
MEAN	10.00	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 16.67	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 293 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	9.129	
MEDIAN	0.00	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-11.11	
SD	9.623	
MEDIAN	-16.67	
Q1, Q3	-16.67, 0.00	
MIN, MAX	-16.7, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 294 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	3.33	
SD	7.454	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 16.7	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-13.33	
SD	7.454	
MEDIAN	-16.67	
Q1, Q3	-16.67, -16.67	
MIN, MAX	-16.7, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	9.623	
MEDIAN	16.67	
Q1, Q3	0.00, 16.67	
MIN, MAX	0.0, 16.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 295 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-5.56	
SD	19.245	
MEDIAN	-16.67	
Q1, Q3	-16.67, 16.67	
MIN, MAX	-16.7, 16.7	
CYCLE 47		
N	1	0
MEAN	50.00	
SD	N.A.	
MEDIAN	50.00	
Q1, Q3	50.00, 50.00	
MIN, MAX	50.0, 50.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	16.67	
SD	N.A.	
MEDIAN	16.67	
Q1, Q3	16.67, 16.67	
MIN, MAX	16.7, 16.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 296 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 297 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	31.25	30.74
SD	36.845	34.988
MEDIAN	16.67	16.67
Q1, Q3	0.00, 66.67	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	0.52	0.74
SD	39.369	38.263
MEDIAN	0.00	0.00
Q1, Q3	-25.00, 8.33	-16.67, 16.67
MIN, MAX	-66.7, 100.0	-83.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 298 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
DYSPNEA		
BASELINE		
N	112	104
MEAN	32.14	29.81
SD	30.976	31.475
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	23.08	26.30
SD	24.170	28.042
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-8.65	-2.22
SD	31.502	22.789
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 299 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	25.74	27.38
SD	26.196	27.942
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-6.60	1.19
SD	34.967	25.584
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 66.7
CYCLE 4		
N	97	81
MEAN	26.80	26.75
SD	27.487	28.097
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 300 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-6.25	0.00
SD	28.741	27.889
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 5		
N	92	73
MEAN	22.83	28.77
SD	25.163	28.499
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	-9.16	3.65
SD	31.843	29.166
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 301 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	22.99	31.40
SD	24.543	31.769
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-8.91	6.76
SD	32.509	34.099
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 7		
N	89	65
MEAN	23.60	32.31
SD	25.723	30.028
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 302 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-7.20	6.15
SD	36.251	31.673
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 8		
N	82	57
MEAN	24.39	24.56
SD	25.686	27.836
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-4.12	-2.92
SD	31.350	34.087
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 303 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	24.21	30.99
SD	23.909	28.771
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-3.61	4.09
SD	32.515	34.544
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 10		
N	81	54
MEAN	24.28	30.86
SD	24.159	31.624
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 304 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-2.92	3.70
SD	27.658	34.669
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 11		
N	72	47
MEAN	25.93	29.79
SD	26.960	28.854
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-0.93	5.67
SD	28.511	36.329
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	0.00, 33.33
MIN, MAX	-66.7, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 305 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	22.38	32.54
SD	25.202	32.500
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-2.90	7.94
SD	30.646	36.670
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 13		
N	73	40
MEAN	25.11	27.50
SD	25.928	29.125
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 306 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-2.78	2.50
SD	29.471	38.034
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 14		
N	55	27
MEAN	27.88	24.69
SD	29.927	27.100
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-0.62	1.23
SD	30.708	37.532
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-33.33, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 307 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	27.69	35.42
SD	28.607	32.723
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-1.04	11.46
SD	31.966	43.675
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-16.67, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 16		
N	58	29
MEAN	26.44	29.89
SD	28.448	32.544
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 308 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-1.75	6.90
SD	28.467	43.076
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 17		
N	56	31
MEAN	27.38	29.03
SD	30.555	29.492
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-0.60	5.38
SD	30.808	40.457
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 309 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	27.62	27.54
SD	28.567	32.802
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-2.94	4.35
SD	34.199	42.999
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 33.33
MIN, MAX	-100.0, 33.3	-66.7, 100.0
CYCLE 19		
N	45	28
MEAN	25.93	35.71
SD	28.328	29.991
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 310 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-0.74	13.10
SD	27.969	37.777
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 100.0
CYCLE 20		
N	31	17
MEAN	29.03	23.53
SD	25.447	19.596
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	1.11	-3.92
SD	22.289	35.123
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-33.3, 33.3	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 311 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	26.13	27.78
SD	31.559	26.197
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-2.70	1.85
SD	32.753	29.087
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 22		
N	44	13
MEAN	30.30	28.21
SD	30.345	32.903
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 312 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	2.33	15.38
SD	32.034	37.553
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 100.0
CYCLE 23		
N	28	10
MEAN	39.29	30.00
SD	32.778	24.595
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	7.14	10.00
SD	35.552	27.442
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 313 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	27.59	36.67
SD	29.639	24.595
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-1.15	20.00
SD	31.475	28.109
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 33.3	-33.3, 66.7
CYCLE 25		
N	35	13
MEAN	24.76	33.33
SD	28.403	36.004
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 314 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-3.81	20.51
SD	35.027	39.764
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 100.0
CYCLE 26		
N	20	9
MEAN	25.00	40.74
SD	21.289	27.778
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-6.67	29.63
SD	31.715	35.136
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	-100.0, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 315 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	28.00	30.56
SD	28.350	33.207
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	0.00	19.44
SD	31.914	38.817
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 33.3	-33.3, 100.0
CYCLE 28		
N	30	9
MEAN	20.00	29.63
SD	29.814	30.932
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 316 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-7.78	14.81
SD	37.837	37.680
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 29		
N	18	7
MEAN	29.63	28.57
SD	25.280	29.991
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	1.85	14.29
SD	24.179	37.796
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	-33.33, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 317 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	19.05	28.57
SD	27.021	23.002
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-7.94	19.05
SD	40.695	32.530
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 31		
N	23	7
MEAN	18.84	38.10
SD	26.258	29.991
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 318 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-7.25	23.81
SD	34.752	37.090
MEDIAN	0.00	33.33
Q1, Q3	-33.33, 0.00	0.00, 66.67
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 32		
N	17	4
MEAN	25.49	50.00
SD	30.114	19.245
MEDIAN	33.33	50.00
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	0.0, 100.0	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	0.00	41.67
SD	31.180	31.914
MEDIAN	0.00	50.00
Q1, Q3	0.00, 0.00	16.67, 66.67
MIN, MAX	-66.7, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 319 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	25.00	33.33
SD	28.545	23.570
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	33.33, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-2.08	26.67
SD	30.957	27.889
MEDIAN	0.00	33.33
Q1, Q3	-16.67, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	0.0, 66.7
CYCLE 34		
N	20	4
MEAN	23.33	41.67
SD	28.817	16.667
MEDIAN	16.67	33.33
Q1, Q3	0.00, 33.33	33.33, 50.00
MIN, MAX	0.0, 100.0	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 320 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-1.67	41.67
SD	27.519	16.667
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	33.33, 50.00
MIN, MAX	-66.7, 66.7	33.3, 66.7
CYCLE 35		
N	13	4
MEAN	23.08	41.67
SD	25.036	31.914
MEDIAN	33.33	50.00
Q1, Q3	0.00, 33.33	16.67, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-2.56	33.33
SD	28.744	27.217
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	16.67, 50.00
MIN, MAX	-66.7, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 321 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	25.64	66.67
SD	30.894	0.000
MEDIAN	33.33	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 100.0	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	2.56	66.67
SD	31.802	0.000
MEDIAN	0.00	66.67
Q1, Q3	0.00, 0.00	66.67, 66.67
MIN, MAX	-66.7, 66.7	66.7, 66.7
CYCLE 37		
N	14	2
MEAN	23.81	33.33
SD	33.150	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 322 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	2.38	16.67
SD	35.720	70.711
MEDIAN	0.00	16.67
Q1, Q3	-33.33, 33.33	-33.33, 66.67
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 38		
N	11	2
MEAN	24.24	66.67
SD	33.635	0.000
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 100.0	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	66.67
SD	33.333	0.000
MEDIAN	0.00	66.67
Q1, Q3	-33.33, 33.33	66.67, 66.67
MIN, MAX	-33.3, 66.7	66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 323 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	16.67	33.33
SD	25.198	33.333
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	22.22
SD	25.198	50.918
MEDIAN	0.00	33.33
Q1, Q3	-16.67, 16.67	-33.33, 66.67
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 40		
N	11	3
MEAN	18.18	44.44
SD	17.408	38.490
MEDIAN	33.33	66.67
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 324 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-3.03	33.33
SD	27.707	57.735
MEDIAN	0.00	66.67
Q1, Q3	-33.33, 33.33	-33.33, 66.67
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 41		
N	9	0
MEAN	14.81	
SD	17.568	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-7.41	
SD	27.778	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 325 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	11.11	0.00
SD	17.213	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-11.11	-33.33
SD	27.217	N.A.
MEDIAN	-16.67	-33.33
Q1, Q3	-33.33, 0.00	-33.33, -33.33
MIN, MAX	-33.3, 33.3	-33.3, -33.3
CYCLE 43		
N	5	0
MEAN	13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 326 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	27.889	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 33.3	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 327 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 328 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	38.490	
MEDIAN	-33.33	
Q1, Q3	-33.33, 33.33	
MIN, MAX	-33.3, 33.3	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 329 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 330 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	34.38	45.19
SD	27.415	37.034
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-2.08	12.59
SD	32.723	33.551
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 331 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
INSOMNIA		
BASELINE		
N	112	104
MEAN	25.30	28.85
SD	29.762	30.831
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	16.03	15.38
SD	23.215	24.499
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-8.65	-13.55
SD	28.252	29.805
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 332 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	8.25	13.49
SD	17.892	22.625
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-15.84	-12.30
SD	28.904	31.380
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 4		
N	97	81
MEAN	7.56	16.87
SD	17.681	21.809
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 333 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-17.01	-10.29
SD	23.691	31.465
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 66.7
CYCLE 5		
N	93	73
MEAN	8.60	12.33
SD	19.599	22.571
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-14.49	-14.61
SD	25.822	29.911
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 334 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	6.98	13.53
SD	16.263	27.605
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-15.69	-13.53
SD	26.018	31.992
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 100.0
CYCLE 7		
N	89	65
MEAN	9.74	17.44
SD	18.938	28.326
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 335 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-13.26	-11.28
SD	26.037	32.423
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 66.7
CYCLE 8		
N	82	57
MEAN	8.54	15.20
SD	17.222	25.253
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-11.93	-15.20
SD	29.016	33.375
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 336 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	8.33	15.79
SD	17.064	23.659
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-14.06	-12.87
SD	29.504	31.342
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 10		
N	81	54
MEAN	7.41	18.52
SD	15.811	25.630
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 337 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-14.17	-10.49
SD	25.311	37.098
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 100.0
CYCLE 11		
N	72	47
MEAN	7.41	18.44
SD	16.990	30.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-14.35	-12.77
SD	26.137	37.140
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 338 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	10.48	16.67
SD	22.374	22.391
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-9.18	-17.46
SD	28.517	31.441
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 13		
N	73	40
MEAN	10.05	18.33
SD	21.289	30.147
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 339 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-12.04	-15.00
SD	25.823	33.716
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 66.7
CYCLE 14		
N	55	26
MEAN	10.30	21.79
SD	19.108	32.581
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	26
MEAN	-11.11	-14.10
SD	26.698	42.346
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 340 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	11.79	25.00
SD	23.147	33.867
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-10.94	-8.33
SD	27.892	31.679
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 16		
N	58	29
MEAN	12.07	18.39
SD	21.356	26.105
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 341 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-9.94	-13.79
SD	28.147	30.234
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 17		
N	56	31
MEAN	7.74	12.90
SD	17.969	28.123
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-13.10	-15.05
SD	28.197	32.017
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 342 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	10.48	23.19
SD	22.537	29.189
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-13.73	-8.70
SD	29.721	25.060
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 19		
N	45	28
MEAN	11.85	21.43
SD	22.647	30.381
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 343 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-10.37	-9.52
SD	31.641	29.893
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 20		
N	31	17
MEAN	7.53	27.45
SD	14.167	35.815
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-13.33	-9.80
SD	27.123	22.866
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 344 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	9.91	22.22
SD	17.329	30.250
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-10.81	-7.41
SD	26.122	21.559
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 22		
N	44	13
MEAN	6.82	17.95
SD	15.384	22.008
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 345 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-14.73	-10.26
SD	25.513	25.036
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	10.71	26.67
SD	20.394	30.631
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-14.29	-3.33
SD	29.297	29.187
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 346 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	9.20	23.33
SD	19.713	27.442
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-12.64	-10.00
SD	32.628	31.623
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	10.48	20.51
SD	23.944	25.598
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 347 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-11.43	-7.69
SD	31.252	19.971
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0
CYCLE 26		
N	20	9
MEAN	10.00	22.22
SD	19.041	28.868
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-15.00	-11.11
SD	29.568	28.868
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 348 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	10.67	13.89
SD	23.014	22.285
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-10.67	-13.89
SD	32.942	26.432
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0
CYCLE 28		
N	30	9
MEAN	15.56	14.81
SD	25.869	17.568
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 349 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-6.67	-14.81
SD	34.352	29.397
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 29		
N	18	7
MEAN	14.81	14.29
SD	26.127	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-11.11	-19.05
SD	36.155	26.227
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 350 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	7.94	19.05
SD	17.965	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-11.11	-19.05
SD	35.486	32.530
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0
CYCLE 31		
N	23	7
MEAN	10.14	14.29
SD	18.627	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 351 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-8.70	-23.81
SD	30.513	31.706
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 0.0
CYCLE 32		
N	17	4
MEAN	13.73	33.33
SD	20.612	38.490
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-3.92	-8.33
SD	38.877	41.944
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 352 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	14.58	26.67
SD	20.972	27.889
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-2.08	-6.67
SD	25.730	43.461
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 34		
N	20	4
MEAN	10.00	25.00
SD	19.041	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 353 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-6.67	-8.33
SD	33.508	41.944
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 35		
N	13	4
MEAN	12.82	8.33
SD	21.681	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	2.56	-33.33
SD	31.802	38.490
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 354 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	10.26	33.33
SD	21.014	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	2.56	-16.67
SD	31.802	70.711
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-66.67, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 37		
N	14	2
MEAN	11.90	0.00
SD	24.832	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 355 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	0.00	-50.00
SD	29.235	23.570
MEDIAN	0.00	-50.00
Q1, Q3	0.00, 0.00	-66.67, -33.33
MIN, MAX	-66.7, 66.7	-66.7, -33.3
CYCLE 38		
N	11	2
MEAN	18.18	0.00
SD	22.918	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	9.09	-50.00
SD	30.151	23.570
MEDIAN	0.00	-50.00
Q1, Q3	0.00, 33.33	-66.67, -33.33
MIN, MAX	-33.3, 66.7	-66.7, -33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 356 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	16.67	11.11
SD	25.198	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	12.50	-44.44
SD	30.538	38.490
MEDIAN	0.00	-66.67
Q1, Q3	0.00, 33.33	-66.67, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0
CYCLE 40		
N	11	3
MEAN	6.06	11.11
SD	13.484	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 357 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-9.09	-44.44
SD	26.208	38.490
MEDIAN	0.00	-66.67
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 0.0
CYCLE 41		
N	9	0
MEAN	14.81	
SD	24.216	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	30.932	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-66.7, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 358 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-5.56	-66.67
SD	13.608	N.A.
MEDIAN	0.00	-66.67
Q1, Q3	0.00, 0.00	-66.67, -66.67
MIN, MAX	-33.3, 0.0	-66.7, -66.7
CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 359 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	33.333	
MEDIAN	0.00	
Q1, Q3	-33.33, 33.33	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 360 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-20.00	
SD	29.814	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-66.7, 0.0	
CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 361 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-33.33	
SD	33.333	
MEDIAN	-33.33	
Q1, Q3	-66.67, 0.00	
MIN, MAX	-66.7, 0.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 362 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 363 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	30.21	29.63
SD	33.182	33.501
MEDIAN	33.33	33.33
Q1, Q3	0.00, 50.00	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	4.17	-3.70
SD	39.486	35.691
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 364 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
APPETITE LOSS		
BASELINE		
N	112	104
MEAN	19.35	18.91
SD	30.557	28.164
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	8.97	7.69
SD	16.895	17.969
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	-10.58	-9.89
SD	27.971	23.038
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 365 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	6.27	5.16
SD	18.082	14.165
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-13.86	-9.92
SD	30.283	24.696
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 4		
N	97	81
MEAN	6.19	7.00
SD	15.463	14.640
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 366 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-13.89	-10.29
SD	30.461	27.204
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 5		
N	93	73
MEAN	6.09	7.76
SD	14.700	16.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-13.04	-8.68
SD	28.796	26.074
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 367 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	4.98	7.73
SD	12.989	14.171
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-13.18	-8.21
SD	29.936	22.438
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 7		
N	89	65
MEAN	5.24	8.72
SD	13.199	20.647
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 368 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-13.64	-9.23
SD	29.312	26.685
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7
CYCLE 8		
N	82	57
MEAN	4.47	6.43
SD	12.573	15.984
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-14.40	-12.28
SD	30.704	29.298
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 369 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	7.14	7.60
SD	13.760	16.688
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-10.84	-10.53
SD	30.403	24.526
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 10		
N	81	54
MEAN	5.76	9.26
SD	13.734	19.870
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 370 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	-12.50	-9.26
SD	30.178	33.905
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0
CYCLE 11		
N	72	47
MEAN	6.02	7.80
SD	14.072	17.324
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	-12.50	-11.35
SD	32.351	25.326
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 371 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	5.71	8.73
SD	13.868	20.900
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-11.59	-11.11
SD	27.312	28.195
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 13		
N	73	40
MEAN	5.02	11.67
SD	15.387	25.654
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 372 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-13.43	-8.33
SD	28.339	36.004
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 100.0
CYCLE 14		
N	55	27
MEAN	5.45	6.17
SD	14.001	20.749
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-14.81	-12.35
SD	35.269	38.284
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 373 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	5.64	7.29
SD	13.906	18.422
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	-14.58	-11.46
SD	31.357	33.451
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 16		
N	58	29
MEAN	7.47	8.05
SD	19.787	17.032
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 374 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-11.70	-8.05
SD	30.532	30.414
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 17		
N	56	31
MEAN	7.14	8.60
SD	20.806	19.183
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-13.10	-6.45
SD	27.472	32.682
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 375 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	14.29	10.14
SD	25.928	23.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-7.84	-7.25
SD	29.654	24.529
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 19		
N	45	28
MEAN	8.15	13.10
SD	16.136	26.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 376 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-11.85	-2.38
SD	29.435	29.991
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7
CYCLE 20		
N	31	17
MEAN	15.05	3.92
SD	28.335	16.169
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-5.56	-17.65
SD	40.194	29.149
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 377 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	11.71	5.56
SD	19.589	17.150
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-8.11	-14.81
SD	32.778	28.520
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 0.0
CYCLE 22		
N	44	13
MEAN	9.09	7.69
SD	23.143	19.971
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 378 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-8.53	-15.38
SD	28.259	29.235
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 0.0
CYCLE 23		
N	28	10
MEAN	11.90	13.33
SD	22.616	23.307
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-13.10	-10.00
SD	27.725	27.442
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 379 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	16.09	10.00
SD	26.157	22.498
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-2.30	-20.00
SD	38.762	39.126
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 33.3
CYCLE 25		
N	35	13
MEAN	7.62	15.38
SD	16.341	25.875
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 380 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-11.43	-7.69
SD	27.939	33.758
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 26		
N	20	9
MEAN	11.67	11.11
SD	24.839	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-10.00	-22.22
SD	34.370	33.333
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 381 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	18.67	8.33
SD	30.551	20.719
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-1.33	-13.89
SD	37.859	30.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 0.0
CYCLE 28		
N	30	9
MEAN	11.11	11.11
SD	23.705	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 382 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-7.78	-14.81
SD	27.240	37.680
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 29		
N	18	7
MEAN	11.11	14.29
SD	16.169	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-9.26	-14.29
SD	31.943	42.414
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 383 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	9.52	9.52
SD	21.455	25.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-6.35	-23.81
SD	30.946	37.090
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0
CYCLE 31		
N	23	7
MEAN	10.14	9.52
SD	18.627	25.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 384 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-7.25	-23.81
SD	34.752	37.090
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0
CYCLE 32		
N	17	4
MEAN	17.65	8.33
SD	31.441	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-1.96	-41.67
SD	38.135	68.718
MEDIAN	0.00	-50.00
Q1, Q3	-33.33, 0.00	-100.00, 16.67
MIN, MAX	-66.7, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 385 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	10.42	0.00
SD	20.069	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-8.33	-20.00
SD	25.820	44.721
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 0.0
CYCLE 34		
N	20	4
MEAN	11.67	16.67
SD	22.361	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 386 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-5.00	-16.67
SD	36.314	43.033
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-50.00, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 35		
N	13	4
MEAN	7.69	0.00
SD	19.971	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-12.82	-25.00
SD	25.598	50.000
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-50.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 387 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	10.26	0.00
SD	21.014	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-10.26	-50.00
SD	25.036	70.711
MEDIAN	0.00	-50.00
Q1, Q3	-33.33, 0.00	-100.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 0.0
CYCLE 37		
N	14	2
MEAN	7.14	0.00
SD	19.298	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 388 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-9.52	0.00
SD	30.462	0.000
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	0.00	16.67
SD	0.000	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-18.18	-33.33
SD	22.918	47.140
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 0.0	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 389 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	4.17	0.00
SD	11.785	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-12.50	-33.33
SD	30.538	57.735
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-100.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 0.0
CYCLE 40		
N	11	3
MEAN	0.00	11.11
SD	0.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 390 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-18.18	-22.22
SD	22.918	38.490
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 0.0	-66.7, 0.0
CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-14.81	
SD	29.397	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-66.7, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 391 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-22.22	0.00
SD	27.217	N.A.
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 392 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-20.00	
SD	18.257	
MEDIAN	-33.33	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-22.22	
SD	19.245	
MEDIAN	-33.33	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 393 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-20.00	
SD	18.257	
MEDIAN	-33.33	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 394 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	38.490	
MEDIAN	-33.33	
Q1, Q3	-33.33, 33.33	
MIN, MAX	-33.3, 33.3	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 395 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-33.33	
SD	N.A.	
MEDIAN	-33.33	
Q1, Q3	-33.33, -33.33	
MIN, MAX	-33.3, -33.3	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 396 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-33.33	
SD	N.A.	
MEDIAN	-33.33	
Q1, Q3	-33.33, -33.33	
MIN, MAX	-33.3, -33.3	
END OF TREATMENT		
N	32	45
MEAN	26.04	28.89
SD	30.214	33.029
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-1.04	8.15
SD	42.742	35.644
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 397 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CONSTIPATION		
BASELINE		
N	112	104
MEAN	12.20	16.99
SD	22.813	26.273
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	91
MEAN	37.18	32.60
SD	32.284	33.325
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	91
MEAN	25.64	15.75
SD	32.591	29.119
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 398 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	30.36	32.94
SD	28.323	34.901
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	17.82	17.46
SD	28.892	30.819
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 100.0
CYCLE 4		
N	97	81
MEAN	30.24	33.74
SD	29.298	33.122
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 399 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	18.40	17.28
SD	31.296	33.380
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 5		
N	93	73
MEAN	30.82	25.11
SD	30.785	28.750
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	19.93	10.05
SD	29.260	30.269
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 400 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	27.20	30.92
SD	28.087	34.922
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	16.67	14.01
SD	29.261	34.492
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 100.0	-100.0, 100.0
CYCLE 7		
N	89	65
MEAN	26.22	30.77
SD	27.281	31.351
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 401 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	15.53	13.33
SD	26.719	28.137
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 8		
N	81	57
MEAN	27.16	32.16
SD	29.397	32.711
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	17.70	15.20
SD	30.316	29.594
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 402 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	28.17	33.33
SD	28.573	33.923
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	17.67	17.54
SD	29.603	32.186
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 100.0
CYCLE 10		
N	81	54
MEAN	29.63	32.10
SD	29.814	34.241
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 403 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	80	54
MEAN	19.58	17.28
SD	29.384	32.852
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 11		
N	72	47
MEAN	28.24	31.21
SD	33.873	32.899
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	17.59	14.89
SD	31.135	31.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 404 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	30.00	29.37
SD	33.164	31.410
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	21.26	13.49
SD	33.806	33.785
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 100.0	-66.7, 100.0
CYCLE 13		
N	73	40
MEAN	28.31	35.00
SD	30.262	33.716
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 405 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	19.44	18.33
SD	30.515	31.078
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 100.0
CYCLE 14		
N	55	26
MEAN	29.70	32.05
SD	31.864	38.275
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	54	26
MEAN	20.37	14.10
SD	35.120	39.070
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 406 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	65	32
MEAN	29.74	37.50
SD	30.688	39.486
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	64	32
MEAN	20.31	17.71
SD	31.211	42.320
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 16		
N	58	29
MEAN	27.59	27.59
SD	30.677	34.583
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 407 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	18.13	9.20
SD	30.906	36.620
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 100.0
CYCLE 17		
N	56	31
MEAN	28.57	35.48
SD	30.767	37.452
MEDIAN	33.33	33.33
Q1, Q3	0.00, 50.00	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	18.45	15.05
SD	30.431	37.356
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 408 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	29.52	33.33
SD	31.072	31.782
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	18.63	11.59
SD	30.913	32.735
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 100.0
CYCLE 19		
N	45	28
MEAN	30.37	39.29
SD	32.429	34.010
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 409 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	18.52	19.05
SD	30.613	38.946
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 100.0
CYCLE 20		
N	31	17
MEAN	32.26	27.45
SD	32.755	33.820
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	18.89	5.88
SD	31.175	33.820
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 410 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	29.73	37.04
SD	31.214	30.008
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	33.33, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	16.22	11.11
SD	36.533	34.300
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 22		
N	44	13
MEAN	28.03	25.64
SD	30.452	30.894
MEDIAN	33.33	33.33
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 411 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	17.83	2.56
SD	34.387	34.592
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	33.33	46.67
SD	32.710	35.832
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	16.67	13.33
SD	40.062	35.832
MEDIAN	16.67	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 412 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	39.08	33.33
SD	30.949	31.427
MEDIAN	33.33	33.33
Q1, Q3	33.33, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	26.44	6.67
SD	34.937	37.843
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	-33.33, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	32.38	38.46
SD	27.399	32.903
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	33.33, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 413 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	23.81	15.38
SD	28.665	42.197
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 100.0
CYCLE 26		
N	20	9
MEAN	35.00	37.04
SD	31.484	26.058
MEDIAN	33.33	33.33
Q1, Q3	0.00, 50.00	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	26.67	7.41
SD	35.210	40.062
MEDIAN	33.33	0.00
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 414 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	38.67	41.67
SD	32.886	20.719
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	33.33, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	28.00	19.44
SD	38.103	36.121
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	-16.67, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 66.7
CYCLE 28		
N	30	9
MEAN	33.33	25.93
SD	32.754	22.222
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 415 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	26.67	3.70
SD	33.218	35.136
MEDIAN	33.33	0.00
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 33.3
CYCLE 29		
N	18	7
MEAN	33.33	38.10
SD	36.155	40.500
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	24.07	14.29
SD	33.927	57.275
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	-33.33, 66.67
MIN, MAX	-33.3, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 416 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	30.16	57.14
SD	31.455	25.198
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	33.33, 66.67
MIN, MAX	0.0, 100.0	33.3, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	23.81	38.10
SD	31.873	40.500
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	-33.3, 66.7	-33.3, 100.0
CYCLE 31		
N	23	7
MEAN	33.33	42.86
SD	31.782	31.706
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 417 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	26.09	19.05
SD	36.177	42.414
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	-33.33, 66.67
MIN, MAX	-66.7, 66.7	-33.3, 66.7
CYCLE 32		
N	17	4
MEAN	43.14	33.33
SD	34.890	27.217
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	16.67, 50.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	37.25	0.00
SD	33.087	66.667
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	-33.33, 33.33
MIN, MAX	-33.3, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 418 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	41.67	40.00
SD	31.032	36.515
MEDIAN	33.33	66.67
Q1, Q3	16.67, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	31.25	33.33
SD	35.421	33.333
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	-33.3, 66.7	0.0, 66.7
CYCLE 34		
N	20	4
MEAN	36.67	25.00
SD	30.397	31.914
MEDIAN	33.33	16.67
Q1, Q3	0.00, 66.67	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 419 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	28.33	16.67
SD	32.936	19.245
MEDIAN	33.33	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 35		
N	13	4
MEAN	38.46	58.33
SD	29.957	41.944
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	33.33, 83.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	33.33	50.00
SD	33.333	43.033
MEDIAN	33.33	50.00
Q1, Q3	0.00, 66.67	16.67, 83.33
MIN, MAX	-33.3, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 420 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	30.77	66.67
SD	28.744	0.000
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	66.67, 66.67
MIN, MAX	0.0, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	25.64	50.00
SD	30.894	23.570
MEDIAN	33.33	50.00
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	-33.3, 66.7	33.3, 66.7
CYCLE 37		
N	14	2
MEAN	33.33	33.33
SD	29.235	47.140
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 421 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	23.81	16.67
SD	30.462	23.570
MEDIAN	33.33	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 38		
N	11	2
MEAN	30.30	66.67
SD	27.707	0.000
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	66.67, 66.67
MIN, MAX	0.0, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	18.18	50.00
SD	34.524	23.570
MEDIAN	33.33	50.00
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	-33.3, 66.7	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 422 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	37.50	33.33
SD	27.817	33.333
MEDIAN	33.33	33.33
Q1, Q3	16.67, 66.67	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	29.17	22.22
SD	37.533	19.245
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 40		
N	11	3
MEAN	36.36	77.78
SD	27.707	19.245
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	66.67, 100.00
MIN, MAX	0.0, 66.7	66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 423 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	24.24	66.67
SD	33.635	33.333
MEDIAN	33.33	66.67
Q1, Q3	0.00, 66.67	33.33, 100.00
MIN, MAX	-33.3, 66.7	33.3, 100.0
CYCLE 41		
N	9	0
MEAN	44.44	
SD	23.570	
MEDIAN	33.33	
Q1, Q3	33.33, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	33.33	
SD	23.570	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	0.0, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 424 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	33.33	100.00
SD	21.082	N.A.
MEDIAN	33.33	100.00
Q1, Q3	33.33, 33.33	100.00, 100.00
MIN, MAX	0.0, 66.7	100.0, 100.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	27.78	100.00
SD	25.092	N.A.
MEDIAN	33.33	100.00
Q1, Q3	0.00, 33.33	100.00, 100.00
MIN, MAX	0.0, 66.7	100.0, 100.0
CYCLE 43		
N	5	0
MEAN	26.67	
SD	27.889	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 425 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	20.00	
SD	29.814	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CYCLE 44		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 426 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	26.67	
SD	27.889	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	20.00	
SD	18.257	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 46		
N	3	0
MEAN	33.33	
SD	33.333	
MEDIAN	33.33	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 427 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 428 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 49		
N	1	0
MEAN	66.67	
SD	N.A.	
MEDIAN	66.67	
Q1, Q3	66.67, 66.67	
MIN, MAX	66.7, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 429 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	32	45
MEAN	31.25	32.59
SD	31.609	39.241
MEDIAN	33.33	33.33
Q1, Q3	0.00, 66.67	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	16.67	13.33
SD	37.864	39.184
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 430 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
DIARRHEA		
BASELINE		
N	112	104
MEAN	4.46	8.65
SD	13.788	18.577
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	3.53	3.70
SD	12.217	10.534
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-1.28	-4.07
SD	13.875	18.581
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 431 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	6.67	5.56
SD	17.082	15.379
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	2.67	-3.17
SD	16.192	19.784
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 4		
N	97	81
MEAN	4.47	5.35
SD	12.387	15.327
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 432 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	0.00	-4.12
SD	17.438	22.597
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 5		
N	93	73
MEAN	4.66	5.02
SD	13.541	14.349
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	0.00	-3.65
SD	20.375	22.609
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 433 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	3.88	6.76
SD	11.902	14.664
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-0.39	-2.42
SD	14.990	20.064
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 7		
N	89	65
MEAN	4.49	8.72
SD	13.476	21.471
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 434 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-0.38	-1.03
SD	17.135	22.798
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 8		
N	82	57
MEAN	4.88	7.02
SD	13.978	17.522
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	0.00	-3.51
SD	14.907	22.435
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 435 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	4.37	6.43
SD	15.332	13.272
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	0.00	-4.09
SD	14.724	21.886
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 10		
N	80	54
MEAN	2.92	7.41
SD	9.478	15.414
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 436 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	0.00	-3.09
SD	13.074	21.736
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 11		
N	72	47
MEAN	3.70	2.13
SD	10.549	8.236
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	0.00	-9.93
SD	13.704	22.963
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 437 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	4.76	8.73
SD	11.748	23.350
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	1.45	-4.76
SD	14.501	30.861
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 100.0
CYCLE 13		
N	73	40
MEAN	5.94	3.33
SD	16.046	10.127
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 438 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	1.85	-10.00
SD	16.680	21.616
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 14		
N	55	27
MEAN	3.03	4.94
SD	9.671	12.067
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	-0.62	-11.11
SD	13.722	26.149
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 439 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	5.73	5.21
SD	13.998	14.930
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	1.06	-8.33
SD	14.626	28.081
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 66.7
CYCLE 16		
N	58	29
MEAN	6.32	5.75
SD	15.866	12.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 440 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	1.75	-8.05
SD	19.335	19.221
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 17		
N	56	31
MEAN	7.14	4.30
SD	16.471	11.359
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	2.98	-8.60
SD	17.147	22.718
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 441 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	6.67	8.70
SD	13.528	18.027
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	1.96	-7.25
SD	20.002	22.375
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 19		
N	45	28
MEAN	8.89	3.57
SD	17.979	10.499
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 442 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	3.70	-9.52
SD	16.240	25.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3
CYCLE 20		
N	31	17
MEAN	6.45	5.88
SD	13.387	13.098
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	2.22	-13.73
SD	14.993	31.311
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 443 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	8.11	3.70
SD	24.095	10.779
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	2.70	-11.11
SD	24.061	30.250
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-100.0, 33.3
CYCLE 22		
N	44	13
MEAN	6.06	5.13
SD	13.005	12.518
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 444 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	1.55	-12.82
SD	17.748	28.991
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	13.10	3.33
SD	22.842	10.541
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	7.14	-23.33
SD	22.874	27.442
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 445 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	8.05	6.67
SD	17.032	14.055
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	3.45	-16.67
SD	20.596	39.284
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 33.3
CYCLE 25		
N	35	13
MEAN	2.86	0.00
SD	12.450	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 446 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-1.90	-17.95
SD	11.269	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 0.0
CYCLE 26		
N	20	9
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-5.00	-25.93
SD	12.212	36.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 0.0	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 447 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	9.33	2.78
SD	20.458	9.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	5.33	-19.44
SD	22.933	36.121
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 33.3
CYCLE 28		
N	30	9
MEAN	7.78	7.41
SD	18.944	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 448 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	3.33	-11.11
SD	18.257	40.825
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 33.3
CYCLE 29		
N	18	7
MEAN	9.26	0.00
SD	15.363	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	5.56	-28.57
SD	20.612	35.635
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 449 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	3.17	0.00
SD	10.026	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-1.59	-23.81
SD	12.807	37.090
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 0.0
CYCLE 31		
N	23	6
MEAN	4.35	11.11
SD	11.478	17.213
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 450 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	0.00	-11.11
SD	14.213	50.185
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-33.3, 33.3	-100.0, 33.3
CYCLE 32		
N	16	4
MEAN	4.17	16.67
SD	16.667	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	2.08	-16.67
SD	19.124	19.245
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 451 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	8.33	0.00
SD	19.245	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	4.17	-13.33
SD	23.960	18.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 34		
N	20	4
MEAN	5.00	0.00
SD	12.212	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 452 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	1.67	-8.33
SD	17.014	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 35		
N	13	4
MEAN	7.69	8.33
SD	19.971	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	5.13	-8.33
SD	18.490	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	0.0, 66.7	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 453 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	5.13	0.00
SD	12.518	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	5.13	-16.67
SD	12.518	23.570
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0
CYCLE 37		
N	14	2
MEAN	7.14	0.00
SD	14.194	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 454 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	4.76	-33.33
SD	17.817	0.000
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, -33.33
MIN, MAX	-33.3, 33.3	-33.3, -33.3
CYCLE 38		
N	11	2
MEAN	3.03	0.00
SD	10.050	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	-16.67
SD	14.907	23.570
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 455 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	-22.22
SD	0.000	19.245
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	0.0, 0.0	-33.3, 0.0
CYCLE 40		
N	11	3
MEAN	6.06	0.00
SD	13.484	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 456 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	3.03	-22.22
SD	17.979	19.245
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	0.00	
SD	16.667	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 457 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	-33.33
SD	13.608	N.A.
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, -33.33
MIN, MAX	0.0, 33.3	-33.3, -33.3
CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 458 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 459 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 460 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 461 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 462 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	4.17	9.63
SD	14.040	22.045
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	0.00	0.00
SD	23.947	28.427
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 463 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
FINANCIAL DIFFICULTIES		
BASELINE		
N	112	104
MEAN	21.13	20.19
SD	26.845	29.893
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	104	90
MEAN	20.51	18.15
SD	26.807	27.442
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	104	90
MEAN	-1.28	0.37
SD	21.247	19.669
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 464 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	22.33	18.25
SD	28.448	28.058
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	0.67	-0.79
SD	23.201	17.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 66.7
CYCLE 4		
N	97	81
MEAN	19.24	19.75
SD	25.836	29.711
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 465 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	81
MEAN	-2.08	-1.23
SD	18.614	25.519
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 66.7
CYCLE 5		
N	93	73
MEAN	20.43	20.09
SD	29.502	29.783
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	92	73
MEAN	-0.72	-0.46
SD	22.088	26.348
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 466 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	19.38	18.84
SD	27.280	26.493
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	0.00	0.00
SD	22.420	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7
CYCLE 7		
N	89	65
MEAN	20.22	23.59
SD	27.806	30.461
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 467 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	88	65
MEAN	-1.14	4.10
SD	24.990	23.941
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-66.7, 66.7
CYCLE 8		
N	82	57
MEAN	21.54	17.54
SD	29.337	26.053
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	0.00	-2.92
SD	21.082	27.661
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 468 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	84	57
MEAN	20.63	18.13
SD	28.296	26.778
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	83	57
MEAN	-2.81	-1.75
SD	24.531	25.527
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 66.7
CYCLE 10		
N	80	54
MEAN	22.08	18.52
SD	28.036	30.141
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 469 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	54
MEAN	0.42	-1.85
SD	24.746	25.424
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 33.3
CYCLE 11		
N	72	47
MEAN	24.07	19.86
SD	31.757	26.612
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	72	47
MEAN	0.93	0.71
SD	26.224	23.559
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 470 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	23.33	20.63
SD	29.679	29.405
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	0.00	2.38
SD	24.918	34.051
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 13		
N	73	40
MEAN	23.74	20.00
SD	31.662	30.940
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 471 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	72	40
MEAN	-0.93	0.83
SD	25.002	27.722
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 14		
N	55	27
MEAN	24.85	16.05
SD	28.845	23.334
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	54	27
MEAN	1.85	2.47
SD	27.023	22.505
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 472 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	26.56	26.04
SD	30.388	35.655
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	1.06	5.21
SD	26.074	28.220
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 16		
N	58	29
MEAN	25.29	24.14
SD	31.413	34.384
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 473 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	1.17	3.45
SD	26.700	34.898
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 100.0
CYCLE 17		
N	56	31
MEAN	26.19	19.35
SD	30.954	26.908
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	2.38	1.08
SD	26.098	27.867
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 474 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	18.10	20.29
SD	28.403	31.365
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	0.00	7.25
SD	30.704	30.078
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 19		
N	45	28
MEAN	24.44	22.62
SD	33.635	34.010
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 475 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	1.48	8.33
SD	28.387	34.694
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 100.0
CYCLE 20		
N	31	17
MEAN	23.66	19.61
SD	31.262	29.009
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	2.22	1.96
SD	30.240	21.955
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 476 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	18
MEAN	22.52	22.22
SD	28.387	30.250
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	18
MEAN	-2.70	-1.85
SD	28.737	26.746
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 22		
N	44	13
MEAN	21.21	25.64
SD	27.927	33.758
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 477 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-0.78	-5.13
SD	25.705	32.903
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	29.76	43.33
SD	34.354	35.312
MEDIAN	33.33	50.00
Q1, Q3	0.00, 50.00	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	2.38	13.33
SD	29.991	28.109
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 478 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	17.24	26.67
SD	24.593	34.427
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-4.60	-3.33
SD	23.101	36.683
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	20.00	25.64
SD	31.519	33.758
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 479 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-2.86	-5.13
SD	21.950	32.903
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 26		
N	20	9
MEAN	23.33	40.74
SD	32.624	40.062
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	1.67	7.41
SD	25.305	36.430
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 480 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	24.00	25.00
SD	29.690	28.868
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	1.33	-8.33
SD	28.021	32.177
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 28		
N	30	9
MEAN	20.00	29.63
SD	29.814	35.136
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 481 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-2.22	-3.70
SD	21.323	38.889
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 29		
N	18	7
MEAN	24.07	23.81
SD	33.927	25.198
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	5.56	4.76
SD	26.197	35.635
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 482 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	14.29	47.62
SD	19.920	42.414
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 100.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-4.76	19.05
SD	24.234	50.395
MEDIAN	0.00	33.33
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-66.7, 100.0
CYCLE 31		
N	23	6
MEAN	17.39	22.22
SD	26.342	27.217
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 483 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	6
MEAN	2.90	0.00
SD	24.439	36.515
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 32		
N	16	4
MEAN	22.92	33.33
SD	26.440	27.217
MEDIAN	16.67	33.33
Q1, Q3	0.00, 33.33	16.67, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	16	4
MEAN	8.33	0.00
SD	25.820	47.140
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	-33.33, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 484 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	16.67	20.00
SD	24.343	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	0.00	13.33
SD	24.343	18.257
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 34		
N	20	4
MEAN	16.67	25.00
SD	25.363	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 485 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	0.00	16.67
SD	21.630	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 35		
N	13	4
MEAN	12.82	16.67
SD	21.681	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	0.00	8.33
SD	23.570	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 486 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	13	2
MEAN	10.26	33.33
SD	16.013	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	13	2
MEAN	-2.56	16.67
SD	21.350	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 37		
N	14	2
MEAN	9.52	33.33
SD	20.375	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 487 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-4.76	16.67
SD	17.817	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3
CYCLE 38		
N	11	2
MEAN	15.15	33.33
SD	22.918	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	16.67
SD	14.907	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 488 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	8.33	22.22
SD	15.430	38.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-8.33	11.11
SD	15.430	19.245
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 0.00	0.00, 33.33
MIN, MAX	-33.3, 0.0	0.0, 33.3
CYCLE 40		
N	11	3
MEAN	12.12	44.44
SD	22.473	38.490
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 489 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-6.06	33.33
SD	20.101	33.333
MEDIAN	0.00	33.33
Q1, Q3	-33.33, 0.00	0.00, 66.67
MIN, MAX	-33.3, 33.3	0.0, 66.7
CYCLE 41		
N	9	0
MEAN	14.81	
SD	24.216	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	20.031	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 490 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	66.67
SD	0.000	N.A.
MEDIAN	0.00	66.67
Q1, Q3	0.00, 0.00	66.67, 66.67
MIN, MAX	0.0, 0.0	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-11.11	66.67
SD	17.213	N.A.
MEDIAN	0.00	66.67
Q1, Q3	-33.33, 0.00	66.67, 66.67
MIN, MAX	-33.3, 0.0	66.7, 66.7
CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 491 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	23.570	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 33.3	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	33.333	
MEDIAN	0.00	
Q1, Q3	-33.33, 33.33	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 492 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 493 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 494 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Ergänzende Analysen

Protocol: TPX-0005-01

Page 495 of 495

Table P.2.1
Summary of EORTC QLQ-C30 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	31	45
MEAN	23.66	28.15
SD	27.479	29.263
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	31	45
MEAN	-1.08	8.15
SD	33.867	24.777
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer QoL Questionnaire-Core 30;

QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-sy-proqlqlc30-ebr2365-b2.sas

17JUL2024:09:53:26

Anhang 4-G 2.2: EORTC QLQ-LC13

Deskription der einzelnen Skalen des EORTC QLQ-LC13 sowie deren Veränderung gegenüber Baseline im Studienverlauf

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
DYSPNEA		
BASELINE		
N	111	103
MEAN	28.23	27.83
SD	23.631	22.965
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	22.44	25.19
SD	19.863	22.272
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 77.8	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 2		
N	103	89
MEAN	-6.36	-1.62
SD	24.184	19.502
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 66.7	-55.6, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	83
MEAN	25.56	27.18
SD	19.566	22.307
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 3		
N	99	82
MEAN	-2.47	2.03
SD	26.109	21.178
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 22.22
MIN, MAX	-77.8, 66.7	-77.8, 66.7
CYCLE 4		
N	96	80
MEAN	26.62	26.25
SD	21.897	22.379
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	95	79
MEAN	-1.75	-0.28
SD	26.249	25.720
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 66.7	-100.0, 55.6
CYCLE 5		
N	90	73
MEAN	22.22	27.55
SD	18.991	23.138
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 88.9	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	89	73
MEAN	-6.37	2.44
SD	23.800	25.137
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 11.11
MIN, MAX	-77.8, 44.4	-88.9, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	23.00	29.47
SD	19.342	23.011
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	-5.49	4.99
SD	25.117	23.534
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	0.00, 11.11
MIN, MAX	-77.8, 55.6	-88.9, 77.8
CYCLE 7		
N	88	64
MEAN	21.97	29.86
SD	18.376	21.033
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	86	64
MEAN	-5.68	4.86
SD	24.208	24.717
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 22.22
MIN, MAX	-77.8, 33.3	-88.9, 77.8
CYCLE 8		
N	82	57
MEAN	23.71	26.90
SD	18.540	21.511
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 88.9	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 8		
N	80	57
MEAN	-3.06	-0.39
SD	23.319	24.931
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 55.6	-88.9, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	56
MEAN	23.69	29.76
SD	18.751	23.604
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 9		
N	81	56
MEAN	-2.61	3.37
SD	24.738	26.710
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	-11.11, 22.22
MIN, MAX	-66.7, 55.6	-88.9, 55.6
CYCLE 10		
N	80	53
MEAN	25.42	28.30
SD	20.632	22.705
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 77.8	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	78	53
MEAN	-1.28	2.10
SD	24.941	26.425
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 22.22
MIN, MAX	-77.8, 44.4	-77.8, 66.7
CYCLE 11		
N	71	47
MEAN	24.26	27.42
SD	21.927	23.610
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-1.41	3.07
SD	25.263	29.095
MEDIAN	0.00	0.00
Q1, Q3	-22.22, 11.11	0.00, 22.22
MIN, MAX	-66.7, 66.7	-100.0, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 8 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	41
MEAN	25.71	29.27
SD	21.026	24.439
MEDIAN	22.22	33.33
Q1, Q3	11.11, 44.44	11.11, 44.44
MIN, MAX	0.0, 66.7	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 12		
N	69	41
MEAN	0.64	4.07
SD	25.486	30.303
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 22.22
MIN, MAX	-66.7, 44.4	-100.0, 66.7
CYCLE 13		
N	72	39
MEAN	25.31	29.63
SD	21.362	23.130
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 88.9	0.0, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 9 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	-1.41	3.99
SD	23.825	28.096
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 22.22
MIN, MAX	-66.7, 55.6	-88.9, 66.7
CYCLE 14		
N	54	27
MEAN	28.40	25.10
SD	23.012	21.919
MEDIAN	33.33	22.22
Q1, Q3	11.11, 44.44	11.11, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	1.68	0.00
SD	25.262	29.878
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 55.6	-88.9, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 10 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	27.78	34.38
SD	21.596	24.983
MEDIAN	22.22	27.78
Q1, Q3	11.11, 38.89	11.11, 55.56
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	1.41	6.94
SD	24.643	33.601
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 22.22	-5.56, 22.22
MIN, MAX	-66.7, 44.4	-88.9, 77.8
CYCLE 16		
N	56	29
MEAN	27.18	27.97
SD	24.058	21.128
MEDIAN	22.22	22.22
Q1, Q3	11.11, 38.89	11.11, 33.33
MIN, MAX	0.0, 100.0	0.0, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 11 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	56	29
MEAN	1.79	4.60
SD	26.360	26.811
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	0.00, 11.11
MIN, MAX	-66.7, 88.9	-77.8, 66.7
CYCLE 17		
N	55	31
MEAN	26.06	27.24
SD	24.118	24.984
MEDIAN	22.22	22.22
Q1, Q3	11.11, 44.44	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9
CHANGE FROM BASELINE AT CYCLE 17		
N	54	31
MEAN	0.41	2.87
SD	25.075	28.250
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 55.6	-88.9, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 12 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	33.33	28.50
SD	26.678	24.579
MEDIAN	33.33	22.22
Q1, Q3	11.11, 55.56	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 18		
N	33	23
MEAN	5.72	2.42
SD	25.778	31.597
MEDIAN	11.11	0.00
Q1, Q3	-11.11, 22.22	-11.11, 22.22
MIN, MAX	-66.7, 55.6	-100.0, 66.7
CYCLE 19		
N	45	28
MEAN	28.40	29.76
SD	24.795	23.822
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 44.44
MIN, MAX	0.0, 100.0	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 13 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	2.22	6.35
SD	26.122	29.230
MEDIAN	0.00	5.56
Q1, Q3	-11.11, 11.11	0.00, 11.11
MIN, MAX	-66.7, 77.8	-77.8, 55.6
CYCLE 20		
N	31	17
MEAN	29.03	24.18
SD	24.792	16.309
MEDIAN	22.22	22.22
Q1, Q3	11.11, 44.44	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	4.44	0.00
SD	23.633	31.180
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-33.3, 77.8	-88.9, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 14 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	25.83	22.88
SD	22.537	19.032
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	11.11, 33.33
MIN, MAX	0.0, 88.9	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-2.40	3.92
SD	24.306	21.851
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 11.11	-11.11, 11.11
MIN, MAX	-66.7, 33.3	-44.4, 55.6
CYCLE 22		
N	44	13
MEAN	26.26	29.06
SD	24.330	23.804
MEDIAN	22.22	22.22
Q1, Q3	11.11, 33.33	22.22, 33.33
MIN, MAX	0.0, 100.0	0.0, 77.8

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 15 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	0.26	12.82
SD	26.835	24.363
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 22.22	0.00, 22.22
MIN, MAX	-66.7, 55.6	-33.3, 66.7
CYCLE 23		
N	28	10
MEAN	34.52	31.11
SD	26.594	20.150
MEDIAN	33.33	22.22
Q1, Q3	16.67, 50.00	22.22, 33.33
MIN, MAX	0.0, 88.9	11.1, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	4.37	6.67
SD	27.441	27.815
MEDIAN	0.00	5.56
Q1, Q3	-5.56, 22.22	-11.11, 22.22
MIN, MAX	-66.7, 44.4	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 16 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	31.80	24.44
SD	25.498	19.458
MEDIAN	33.33	27.78
Q1, Q3	11.11, 44.44	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 55.6
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	3.83	6.67
SD	28.215	23.541
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 22.22	0.00, 22.22
MIN, MAX	-66.7, 55.6	-33.3, 55.6
CYCLE 25		
N	35	13
MEAN	26.67	33.33
SD	24.874	25.660
MEDIAN	22.22	22.22
Q1, Q3	0.00, 44.44	11.11, 44.44
MIN, MAX	0.0, 88.9	0.0, 88.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 17 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-1.27	15.38
SD	29.615	24.232
MEDIAN	0.00	11.11
Q1, Q3	-22.22, 22.22	0.00, 22.22
MIN, MAX	-66.7, 55.6	-22.2, 66.7
CYCLE 26		
N	20	9
MEAN	27.78	39.51
SD	18.204	22.981
MEDIAN	27.78	33.33
Q1, Q3	16.67, 38.89	22.22, 66.67
MIN, MAX	0.0, 66.7	11.1, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-1.67	19.75
SD	29.568	25.926
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 16.67	11.11, 33.33
MIN, MAX	-66.7, 55.6	-22.2, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 18 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	32.00	36.11
SD	23.421	26.853
MEDIAN	33.33	27.78
Q1, Q3	22.22, 44.44	11.11, 61.11
MIN, MAX	0.0, 88.9	0.0, 77.8
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	2.67	16.67
SD	29.271	19.820
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 22.22	0.00, 27.78
MIN, MAX	-66.7, 55.6	0.0, 66.7
CYCLE 28		
N	30	9
MEAN	27.78	38.27
SD	25.563	22.981
MEDIAN	22.22	33.33
Q1, Q3	0.00, 44.44	22.22, 55.56
MIN, MAX	0.0, 100.0	11.1, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 19 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	0.37	20.99
SD	30.531	22.529
MEDIAN	0.00	22.22
Q1, Q3	-11.11, 22.22	11.11, 33.33
MIN, MAX	-66.7, 55.6	-11.1, 66.7
CYCLE 29		
N	18	7
MEAN	28.40	33.33
SD	20.602	19.245
MEDIAN	33.33	33.33
Q1, Q3	11.11, 44.44	11.11, 55.56
MIN, MAX	0.0, 66.7	11.1, 55.6
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-0.62	7.94
SD	29.880	24.607
MEDIAN	0.00	11.11
Q1, Q3	-33.33, 22.22	-11.11, 11.11
MIN, MAX	-44.4, 55.6	-22.2, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 20 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	23.28	34.92
SD	22.745	18.624
MEDIAN	22.22	33.33
Q1, Q3	0.00, 44.44	22.22, 44.44
MIN, MAX	0.0, 66.7	11.1, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-3.17	12.70
SD	35.162	27.539
MEDIAN	0.00	22.22
Q1, Q3	-22.22, 33.33	11.11, 22.22
MIN, MAX	-66.7, 55.6	-44.4, 44.4
CYCLE 31		
N	23	7
MEAN	24.15	36.51
SD	20.828	19.994
MEDIAN	22.22	33.33
Q1, Q3	11.11, 44.44	22.22, 55.56
MIN, MAX	0.0, 66.7	11.1, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 21 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-0.97	12.70
SD	30.871	28.995
MEDIAN	0.00	11.11
Q1, Q3	-22.22, 22.22	-11.11, 22.22
MIN, MAX	-66.7, 55.6	-22.2, 66.7
CYCLE 32		
N	17	4
MEAN	30.72	44.44
SD	24.699	20.286
MEDIAN	22.22	44.44
Q1, Q3	11.11, 55.56	27.78, 61.11
MIN, MAX	0.0, 66.7	22.2, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	5.23	19.44
SD	31.700	46.592
MEDIAN	0.00	27.78
Q1, Q3	-11.11, 33.33	-11.11, 50.00
MIN, MAX	-66.7, 55.6	-44.4, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 22 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	27.78	44.44
SD	22.222	28.328
MEDIAN	22.22	44.44
Q1, Q3	11.11, 44.44	22.22, 66.67
MIN, MAX	0.0, 66.7	11.1, 77.8
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	0.00	24.44
SD	30.631	34.605
MEDIAN	0.00	11.11
Q1, Q3	-22.22, 27.78	0.00, 55.56
MIN, MAX	-44.4, 55.6	-11.1, 66.7
CYCLE 34		
N	19	4
MEAN	25.73	36.11
SD	21.928	21.033
MEDIAN	22.22	27.78
Q1, Q3	11.11, 33.33	22.22, 50.00
MIN, MAX	0.0, 77.8	22.2, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 23 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	19	4
MEAN	3.51	25.00
SD	30.999	29.222
MEDIAN	0.00	16.67
Q1, Q3	-11.11, 33.33	5.56, 44.44
MIN, MAX	-66.7, 66.7	0.0, 66.7
CYCLE 35		
N	13	4
MEAN	34.19	33.33
SD	27.012	20.286
MEDIAN	33.33	33.33
Q1, Q3	22.22, 44.44	16.67, 50.00
MIN, MAX	0.0, 88.9	11.1, 55.6
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	9.40	11.11
SD	33.286	30.089
MEDIAN	0.00	0.00
Q1, Q3	-11.11, 33.33	-5.56, 27.78
MIN, MAX	-44.4, 77.8	-11.1, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 24 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	30.56	61.11
SD	21.776	7.857
MEDIAN	33.33	61.11
Q1, Q3	11.11, 44.44	55.56, 66.67
MIN, MAX	0.0, 66.7	55.6, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	4.63	50.00
SD	26.573	23.570
MEDIAN	0.00	50.00
Q1, Q3	-11.11, 22.22	33.33, 66.67
MIN, MAX	-44.4, 44.4	33.3, 66.7
CYCLE 37		
N	14	2
MEAN	24.60	33.33
SD	22.720	47.140
MEDIAN	22.22	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 25 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	3.17	11.11
SD	24.818	78.567
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 22.22	-44.44, 66.67
MIN, MAX	-33.3, 44.4	-44.4, 66.7
CYCLE 38		
N	11	2
MEAN	28.28	50.00
SD	29.964	7.857
MEDIAN	22.22	50.00
Q1, Q3	0.00, 55.56	44.44, 55.56
MIN, MAX	0.0, 88.9	44.4, 55.6
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	4.04	38.89
SD	31.140	23.570
MEDIAN	0.00	38.89
Q1, Q3	-11.11, 0.00	22.22, 55.56
MIN, MAX	-33.3, 77.8	22.2, 55.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 26 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	22.22	44.44
SD	22.222	22.222
MEDIAN	16.67	44.44
Q1, Q3	5.56, 33.33	22.22, 66.67
MIN, MAX	0.0, 66.7	22.2, 66.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	4.17	22.22
SD	20.520	38.490
MEDIAN	5.56	0.00
Q1, Q3	-11.11, 11.11	0.00, 66.67
MIN, MAX	-22.2, 44.4	0.0, 66.7
CYCLE 40		
N	11	3
MEAN	20.20	66.67
SD	19.128	0.000
MEDIAN	11.11	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 55.6	66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 27 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	0.00	44.44
SD	16.480	22.222
MEDIAN	0.00	44.44
Q1, Q3	-11.11, 11.11	22.22, 66.67
MIN, MAX	-22.2, 33.3	22.2, 66.7
CYCLE 41		
N	9	0
MEAN	22.22	
SD	20.787	
MEDIAN	22.22	
Q1, Q3	11.11, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-1.23	
SD	11.712	
MEDIAN	0.00	
Q1, Q3	-11.11, 11.11	
MIN, MAX	-22.2, 11.1	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 28 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	16.67	66.67
SD	15.316	N.A.
MEDIAN	16.67	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 33.3	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-5.56	22.22
SD	11.653	N.A.
MEDIAN	-5.56	22.22
Q1, Q3	-11.11, 0.00	22.22, 22.22
MIN, MAX	-22.2, 11.1	22.2, 22.2
CYCLE 43		
N	5	0
MEAN	17.78	
SD	16.851	
MEDIAN	11.11	
Q1, Q3	11.11, 22.22	
MIN, MAX	0.0, 44.4	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 29 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	2.22	
SD	25.337	
MEDIAN	0.00	
Q1, Q3	-11.11, 0.00	
MIN, MAX	-22.2, 44.4	
CYCLE 44		
N	3	0
MEAN	7.41	
SD	6.415	
MEDIAN	11.11	
Q1, Q3	0.00, 11.11	
MIN, MAX	0.0, 11.1	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-14.81	
SD	6.415	
MEDIAN	-11.11	
Q1, Q3	-22.22, -11.11	
MIN, MAX	-22.2, -11.1	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 30 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	8.89	
SD	4.969	
MEDIAN	11.11	
Q1, Q3	11.11, 11.11	
MIN, MAX	0.0, 11.1	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	12.669	
MEDIAN	-11.11	
Q1, Q3	-11.11, 0.00	
MIN, MAX	-22.2, 11.1	
CYCLE 46		
N	3	0
MEAN	18.52	
SD	16.973	
MEDIAN	22.22	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 31 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	3.70	
SD	27.962	
MEDIAN	0.00	
Q1, Q3	-22.22, 33.33	
MIN, MAX	-22.2, 33.3	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	11.11	
SD	N.A.	
MEDIAN	11.11	
Q1, Q3	11.11, 11.11	
MIN, MAX	11.1, 11.1	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 32 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	22.22	
SD	N.A.	
MEDIAN	22.22	
Q1, Q3	22.22, 22.22	
MIN, MAX	22.2, 22.2	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 33 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	11.11	
SD	N.A.	
MEDIAN	11.11	
Q1, Q3	11.11, 11.11	
MIN, MAX	11.1, 11.1	
END OF TREATMENT		
N	30	45
MEAN	33.33	44.44
SD	25.605	32.220
MEDIAN	22.22	33.33
Q1, Q3	22.22, 33.33	22.22, 77.78
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	30	44
MEAN	4.07	13.13
SD	25.519	29.570
MEDIAN	0.00	11.11
Q1, Q3	-11.11, 22.22	0.00, 33.33
MIN, MAX	-44.4, 55.6	-77.8, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 34 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
COUGHING		
BASELINE		
N	112	104
MEAN	33.93	31.09
SD	26.840	29.838
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	16.50	17.04
SD	18.597	20.140
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	-17.48	-13.70
SD	31.604	26.860
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 35 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	12.87	17.06
SD	18.839	25.080
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-21.45	-13.10
SD	31.827	33.541
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 4		
N	97	80
MEAN	13.40	15.42
SD	18.421	20.503
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 36 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	-21.88	-15.00
SD	31.652	29.001
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 5		
N	92	73
MEAN	10.87	15.07
SD	16.470	20.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	-23.08	-15.53
SD	30.100	29.960
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 37 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	13.03	14.98
SD	16.359	21.032
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-20.16	-14.98
SD	32.045	30.538
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 7		
N	88	64
MEAN	12.12	19.27
SD	16.900	25.755
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 38 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	64
MEAN	-22.22	-14.06
SD	31.609	31.875
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7
CYCLE 8		
N	82	57
MEAN	10.98	17.54
SD	16.609	23.659
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-22.22	-15.79
SD	30.732	32.186
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 39 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	14.46	16.96
SD	20.291	21.009
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	-18.70	-16.37
SD	34.386	29.629
MEDIAN	-16.67	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 10		
N	80	53
MEAN	10.83	14.47
SD	17.410	20.159
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 40 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	-21.52	-18.24
SD	29.254	33.694
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 11		
N	71	47
MEAN	11.27	17.02
SD	18.639	24.937
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-20.19	-14.18
SD	30.591	30.884
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 41 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	12.38	19.05
SD	17.187	23.447
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-18.36	-13.49
SD	31.068	30.408
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 13		
N	72	39
MEAN	8.33	16.24
SD	15.575	25.215
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 42 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	-23.47	-17.09
SD	31.063	34.089
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3
CYCLE 14		
N	54	27
MEAN	11.11	20.99
SD	19.426	26.390
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	-21.38	-16.05
SD	27.808	31.174
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 43 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	11.46	14.58
SD	20.760	22.300
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-21.69	-17.71
SD	32.878	28.061
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 16		
N	58	29
MEAN	13.22	19.54
SD	24.134	22.743
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 44 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-17.54	-12.64
SD	35.693	30.097
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 33.3
CYCLE 17		
N	56	31
MEAN	12.50	16.13
SD	21.614	16.933
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-19.64	-13.98
SD	31.640	28.250
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 45 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	18.10	23.19
SD	21.907	25.495
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-11.76	-11.59
SD	34.702	32.735
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 66.7
CYCLE 19		
N	45	28
MEAN	10.37	15.48
SD	15.606	19.207
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 46 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-24.44	-14.29
SD	32.876	30.670
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 66.7
CYCLE 20		
N	31	17
MEAN	17.20	23.53
SD	18.995	19.596
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-18.89	-15.69
SD	34.667	33.578
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 47 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	15.32	9.80
SD	18.583	15.656
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-19.82	-15.69
SD	29.876	23.914
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 22		
N	44	13
MEAN	12.88	10.26
SD	21.824	16.013
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 48 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-21.71	-17.95
SD	30.761	25.875
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	13.10	16.67
SD	18.898	17.568
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-23.81	-23.33
SD	31.239	22.498
MEDIAN	0.00	-33.33
Q1, Q3	-50.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 0.0	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 49 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	11.49	16.67
SD	16.124	17.568
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-19.54	-20.00
SD	31.519	23.307
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 0.0
CYCLE 25		
N	35	13
MEAN	10.48	15.38
SD	17.660	22.008
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 50 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-26.67	-15.38
SD	33.137	25.875
MEDIAN	-33.33	0.00
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3
CYCLE 26		
N	20	9
MEAN	11.67	18.52
SD	19.571	17.568
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-28.33	-18.52
SD	39.403	29.397
MEDIAN	-33.33	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 51 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	16.00	5.56
SD	19.532	12.975
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-20.00	-19.44
SD	33.333	22.285
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 0.0
CYCLE 28		
N	30	9
MEAN	14.44	7.41
SD	22.630	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 52 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-24.44	-25.93
SD	33.828	22.222
MEDIAN	-33.33	-33.33
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 0.0
CYCLE 29		
N	18	7
MEAN	14.81	9.52
SD	17.044	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-27.78	-23.81
SD	41.618	16.265
MEDIAN	-16.67	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 53 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	7.94	14.29
SD	14.548	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-25.40	-23.81
SD	34.809	25.198
MEDIAN	0.00	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 0.0
CYCLE 31		
N	23	7
MEAN	7.25	19.05
SD	14.058	17.817
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 54 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-28.99	-23.81
SD	32.262	25.198
MEDIAN	-33.33	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 0.0
CYCLE 32		
N	17	4
MEAN	15.69	16.67
SD	17.150	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-21.57	-16.67
SD	33.211	19.245
MEDIAN	0.00	-16.67
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 55 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	10.42	20.00
SD	15.957	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-25.00	-13.33
SD	37.515	29.814
MEDIAN	0.00	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3
CYCLE 34		
N	20	4
MEAN	11.67	16.67
SD	16.312	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 56 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-25.00	-33.33
SD	33.985	27.217
MEDIAN	-16.67	-33.33
Q1, Q3	-50.00, 0.00	-50.00, -16.67
MIN, MAX	-100.0, 33.3	-66.7, 0.0
CYCLE 35		
N	13	4
MEAN	12.82	0.00
SD	16.879	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-23.08	-33.33
SD	39.404	0.000
MEDIAN	0.00	-33.33
Q1, Q3	-66.67, 0.00	-33.33, -33.33
MIN, MAX	-100.0, 33.3	-33.3, -33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 57 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	11.11	16.67
SD	21.711	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	-25.00	-16.67
SD	47.408	23.570
MEDIAN	-33.33	-16.67
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 0.0
CYCLE 37		
N	14	2
MEAN	11.90	0.00
SD	16.575	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 58 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-21.43	-33.33
SD	30.959	0.000
MEDIAN	-16.67	-33.33
Q1, Q3	-33.33, 0.00	-33.33, -33.33
MIN, MAX	-66.7, 33.3	-33.3, -33.3
CYCLE 38		
N	11	2
MEAN	3.03	16.67
SD	10.050	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-30.30	-16.67
SD	34.816	23.570
MEDIAN	-33.33	-16.67
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 59 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	4.17	11.11
SD	11.785	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	-29.17	-22.22
SD	33.034	19.245
MEDIAN	-16.67	-33.33
Q1, Q3	-66.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 40		
N	11	3
MEAN	6.06	33.33
SD	13.484	33.333
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 60 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-33.33	0.00
SD	29.814	33.333
MEDIAN	-33.33	0.00
Q1, Q3	-66.67, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 0.0	-33.3, 33.3
CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-37.04	
SD	30.932	
MEDIAN	-33.33	
Q1, Q3	-66.67, 0.00	
MIN, MAX	-66.7, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 61 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-38.89	-33.33
SD	32.773	N.A.
MEDIAN	-50.00	-33.33
Q1, Q3	-66.67, 0.00	-33.33, -33.33
MIN, MAX	-66.7, 0.0	-33.3, -33.3
CYCLE 43		
N	5	0
MEAN	26.67	
SD	43.461	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 100.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 62 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-20.00	
SD	55.777	
MEDIAN	-33.33	
Q1, Q3	-66.67, 0.00	
MIN, MAX	-66.7, 66.7	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-44.44	
SD	38.490	
MEDIAN	-66.67	
Q1, Q3	-66.67, 0.00	
MIN, MAX	-66.7, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 63 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	20.00	
SD	18.257	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-26.67	
SD	27.889	
MEDIAN	-33.33	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-66.7, 0.0	
CYCLE 46		
N	3	0
MEAN	22.22	
SD	38.490	
MEDIAN	0.00	
Q1, Q3	0.00, 66.67	
MIN, MAX	0.0, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 64 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-33.33	
SD	57.735	
MEDIAN	-66.67	
Q1, Q3	-66.67, 33.33	
MIN, MAX	-66.7, 33.3	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 65 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 66 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	-66.67	
SD	N.A.	
MEDIAN	-66.67	
Q1, Q3	-66.67, -66.67	
MIN, MAX	-66.7, -66.7	
END OF TREATMENT		
N	32	45
MEAN	23.96	20.74
SD	33.046	23.878
MEDIAN	0.00	33.33
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-9.38	-10.37
SD	29.614	30.832
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 67 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
HEMOPTYSIS		
BASELINE		
N	112	104
MEAN	2.98	1.92
SD	11.454	7.810
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CYCLE 2		
N	103	90
MEAN	0.65	0.74
SD	4.622	4.941
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	-2.27	-0.74
SD	10.707	7.027
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 68 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	0.33	0.40
SD	3.333	3.637
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	-2.67	-1.19
SD	12.245	8.093
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 4		
N	97	80
MEAN	1.37	0.42
SD	10.669	3.727
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 69 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	-1.39	-0.83
SD	15.980	7.454
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 5		
N	92	73
MEAN	0.36	0.00
SD	3.475	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	-2.20	-1.83
SD	11.969	7.638
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 70 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	0.00	0.48
SD	0.000	4.013
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-2.71	-1.45
SD	11.677	8.920
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 33.3
CYCLE 7		
N	88	65
MEAN	0.38	0.00
SD	3.553	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 71 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	-2.30	-2.05
SD	12.235	8.073
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 8		
N	82	57
MEAN	0.81	0.00
SD	5.174	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-2.06	-1.75
SD	13.277	7.509
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 72 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	0.80	0.58
SD	5.143	4.415
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	-2.03	-1.17
SD	13.196	8.830
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 10		
N	80	53
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 73 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	-2.95	-1.26
SD	12.160	6.413
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 11		
N	71	47
MEAN	0.47	0.00
SD	3.956	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-2.82	-1.42
SD	13.507	6.801
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 74 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	0.48	0.79
SD	3.984	5.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-2.90	-0.79
SD	13.695	5.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 13		
N	72	39
MEAN	0.46	0.85
SD	3.928	5.338
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 75 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	-2.82	-0.85
SD	10.906	5.338
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 14		
N	54	27
MEAN	0.62	1.23
SD	4.536	6.415
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	-3.14	-1.23
SD	11.811	6.415
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 76 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-3.70	-2.08
SD	13.535	8.198
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 16		
N	58	29
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 77 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-2.92	-2.30
SD	13.033	8.596
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 17		
N	56	31
MEAN	0.60	0.00
SD	4.454	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-2.98	-2.15
SD	11.506	8.324
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 78 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	0.00	1.45
SD	0.000	6.950
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-2.94	-1.45
SD	12.627	6.950
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 19		
N	45	28
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 79 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-2.96	-1.19
SD	11.939	6.299
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	-33.3, 0.0
CYCLE 20		
N	31	17
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-1.11	-1.96
SD	6.086	8.085
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 0.0	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 80 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-3.60	0.00
SD	13.109	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 22		
N	44	13
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 81 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-3.10	0.00
SD	12.202	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 23		
N	28	10
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-2.38	0.00
SD	8.742	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 82 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-3.45	0.00
SD	13.642	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 25		
N	35	13
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 83 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-2.86	0.00
SD	12.450	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 26		
N	20	9
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 84 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	1.33	0.00
SD	6.667	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-2.67	0.00
SD	16.443	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	0.0, 0.0
CYCLE 28		
N	30	9
MEAN	1.11	0.00
SD	6.086	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 85 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-2.22	0.00
SD	14.993	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	0.0, 0.0
CYCLE 29		
N	18	7
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 86 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-3.17	0.00
SD	14.548	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 31		
N	23	7
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 87 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-2.90	0.00
SD	13.901	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 32		
N	17	4
MEAN	1.96	0.00
SD	8.085	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-1.96	0.00
SD	18.524	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 88 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 34		
N	20	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 89 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 35		
N	13	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 90 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 37		
N	14	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 91 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 92 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 40		
N	11	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 93 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 41		
N	9	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 94 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 95 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 96 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 97 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 98 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 99 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	5.21	2.22
SD	17.163	8.409
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	0.00	0.00
SD	20.739	12.309
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 100 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
SORE MOUTH		
BASELINE		
N	112	104
MEAN	2.98	5.13
SD	10.544	13.755
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CYCLE 2		
N	103	90
MEAN	8.09	5.93
SD	18.356	16.252
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	5.18	0.37
SD	19.107	18.356
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 101 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	7.26	3.97
SD	19.209	12.029
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	4.29	-1.19
SD	18.051	15.903
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 66.7
CYCLE 4		
N	97	80
MEAN	3.09	8.33
SD	12.804	17.186
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 102 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	0.35	3.33
SD	10.254	19.559
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7
CYCLE 5		
N	92	72
MEAN	4.71	3.70
SD	12.678	10.549
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 5		
N	91	72
MEAN	1.83	-1.39
SD	12.534	14.195
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 103 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	3.83	6.76
SD	11.840	14.664
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	1.16	1.93
SD	11.934	18.860
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7
CYCLE 7		
N	88	65
MEAN	4.55	5.13
SD	13.544	13.477
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 104 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	1.92	0.00
SD	16.359	17.678
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 8		
N	82	57
MEAN	5.69	5.26
SD	15.542	13.786
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	2.47	-0.58
SD	15.615	18.356
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 105 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	6.83	4.09
SD	16.263	12.709
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	4.07	-1.75
SD	17.677	15.963
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 33.3
CYCLE 10		
N	80	53
MEAN	5.00	6.29
SD	13.099	17.366
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 106 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	2.53	0.00
SD	15.809	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 11		
N	71	47
MEAN	7.04	4.26
SD	15.852	11.244
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	4.23	-1.42
SD	18.627	11.953
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 107 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	5.24	3.97
SD	12.219	10.926
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	2.42	-0.79
SD	14.370	15.597
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 13		
N	72	39
MEAN	5.09	5.98
SD	13.310	18.531
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 108 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	1.88	0.85
SD	15.824	22.278
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 100.0
CYCLE 14		
N	54	27
MEAN	4.94	4.94
SD	13.594	12.067
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	2.52	-2.47
SD	12.825	15.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 109 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	5.21	4.17
SD	13.568	11.200
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	2.12	-2.08
SD	11.782	11.785
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 16		
N	58	29
MEAN	5.17	6.90
SD	13.682	16.377
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 110 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	1.75	0.00
SD	11.651	21.822
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7
CYCLE 17		
N	56	31
MEAN	6.55	3.23
SD	18.444	10.018
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	3.57	-3.23
SD	17.614	15.764
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 111 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	9.52	2.90
SD	19.083	9.603
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	5.88	-5.80
SD	17.351	16.368
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0
CYCLE 19		
N	45	28
MEAN	6.67	8.33
SD	13.484	19.510
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 112 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	5.19	2.38
SD	14.134	15.525
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 20		
N	31	17
MEAN	8.60	3.92
SD	21.025	11.070
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	6.67	-5.88
SD	18.362	17.620
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 113 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	7.21	1.96
SD	13.911	8.085
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	5.41	-5.88
SD	16.692	17.620
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 0.0
CYCLE 22		
N	44	13
MEAN	6.06	2.56
SD	14.860	9.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 114 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	4.65	-5.13
SD	17.185	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0
CYCLE 23		
N	28	10
MEAN	10.71	13.33
SD	22.321	23.307
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	8.33	3.33
SD	25.051	33.148
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 115 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	9.20	3.33
SD	17.586	10.541
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	6.90	-6.67
SD	16.377	21.082
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 0.0
CYCLE 25		
N	35	13
MEAN	7.62	0.00
SD	18.232	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 116 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	7.62	-7.69
SD	18.232	19.971
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	-66.7, 0.0
CYCLE 26		
N	20	9
MEAN	3.33	7.41
SD	10.260	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	3.33	-3.70
SD	10.260	26.058
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 117 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	9.33	5.56
SD	18.053	12.975
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	9.33	-2.78
SD	18.053	22.285
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	-66.7, 33.3
CYCLE 28		
N	30	9
MEAN	8.89	3.70
SD	14.993	11.111
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 118 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	8.89	0.00
SD	14.993	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 29		
N	18	7
MEAN	7.41	14.29
SD	14.260	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	7.41	9.52
SD	14.260	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 119 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	7.94	14.29
SD	14.548	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	7.94	9.52
SD	14.548	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CYCLE 31		
N	23	7
MEAN	5.80	4.76
SD	16.368	12.599
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 120 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	5.80	0.00
SD	16.368	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CYCLE 32		
N	17	4
MEAN	7.84	8.33
SD	14.575	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	7.84	0.00
SD	14.575	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 121 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	8.33	6.67
SD	14.907	14.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	8.33	0.00
SD	14.907	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 34		
N	20	4
MEAN	8.33	8.33
SD	14.809	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 122 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	8.33	0.00
SD	14.809	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 35		
N	13	4
MEAN	2.56	8.33
SD	9.245	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	2.56	0.00
SD	9.245	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 123 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	0.00	16.67
SD	0.000	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 37		
N	14	2
MEAN	2.38	16.67
SD	8.909	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 124 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	2.38	0.00
SD	8.909	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	0.00	16.67
SD	0.000	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 125 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	0.00	11.11
SD	0.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 40		
N	11	3
MEAN	0.00	11.11
SD	0.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 126 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	0.00	0.00
SD	0.000	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 127 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	0.000	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 0.0	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 128 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 129 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 130 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 131 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 132 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	3.13	8.15
SD	9.871	21.504
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	1.04	1.48
SD	13.345	25.580
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 133 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
DYSPHAGIA		
BASELINE		
N	112	104
MEAN	6.85	9.62
SD	17.409	20.072
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	12.94	11.85
SD	20.995	21.382
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	5.50	2.22
SD	24.741	26.346
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 134 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	9.57	17.46
SD	19.628	27.612
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	2.31	7.94
SD	24.156	29.552
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 100.0	-100.0, 100.0
CYCLE 4		
N	97	80
MEAN	11.34	14.17
SD	21.455	24.174
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 135 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	4.17	5.00
SD	23.817	29.098
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 100.0	-66.7, 100.0
CYCLE 5		
N	92	73
MEAN	6.52	8.22
SD	14.184	18.241
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	0.37	-0.91
SD	18.254	24.199
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 136 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	69
MEAN	9.30	10.14
SD	17.453	16.474
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 6		
N	85	69
MEAN	3.92	-0.48
SD	20.192	26.502
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 7		
N	88	65
MEAN	8.71	10.26
SD	18.566	16.586
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 137 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	2.30	-1.03
SD	23.180	24.979
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 66.7
CYCLE 8		
N	82	57
MEAN	8.13	8.77
SD	16.196	18.394
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	1.23	-1.75
SD	17.033	27.037
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 138 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	10.44	8.19
SD	19.428	15.787
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	3.66	-2.92
SD	20.290	24.625
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 10		
N	80	53
MEAN	7.50	11.32
SD	16.751	21.626
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 139 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	0.84	1.26
SD	15.073	28.467
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 100.0
CYCLE 11		
N	71	47
MEAN	7.51	8.51
SD	17.087	17.677
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	0.94	-2.13
SD	19.495	26.379
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 140 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	8.10	8.73
SD	15.475	16.560
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	1.45	-2.38
SD	17.559	20.017
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 13		
N	72	39
MEAN	8.33	12.82
SD	15.575	21.103
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 141 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	1.88	0.85
SD	20.997	20.925
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 14		
N	54	27
MEAN	7.41	8.64
SD	16.719	14.886
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	2.52	-4.94
SD	21.532	27.275
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 142 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	12.50	8.33
SD	20.998	22.401
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	6.88	-3.13
SD	20.876	28.536
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 16		
N	58	29
MEAN	9.77	11.49
SD	19.753	24.030
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 143 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	5.26	-1.15
SD	15.157	30.188
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 66.7
CYCLE 17		
N	56	31
MEAN	14.29	12.90
SD	20.945	20.507
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	7.74	1.08
SD	22.011	26.505
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 144 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	16.19	10.14
SD	28.436	21.165
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	9.80	-5.80
SD	20.969	29.563
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 19		
N	45	28
MEAN	9.63	9.52
SD	16.851	15.335
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 145 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	2.96	-1.19
SD	15.606	23.098
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 20		
N	31	17
MEAN	18.28	11.76
SD	22.507	20.211
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	12.22	-5.88
SD	22.289	26.965
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 146 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	10.81	3.92
SD	17.663	11.070
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	3.60	-11.76
SD	17.184	26.197
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 22		
N	44	13
MEAN	8.33	10.26
SD	19.189	16.013
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 147 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	3.10	0.00
SD	12.202	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 23		
N	28	10
MEAN	17.86	13.33
SD	21.242	17.213
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	7.14	6.67
SD	22.874	14.055
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 148 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	10.34	6.67
SD	18.046	14.055
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	4.60	-6.67
SD	17.192	26.294
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 25		
N	35	13
MEAN	10.48	5.13
SD	17.660	12.518
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 149 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	3.81	-5.13
SD	15.700	12.518
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 26		
N	20	9
MEAN	11.67	7.41
SD	19.571	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	5.00	-7.41
SD	16.312	22.222
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 150 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	12.00	5.56
SD	21.257	12.975
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	6.67	-2.78
SD	19.245	17.164
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3
CYCLE 28		
N	30	9
MEAN	12.22	7.41
SD	20.498	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 151 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	4.44	-7.41
SD	16.914	27.778
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 29		
N	18	7
MEAN	14.81	4.76
SD	20.523	12.599
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	7.41	-9.52
SD	21.559	31.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 152 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	7.94	14.29
SD	14.548	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	3.17	-4.76
SD	20.829	23.002
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 31		
N	23	7
MEAN	8.70	9.52
SD	18.027	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 153 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	4.35	-9.52
SD	15.257	31.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-66.7, 33.3
CYCLE 32		
N	17	4
MEAN	17.65	8.33
SD	29.149	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	11.76	-16.67
SD	20.211	43.033
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 33.33	-50.00, 16.67
MIN, MAX	0.0, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 154 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	10.42	13.33
SD	20.069	18.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	4.17	0.00
SD	16.667	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 34		
N	20	4
MEAN	10.00	25.00
SD	24.423	16.667
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	16.67, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 155 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	5.00	0.00
SD	12.212	27.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	0.0, 33.3	-33.3, 33.3
CYCLE 35		
N	13	4
MEAN	5.13	8.33
SD	18.490	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-2.56	-8.33
SD	9.245	41.944
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 16.67
MIN, MAX	-33.3, 0.0	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 156 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	8.33	33.33
SD	20.719	0.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	33.33, 33.33
MIN, MAX	0.0, 66.7	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	0.00	0.00
SD	14.213	47.140
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 37		
N	14	2
MEAN	2.38	16.67
SD	8.909	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 157 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	2.38	16.67
SD	8.909	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CYCLE 38		
N	11	2
MEAN	6.06	33.33
SD	13.484	0.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	33.33, 33.33
MIN, MAX	0.0, 33.3	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	6.06	0.00
SD	13.484	47.140
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	0.0, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 158 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	0.00	11.11
SD	0.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	-11.11
SD	0.000	50.918
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-66.67, 33.33
MIN, MAX	0.0, 0.0	-66.7, 33.3
CYCLE 40		
N	11	3
MEAN	0.00	22.22
SD	0.000	19.245
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 0.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 159 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	0.00	0.00
SD	0.000	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	0.0, 0.0	-33.3, 33.3
CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	3.70	
SD	11.111	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 160 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 161 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 162 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 163 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 164 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 165 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	12.50	20.74
SD	23.570	29.550
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	4.17	12.59
SD	26.437	32.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 166 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PERIPHERAL NEUROPATHY		
BASELINE		
N	112	104
MEAN	8.04	10.26
SD	16.284	18.624
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CYCLE 2		
N	103	90
MEAN	11.97	11.85
SD	21.315	20.181
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	4.21	1.11
SD	24.557	23.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 167 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	13.33	12.30
SD	20.101	18.498
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	100	84
MEAN	5.33	3.17
SD	19.373	22.919
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 4		
N	97	79
MEAN	14.78	12.66
SD	19.819	19.469
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 168 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	79
MEAN	6.94	3.38
SD	20.472	24.804
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 66.7
CYCLE 5		
N	92	73
MEAN	14.13	15.98
SD	19.287	24.286
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	6.23	6.39
SD	20.435	27.587
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 169 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	12.64	17.39
SD	19.183	23.988
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	4.26	7.73
SD	21.570	25.013
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-33.3, 100.0
CYCLE 7		
N	88	65
MEAN	13.26	17.95
SD	19.923	26.403
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 170 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	4.60	7.18
SD	23.390	26.675
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 8		
N	82	57
MEAN	12.20	14.04
SD	21.284	23.526
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	3.29	3.51
SD	22.114	24.948
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 171 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	13.65	18.13
SD	20.847	26.778
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	4.07	7.02
SD	22.462	30.038
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 10		
N	80	52
MEAN	12.92	17.95
SD	20.877	29.120
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 172 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	52
MEAN	3.80	5.77
SD	23.258	29.314
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 100.0	-33.3, 100.0
CYCLE 11		
N	71	47
MEAN	13.62	19.15
SD	19.982	28.442
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	3.76	8.51
SD	22.921	30.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 173 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	14.76	23.81
SD	23.147	33.159
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	4.35	13.49
SD	20.543	32.141
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 100.0
CYCLE 13		
N	72	39
MEAN	17.13	21.37
SD	25.633	34.613
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 174 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	7.51	12.82
SD	25.941	35.554
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 100.0
CYCLE 14		
N	54	27
MEAN	15.43	17.28
SD	20.180	23.334
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	3.77	7.41
SD	23.260	23.266
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 175 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	12.50	26.04
SD	20.141	29.003
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	2.12	14.58
SD	18.811	30.454
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 16		
N	58	29
MEAN	11.49	20.69
SD	21.222	32.628
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 176 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	1.17	10.34
SD	21.790	29.685
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 17		
N	56	31
MEAN	13.10	19.35
SD	22.633	26.908
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	3.57	10.75
SD	21.722	24.925
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 177 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	18.10	20.29
SD	26.000	24.077
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	3.92	13.04
SD	21.343	21.879
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 19		
N	45	28
MEAN	14.07	23.81
SD	23.016	27.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 178 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	4.44	17.86
SD	19.592	27.936
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 20		
N	31	16
MEAN	15.05	12.50
SD	20.797	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	16
MEAN	2.22	10.42
SD	21.323	20.069
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 179 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	16.22	7.84
SD	26.784	14.575
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	6.31	3.92
SD	24.643	20.008
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 33.3
CYCLE 22		
N	44	13
MEAN	12.12	12.82
SD	19.143	21.681
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 180 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	3.88	7.69
SD	19.531	24.167
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7
CYCLE 23		
N	28	10
MEAN	17.86	30.00
SD	23.098	33.148
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	3.57	23.33
SD	20.963	31.623
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 181 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	18.39	16.67
SD	21.056	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	8.05	10.00
SD	21.185	31.623
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 25		
N	35	12
MEAN	18.10	11.11
SD	27.228	21.711
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 182 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	12
MEAN	8.57	5.56
SD	27.228	23.925
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 100.0	-33.3, 66.7
CYCLE 26		
N	20	9
MEAN	18.33	25.93
SD	29.568	36.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	3.33	22.22
SD	37.307	37.268
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 33.33
MIN, MAX	-66.7, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 183 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	21.33	19.44
SD	28.674	30.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	10.67	16.67
SD	32.942	30.151
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	0.0, 100.0
CYCLE 28		
N	30	9
MEAN	21.11	18.52
SD	29.664	17.568
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 184 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	11.11	11.11
SD	31.964	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 33.3
CYCLE 29		
N	18	7
MEAN	27.78	28.57
SD	34.773	23.002
MEDIAN	0.00	33.33
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	11.11	23.81
SD	41.223	31.706
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-66.7, 100.0	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 185 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	17.46	19.05
SD	22.655	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	6.35	14.29
SD	20.053	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 66.7
CYCLE 31		
N	23	7
MEAN	17.39	14.29
SD	28.194	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 186 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	5.80	4.76
SD	27.802	23.002
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 33.3
CYCLE 32		
N	17	4
MEAN	23.53	16.67
SD	32.839	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	9.80	8.33
SD	32.839	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	-16.67, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 187 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	20.83	26.67
SD	23.960	27.889
MEDIAN	16.67	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	4.17	20.00
SD	23.960	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 33.3	0.0, 66.7
CYCLE 34		
N	20	4
MEAN	20.00	25.00
SD	27.359	16.667
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	16.67, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 188 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	6.67	16.67
SD	31.715	19.245
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 100.0	0.0, 33.3
CYCLE 35		
N	13	4
MEAN	17.95	33.33
SD	25.875	0.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	33.33, 33.33
MIN, MAX	0.0, 66.7	33.3, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	0.00	25.00
SD	19.245	16.667
MEDIAN	0.00	33.33
Q1, Q3	0.00, 0.00	16.67, 33.33
MIN, MAX	-33.3, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 189 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	13.89	16.67
SD	26.432	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	-2.78	0.00
SD	26.432	47.140
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 37		
N	14	2
MEAN	9.52	16.67
SD	20.375	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 190 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-7.14	0.00
SD	26.726	0.000
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	21.21	16.67
SD	26.968	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	0.00
SD	21.082	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 191 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	29.17	0.00
SD	27.817	0.000
MEDIAN	33.33	0.00
Q1, Q3	0.00, 50.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	8.33	-11.11
SD	23.570	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 40		
N	11	3
MEAN	24.24	11.11
SD	33.635	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 192 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	6.06	0.00
SD	35.957	33.333
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 33.33
MIN, MAX	-33.3, 100.0	-33.3, 33.3
CYCLE 41		
N	9	0
MEAN	18.52	
SD	24.216	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	26.058	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 193 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	22.22	0.00
SD	17.213	N.A.
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	20.00	
SD	18.257	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 194 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 44		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 195 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 196 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 197 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 198 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	11.46	16.30
SD	21.767	26.230
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	8.33	3.70
SD	23.947	29.493
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-33.3, 100.0	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 199 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
ALOPECIA		
BASELINE		
N	112	104
MEAN	7.44	8.97
SD	18.290	18.713
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	8.41	11.11
SD	15.978	21.781
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	0.97	1.48
SD	20.052	19.932
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 200 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	7.92	10.32
SD	16.431	20.682
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	0.33	0.79
SD	17.947	17.143
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 66.7
CYCLE 4		
N	97	80
MEAN	9.97	10.00
SD	18.108	17.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 201 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	2.08	0.42
SD	18.614	13.515
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3
CYCLE 5		
N	92	73
MEAN	8.70	11.42
SD	16.292	17.760
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	1.10	2.74
SD	24.063	17.350
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 202 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	9.58	15.46
SD	16.789	22.564
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	2.33	4.83
SD	20.952	23.062
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 7		
N	88	65
MEAN	8.71	18.46
SD	17.864	25.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 203 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	1.92	7.69
SD	23.491	21.056
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 100.0	-33.3, 66.7
CYCLE 8		
N	82	57
MEAN	9.76	14.62
SD	16.134	24.412
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	3.29	4.68
SD	20.142	20.353
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 204 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	8.03	14.04
SD	15.258	22.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	1.22	5.26
SD	21.877	20.692
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 10		
N	80	53
MEAN	7.08	10.06
SD	13.722	16.775
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 205 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	0.00	2.52
SD	17.703	18.315
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 11		
N	71	47
MEAN	6.10	10.64
SD	12.983	19.789
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-1.88	2.13
SD	18.591	17.589
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 206 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	7.14	12.70
SD	13.776	19.412
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-0.48	3.97
SD	18.518	16.792
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 13		
N	72	38
MEAN	6.94	13.16
SD	14.736	19.818
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 207 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	38
MEAN	-0.94	4.39
SD	21.061	20.753
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 66.7
CYCLE 14		
N	54	26
MEAN	6.79	14.10
SD	13.551	19.260
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	53	26
MEAN	-1.89	5.13
SD	18.964	15.470
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 208 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	6.77	18.75
SD	13.517	23.854
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-2.12	9.38
SD	20.629	19.371
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-100.0, 33.3	-33.3, 66.7
CYCLE 16		
N	58	29
MEAN	5.17	16.09
SD	12.174	24.593
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 209 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-3.51	6.90
SD	19.603	20.662
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 66.7
CYCLE 17		
N	56	31
MEAN	8.93	13.98
SD	14.895	20.681
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	0.00	4.30
SD	17.979	18.742
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 210 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	7.62	17.39
SD	14.201	24.349
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-1.96	10.14
SD	16.291	25.495
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 100.0
CYCLE 19		
N	45	28
MEAN	11.11	19.05
SD	17.408	29.297
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 211 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	3.70	9.52
SD	14.603	23.757
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	-33.3, 100.0
CYCLE 20		
N	31	17
MEAN	10.75	15.69
SD	15.840	17.150
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	3.33	7.84
SD	16.022	18.743
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 212 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	10.81	9.80
SD	15.819	15.656
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	2.70	1.96
SD	18.221	18.524
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 22		
N	44	13
MEAN	9.09	10.26
SD	15.017	16.013
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 213 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	1.55	2.56
SD	14.463	16.452
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 23		
N	28	10
MEAN	14.29	20.00
SD	16.798	23.307
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	5.95	6.67
SD	18.265	21.082
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 214 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	13.79	16.67
SD	18.934	23.570
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	3.45	6.67
SD	18.570	21.082
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 25		
N	35	13
MEAN	9.52	12.82
SD	15.278	21.681
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 215 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	1.90	5.13
SD	16.053	18.490
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 26		
N	20	9
MEAN	10.00	14.81
SD	15.672	24.216
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	3.33	3.70
SD	14.907	26.058
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 216 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	13.33	19.44
SD	19.245	30.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	4.00	5.56
SD	20.000	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 28		
N	30	9
MEAN	8.89	18.52
SD	14.993	29.397
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 217 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	1.11	7.41
SD	18.535	22.222
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 33.3	-33.3, 33.3
CYCLE 29		
N	18	7
MEAN	11.11	28.57
SD	19.803	29.991
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	3.70	4.76
SD	22.547	23.002
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 218 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	11.11	38.10
SD	19.245	40.500
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	1.59	19.05
SD	22.301	26.227
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 66.7
CYCLE 31		
N	23	7
MEAN	7.25	19.05
SD	17.281	32.530
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 219 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-1.45	9.52
SD	21.269	31.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 66.7
CYCLE 32		
N	17	4
MEAN	9.80	25.00
SD	19.596	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	0.00	8.33
SD	23.570	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	-16.67, 33.33
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 220 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	16.67	40.00
SD	21.082	43.461
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	8.33	13.33
SD	22.771	18.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 34		
N	20	4
MEAN	11.67	8.33
SD	19.571	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 221 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	5.00	-8.33
SD	22.361	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 35		
N	13	4
MEAN	12.82	33.33
SD	21.681	38.490
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	5.13	0.00
SD	26.688	27.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-33.3, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 222 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	16.67	66.67
SD	22.473	0.000
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	8.33	33.33
SD	25.126	0.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 16.67	33.33, 33.33
MIN, MAX	-33.3, 66.7	33.3, 33.3
CYCLE 37		
N	14	2
MEAN	14.29	50.00
SD	21.540	23.570
MEDIAN	0.00	50.00
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	0.0, 66.7	33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 223 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	7.14	0.00
SD	26.726	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	-33.3, 66.7	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	18.18	66.67
SD	22.918	0.000
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 66.7	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	9.09	33.33
SD	30.151	0.000
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	33.33, 33.33
MIN, MAX	-33.3, 66.7	33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 224 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	16.67	55.56
SD	25.198	19.245
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	33.33, 66.67
MIN, MAX	0.0, 66.7	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	4.17	11.11
SD	33.034	19.245
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 40		
N	11	3
MEAN	21.21	66.67
SD	26.968	0.000
MEDIAN	0.00	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 66.7	66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 225 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	12.12	22.22
SD	34.230	19.245
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	-33.3, 66.7	0.0, 33.3
CYCLE 41		
N	9	0
MEAN	22.22	
SD	28.868	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	11.11	
SD	37.268	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	-33.3, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 226 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	16.67	66.67
SD	18.257	N.A.
MEDIAN	16.67	66.67
Q1, Q3	0.00, 33.33	66.67, 66.67
MIN, MAX	0.0, 33.3	66.7, 66.7
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	0.00	0.00
SD	29.814	N.A.
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 33.33	0.00, 0.00
MIN, MAX	-33.3, 33.3	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 227 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	-11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 228 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 229 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 230 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 231 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	6.25	14.81
SD	13.219	24.158
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-2.08	4.44
SD	22.300	22.019
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 232 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PAIN IN CHEST		
BASELINE		
N	112	104
MEAN	16.07	14.10
SD	22.807	23.081
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	7.12	8.15
SD	18.465	16.045
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	-9.39	-5.93
SD	21.091	20.345
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 233 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	6.27	7.14
SD	15.429	14.700
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-10.56	-5.56
SD	22.076	19.928
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 4		
N	97	80
MEAN	6.53	9.58
SD	15.693	18.520
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 234 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	80
MEAN	-11.11	-3.33
SD	20.896	21.609
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 66.7
CYCLE 5		
N	92	73
MEAN	6.88	7.31
SD	16.042	16.893
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	-9.52	-6.39
SD	22.380	18.137
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 235 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	4.21	6.28
SD	13.260	16.445
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-11.63	-7.25
SD	22.151	22.044
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 7		
N	88	65
MEAN	6.06	10.26
SD	15.615	18.562
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 236 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	-11.88	-4.62
SD	20.945	20.307
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 8		
N	81	57
MEAN	4.94	7.60
SD	13.029	16.688
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 8		
N	80	57
MEAN	-11.25	-7.60
SD	22.467	22.728
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 237 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	5.62	7.60
SD	13.594	15.453
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	-11.79	-7.02
SD	21.193	17.522
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 10		
N	80	53
MEAN	3.75	7.55
SD	12.985	19.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 238 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	53
MEAN	-12.66	-6.92
SD	22.836	25.619
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 100.0
CYCLE 11		
N	71	47
MEAN	6.57	4.96
SD	19.206	11.996
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-10.80	-5.67
SD	23.754	16.030
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 239 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	5.71	8.73
SD	13.868	22.159
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-10.63	-1.59
SD	22.501	23.226
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 100.0
CYCLE 13		
N	72	39
MEAN	9.26	10.26
SD	21.827	24.368
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 240 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	71	39
MEAN	-7.98	0.00
SD	24.211	24.183
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 100.0
CYCLE 14		
N	54	27
MEAN	7.41	9.88
SD	22.117	18.057
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	-10.69	0.00
SD	23.364	20.672
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 241 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	7.81	14.58
SD	19.466	22.300
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-10.05	3.13
SD	21.281	24.479
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 16		
N	58	29
MEAN	4.60	6.90
SD	11.595	13.742
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 242 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-11.70	-3.45
SD	24.794	20.596
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 17		
N	56	31
MEAN	3.57	11.83
SD	12.191	22.024
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 17		
N	56	31
MEAN	-11.90	2.15
SD	21.489	19.120
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 243 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	6.67	4.35
SD	19.470	15.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-10.78	-5.80
SD	22.801	19.207
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 19		
N	45	28
MEAN	8.15	13.10
SD	19.010	20.963
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 244 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-10.37	3.57
SD	26.421	18.898
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3
CYCLE 20		
N	31	17
MEAN	9.68	9.80
SD	21.419	15.656
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-8.89	0.00
SD	24.656	20.412
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 245 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	9.91	11.76
SD	19.027	20.211
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-11.71	1.96
SD	23.852	24.918
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 22		
N	44	13
MEAN	6.82	2.56
SD	15.384	9.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 246 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-10.85	-5.13
SD	20.212	12.518
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 23		
N	28	10
MEAN	13.10	20.00
SD	22.842	23.307
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-9.52	10.00
SD	23.757	27.442
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 247 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	4.60	10.00
SD	11.698	16.102
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	-14.94	0.00
SD	26.105	22.222
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 25		
N	35	13
MEAN	10.48	5.13
SD	22.537	12.518
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 248 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-8.57	-2.56
SD	24.711	16.452
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 33.3
CYCLE 26		
N	20	9
MEAN	10.00	11.11
SD	19.041	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-10.00	0.00
SD	26.710	23.570
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 249 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	5.33	5.56
SD	12.472	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	-18.67	0.00
SD	32.030	24.618
MEDIAN	-33.33	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 66.7
CYCLE 28		
N	30	9
MEAN	7.78	0.00
SD	20.869	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 250 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	-7.78	-11.11
SD	25.795	16.667
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 0.0
CYCLE 29		
N	18	7
MEAN	9.26	14.29
SD	19.150	17.817
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-9.26	4.76
SD	29.826	23.002
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 33.33
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 251 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	6.35	4.76
SD	17.059	12.599
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	-7.94	-4.76
SD	23.345	23.002
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 31		
N	23	7
MEAN	4.35	9.52
SD	11.478	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 252 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-13.04	0.00
SD	24.077	0.000
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	0.0, 0.0
CYCLE 32		
N	17	4
MEAN	7.84	8.33
SD	18.743	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	-7.84	0.00
SD	27.712	27.217
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 253 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	10.42	6.67
SD	20.069	14.907
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-8.33	0.00
SD	31.032	23.570
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 34		
N	20	4
MEAN	5.00	8.33
SD	12.212	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 254 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-13.33	-8.33
SD	25.131	31.914
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 33.3
CYCLE 35		
N	13	4
MEAN	7.69	8.33
SD	19.971	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-5.13	0.00
SD	26.688	27.217
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-16.67, 16.67
MIN, MAX	-66.7, 33.3	-33.3, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 255 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	5.56	0.00
SD	19.245	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	-8.33	-16.67
SD	25.126	23.570
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0
CYCLE 37		
N	14	2
MEAN	2.38	0.00
SD	8.909	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 256 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-14.29	0.00
SD	21.540	0.000
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 0.0	0.0, 0.0
CYCLE 38		
N	11	2
MEAN	9.09	0.00
SD	21.556	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	-9.09	-16.67
SD	26.208	23.570
MEDIAN	0.00	-16.67
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 257 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	8.33	0.00
SD	23.570	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	4.17	-11.11
SD	11.785	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	0.0, 33.3	-33.3, 0.0
CYCLE 40		
N	10	3
MEAN	6.67	0.00
SD	14.055	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 258 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	10	3
MEAN	0.00	-11.11
SD	15.713	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-33.3, 0.0
CYCLE 41		
N	9	0
MEAN	11.11	
SD	23.570	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	26.058	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-66.7, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 259 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	11.11	0.00
SD	27.217	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CYCLE 43		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 260 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 261 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 262 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 263 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 264 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
END OF TREATMENT		
N	32	45
MEAN	11.46	14.07
SD	20.053	23.016
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-11.46	-1.48
SD	23.355	20.045
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 265 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PAIN IN ARM OR SHOULDER		
BASELINE		
N	112	104
MEAN	16.67	22.44
SD	24.095	30.260
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	103	90
MEAN	9.71	9.63
SD	21.709	18.185
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 2		
N	103	90
MEAN	-7.77	-12.96
SD	21.493	27.684
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 266 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	101	84
MEAN	8.58	7.14
SD	21.423	16.421
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 3		
N	101	84
MEAN	-8.91	-13.10
SD	22.056	28.349
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 4		
N	97	79
MEAN	9.62	8.44
SD	20.949	16.424
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 267 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	96	79
MEAN	-7.99	-11.39
SD	20.374	31.071
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3
CYCLE 5		
N	92	73
MEAN	7.61	7.31
SD	17.192	16.893
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	91	73
MEAN	-9.16	-11.87
SD	21.120	30.108
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 268 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	87	69
MEAN	7.66	12.08
SD	17.388	24.234
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	86	69
MEAN	-8.14	-8.70
SD	19.761	34.609
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0
CYCLE 7		
N	88	65
MEAN	7.58	7.69
SD	18.030	16.425
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 269 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	87	65
MEAN	-9.20	-15.38
SD	19.483	28.914
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 33.3
CYCLE 8		
N	82	57
MEAN	8.94	10.53
SD	18.181	20.077
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	57
MEAN	-7.82	-14.04
SD	23.730	32.088
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 270 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	83	57
MEAN	10.44	8.19
SD	20.776	16.998
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 9		
N	82	57
MEAN	-6.91	-14.62
SD	24.421	30.222
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 66.7
CYCLE 10		
N	79	52
MEAN	9.70	9.62
SD	19.357	23.185
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 271 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	78	52
MEAN	-6.41	-12.18
SD	24.652	35.565
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0
CYCLE 11		
N	71	47
MEAN	12.21	9.93
SD	25.348	19.554
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	71	47
MEAN	-5.16	-9.93
SD	24.975	32.538
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 272 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	42
MEAN	8.10	14.29
SD	18.333	29.580
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	42
MEAN	-7.73	-6.35
SD	18.208	43.078
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 100.0
CYCLE 13		
N	71	39
MEAN	14.08	17.95
SD	26.822	28.456
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 273 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	70	39
MEAN	-2.86	-1.71
SD	23.221	38.197
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 100.0
CYCLE 14		
N	54	27
MEAN	10.49	4.94
SD	24.075	12.067
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 14		
N	53	27
MEAN	-7.55	-14.81
SD	18.071	33.758
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 274 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	64	32
MEAN	11.46	12.50
SD	24.645	27.760
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	63	32
MEAN	-6.35	-9.38
SD	21.467	40.811
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 33.3	-100.0, 100.0
CYCLE 16		
N	58	29
MEAN	14.37	14.94
SD	25.063	24.537
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 275 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	57	29
MEAN	-3.51	-4.60
SD	22.435	37.506
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 100.0
CYCLE 17		
N	56	30
MEAN	11.90	12.22
SD	21.489	23.947
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	56	30
MEAN	-5.36	-4.44
SD	21.814	36.863
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 276 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	35	23
MEAN	17.14	15.94
SD	28.436	24.349
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 18		
N	34	23
MEAN	-1.96	-4.35
SD	27.144	42.999
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 33.33
MIN, MAX	-33.3, 66.7	-100.0, 66.7
CYCLE 19		
N	45	28
MEAN	12.59	15.48
SD	21.660	24.816
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 277 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	-5.93	-3.57
SD	24.913	36.671
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0
CYCLE 20		
N	31	17
MEAN	19.35	3.92
SD	28.250	11.070
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-3.33	-19.61
SD	26.767	33.456
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 278 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	16.22	11.76
SD	26.784	20.211
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-3.60	-11.76
SD	28.091	33.211
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 22		
N	44	13
MEAN	14.39	15.38
SD	24.270	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 279 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-2.33	-10.26
SD	28.541	39.404
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 100.0
CYCLE 23		
N	28	10
MEAN	22.62	23.33
SD	27.297	31.623
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	10
MEAN	-1.19	-3.33
SD	34.525	48.305
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 16.67	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 280 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	29	10
MEAN	17.24	10.00
SD	24.593	22.498
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 24		
N	29	10
MEAN	0.00	-20.00
SD	28.172	39.126
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 25		
N	35	13
MEAN	13.33	15.38
SD	23.151	29.235
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 281 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	-2.86	-10.26
SD	28.436	43.853
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0
CYCLE 26		
N	20	9
MEAN	15.00	18.52
SD	27.519	33.793
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-3.33	-14.81
SD	34.028	52.997
MEDIAN	0.00	-33.33
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 282 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	25	12
MEAN	18.67	19.44
SD	23.727	30.011
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	25	12
MEAN	0.00	-8.33
SD	31.914	32.177
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 66.7
CYCLE 28		
N	30	9
MEAN	15.56	7.41
SD	24.343	14.699
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 283 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	3.33	-25.93
SD	23.732	36.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 0.0
CYCLE 29		
N	18	7
MEAN	12.96	0.00
SD	23.260	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	-3.70	-42.86
SD	30.008	37.090
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 284 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	15.87	9.52
SD	29.096	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	4.76	-33.33
SD	28.452	43.033
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-66.67, 0.00
MIN, MAX	-33.3, 66.7	-100.0, 33.3
CYCLE 31		
N	23	7
MEAN	11.59	9.52
SD	23.802	16.265
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 285 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-2.90	-28.57
SD	31.644	35.635
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 0.0
CYCLE 32		
N	17	4
MEAN	19.61	0.00
SD	31.311	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 100.0	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	7.84	-50.00
SD	27.712	43.033
MEDIAN	0.00	-50.00
Q1, Q3	0.00, 0.00	-83.33, -16.67
MIN, MAX	-33.3, 66.7	-100.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 286 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	14.58	13.33
SD	24.248	18.257
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-2.08	-20.00
SD	35.421	29.814
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 0.0
CYCLE 34		
N	20	4
MEAN	11.67	25.00
SD	22.361	16.667
MEDIAN	0.00	33.33
Q1, Q3	0.00, 16.67	16.67, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 287 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	-5.00	-8.33
SD	34.666	16.667
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-16.67, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 0.0
CYCLE 35		
N	13	4
MEAN	10.26	8.33
SD	25.036	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	-2.56	-33.33
SD	28.744	38.490
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-66.67, 0.00
MIN, MAX	-33.3, 66.7	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 288 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	11.11	33.33
SD	21.711	47.140
MEDIAN	0.00	33.33
Q1, Q3	0.00, 16.67	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	0.00	-16.67
SD	28.427	23.570
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-33.3, 66.7	-33.3, 0.0
CYCLE 37		
N	14	2
MEAN	9.52	0.00
SD	20.375	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 289 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-4.76	-50.00
SD	31.642	23.570
MEDIAN	0.00	-50.00
Q1, Q3	-33.33, 0.00	-66.67, -33.33
MIN, MAX	-66.7, 66.7	-66.7, -33.3
CYCLE 38		
N	11	2
MEAN	18.18	16.67
SD	27.340	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	3.03	-33.33
SD	45.837	0.000
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 33.33	-33.33, -33.33
MIN, MAX	-100.0, 66.7	-33.3, -33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 290 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	12.50	0.00
SD	24.801	0.000
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	4.17	-55.56
SD	27.817	19.245
MEDIAN	0.00	-66.67
Q1, Q3	0.00, 0.00	-66.67, -33.33
MIN, MAX	-33.3, 66.7	-66.7, -33.3
CYCLE 40		
N	11	3
MEAN	9.09	11.11
SD	15.570	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 33.3	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 291 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-9.09	-44.44
SD	26.208	19.245
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-66.67, -33.33
MIN, MAX	-66.7, 33.3	-66.7, -33.3
CYCLE 41		
N	9	0
MEAN	11.11	
SD	23.570	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-7.41	
SD	43.390	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-100.0, 66.7	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 292 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	5.56	0.00
SD	13.608	N.A.
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	0.0, 33.3	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	-5.56	-66.67
SD	25.092	N.A.
MEDIAN	0.00	-66.67
Q1, Q3	-33.33, 0.00	-66.67, -66.67
MIN, MAX	-33.3, 33.3	-66.7, -66.7
CYCLE 43		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 293 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 44		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 294 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	-6.67	
SD	14.907	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 295 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 296 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 297 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	45
MEAN	11.46	19.26
SD	20.053	28.858
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	32	45
MEAN	-11.46	-3.70
SD	27.578	28.623
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	0.00, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 298 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
PAIN IN OTHER PARTS		
BASELINE		
N	111	104
MEAN	23.12	31.09
SD	27.995	32.269
MEDIAN	33.33	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CYCLE 2		
N	101	88
MEAN	12.87	14.77
SD	22.096	23.629
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 2		
N	100	88
MEAN	-8.33	-17.80
SD	26.538	33.884
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 299 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 3		
N	100	84
MEAN	14.00	15.48
SD	25.151	22.818
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 3		
N	99	84
MEAN	-6.73	-15.48
SD	27.347	30.369
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 4		
N	94	76
MEAN	15.60	17.11
SD	25.728	24.033
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 300 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 4		
N	92	76
MEAN	-6.16	-14.04
SD	28.785	36.621
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 100.0
CYCLE 5		
N	90	72
MEAN	15.56	17.13
SD	21.317	25.015
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 5		
N	89	72
MEAN	-5.24	-13.89
SD	25.574	32.501
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 301 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 6		
N	86	65
MEAN	11.63	18.46
SD	19.649	28.886
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 6		
N	85	65
MEAN	-7.45	-14.36
SD	24.868	37.253
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0
CYCLE 7		
N	85	64
MEAN	11.76	18.75
SD	22.246	28.406
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 302 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 7		
N	84	64
MEAN	-9.52	-16.15
SD	27.170	37.086
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0
CYCLE 8		
N	82	56
MEAN	10.98	20.24
SD	18.186	30.271
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 8		
N	81	56
MEAN	-7.41	-14.29
SD	25.820	36.986
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 303 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 9		
N	82	53
MEAN	15.85	21.38
SD	24.693	30.728
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 9		
N	81	53
MEAN	-6.58	-11.32
SD	29.543	41.830
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0
CYCLE 10		
N	80	52
MEAN	15.00	20.51
SD	24.247	31.069
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 304 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 10		
N	79	52
MEAN	-6.75	-13.46
SD	30.373	39.748
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0
CYCLE 11		
N	69	45
MEAN	14.98	17.04
SD	25.267	28.089
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 11		
N	69	45
MEAN	-5.80	-14.81
SD	29.681	38.636
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 305 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 12		
N	70	41
MEAN	13.81	15.45
SD	23.736	26.975
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 12		
N	69	41
MEAN	-5.80	-19.51
SD	25.538	34.941
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 33.3
CYCLE 13		
N	70	38
MEAN	14.76	23.68
SD	28.168	34.578
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 306 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 13		
N	69	38
MEAN	-6.28	-12.28
SD	30.398	36.696
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 14		
N	54	26
MEAN	16.67	19.23
SD	27.281	30.071
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 14		
N	53	26
MEAN	-5.03	-16.67
SD	30.937	42.426
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 307 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 15		
N	63	32
MEAN	16.40	23.96
SD	27.352	31.943
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 15		
N	62	32
MEAN	-4.84	-11.46
SD	29.474	38.437
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-100.0, 100.0
CYCLE 16		
N	56	29
MEAN	12.50	14.94
SD	21.614	28.986
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 308 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 16		
N	55	29
MEAN	-8.48	-18.39
SD	27.381	37.359
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-100.0, 100.0
CYCLE 17		
N	55	28
MEAN	17.58	15.48
SD	27.855	30.741
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 17		
N	55	28
MEAN	0.61	-17.86
SD	29.039	39.002
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 309 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 18		
N	34	22
MEAN	20.59	18.18
SD	35.783	32.083
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 18		
N	33	22
MEAN	1.01	-13.64
SD	32.792	44.435
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 100.0
CYCLE 19		
N	45	28
MEAN	19.26	20.24
SD	28.858	33.134
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 310 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 19		
N	45	28
MEAN	0.00	-14.29
SD	30.977	41.996
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 100.0
CYCLE 20		
N	31	17
MEAN	10.75	15.69
SD	18.027	20.809
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 20		
N	30	17
MEAN	-12.22	-21.57
SD	23.947	31.049
MEDIAN	0.00	-33.33
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 311 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 21		
N	37	17
MEAN	16.22	13.73
SD	26.784	26.507
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 21		
N	37	17
MEAN	-2.70	-25.49
SD	24.061	32.338
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0
CYCLE 22		
N	44	13
MEAN	11.36	15.38
SD	22.668	25.875
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 312 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 22		
N	43	13
MEAN	-6.20	-23.08
SD	27.464	41.688
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-100.0, 66.7
CYCLE 23		
N	28	9
MEAN	20.24	29.63
SD	27.725	35.136
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 23		
N	28	9
MEAN	-2.38	-7.41
SD	32.620	27.778
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	0.00, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 313 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 24		
N	28	10
MEAN	21.43	20.00
SD	31.706	32.203
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 24		
N	28	10
MEAN	3.57	-26.67
SD	35.532	37.843
MEDIAN	0.00	0.00
Q1, Q3	-16.67, 16.67	-66.67, 0.00
MIN, MAX	-66.7, 100.0	-100.0, 0.0
CYCLE 25		
N	35	13
MEAN	20.00	17.95
SD	29.373	32.247
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 314 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 25		
N	35	13
MEAN	4.76	-23.08
SD	26.987	34.385
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-100.0, 0.0
CYCLE 26		
N	20	9
MEAN	16.67	25.93
SD	27.572	36.430
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 26		
N	20	9
MEAN	-1.67	-18.52
SD	33.289	24.216
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 100.0	-66.7, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 315 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 27		
N	24	12
MEAN	16.67	16.67
SD	29.488	26.591
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 27		
N	24	12
MEAN	-1.39	-19.44
SD	38.673	22.285
MEDIAN	0.00	-16.67
Q1, Q3	-16.67, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 0.0
CYCLE 28		
N	30	9
MEAN	24.44	18.52
SD	28.945	24.216
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 316 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 28		
N	30	9
MEAN	11.11	-22.22
SD	30.742	28.868
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 0.0
CYCLE 29		
N	18	7
MEAN	20.37	23.81
SD	20.256	37.090
MEDIAN	33.33	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 29		
N	18	7
MEAN	0.00	-19.05
SD	30.250	37.796
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-66.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 317 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 30		
N	21	7
MEAN	15.87	23.81
SD	24.987	37.090
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 30		
N	21	7
MEAN	3.17	-19.05
SD	29.636	37.796
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	-66.67, 0.00
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 31		
N	23	7
MEAN	13.04	28.57
SD	24.077	35.635
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 318 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 31		
N	23	7
MEAN	-1.45	-23.81
SD	35.503	31.706
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-66.67, 0.00
MIN, MAX	-100.0, 66.7	-66.7, 0.0
CYCLE 32		
N	17	4
MEAN	13.73	25.00
SD	23.743	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 32		
N	17	4
MEAN	0.00	-16.67
SD	28.868	63.828
MEDIAN	0.00	-33.33
Q1, Q3	0.00, 0.00	-66.67, 33.33
MIN, MAX	-66.7, 66.7	-66.7, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 319 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 33		
N	16	5
MEAN	12.50	26.67
SD	23.960	27.889
MEDIAN	0.00	33.33
Q1, Q3	0.00, 16.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 66.7
CHANGE FROM BASELINE AT CYCLE 33		
N	16	5
MEAN	-6.25	-6.67
SD	36.956	27.889
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 66.7	-33.3, 33.3
CYCLE 34		
N	20	4
MEAN	16.67	25.00
SD	25.363	31.914
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 50.00
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 320 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 34		
N	20	4
MEAN	1.67	-8.33
SD	31.484	41.944
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-33.33, 16.67
MIN, MAX	-66.7, 66.7	-66.7, 33.3
CYCLE 35		
N	13	4
MEAN	12.82	8.33
SD	21.681	16.667
MEDIAN	0.00	0.00
Q1, Q3	0.00, 33.33	0.00, 16.67
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 35		
N	13	4
MEAN	0.00	-33.33
SD	23.570	47.140
MEDIAN	0.00	-50.00
Q1, Q3	0.00, 0.00	-66.67, 0.00
MIN, MAX	-66.7, 33.3	-66.7, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 321 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 36		
N	12	2
MEAN	11.11	50.00
SD	21.711	23.570
MEDIAN	0.00	50.00
Q1, Q3	0.00, 16.67	33.33, 66.67
MIN, MAX	0.0, 66.7	33.3, 66.7
CHANGE FROM BASELINE AT CYCLE 36		
N	12	2
MEAN	-2.78	16.67
SD	22.285	70.711
MEDIAN	0.00	16.67
Q1, Q3	0.00, 0.00	-33.33, 66.67
MIN, MAX	-66.7, 33.3	-33.3, 66.7
CYCLE 37		
N	14	2
MEAN	14.29	16.67
SD	21.540	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 33.33	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 322 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 37		
N	14	2
MEAN	-4.76	-16.67
SD	28.815	70.711
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-66.67, 33.33
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 38		
N	11	2
MEAN	24.24	16.67
SD	30.151	23.570
MEDIAN	0.00	16.67
Q1, Q3	0.00, 66.67	0.00, 33.33
MIN, MAX	0.0, 66.7	0.0, 33.3
CHANGE FROM BASELINE AT CYCLE 38		
N	11	2
MEAN	0.00	-16.67
SD	33.333	23.570
MEDIAN	0.00	-16.67
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-66.7, 66.7	-33.3, 0.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 323 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 39		
N	8	3
MEAN	20.83	33.33
SD	24.801	57.735
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 100.00
MIN, MAX	0.0, 66.7	0.0, 100.0
CHANGE FROM BASELINE AT CYCLE 39		
N	8	3
MEAN	0.00	-11.11
SD	30.861	50.918
MEDIAN	0.00	0.00
Q1, Q3	0.00, 16.67	-66.67, 33.33
MIN, MAX	-66.7, 33.3	-66.7, 33.3
CYCLE 40		
N	11	3
MEAN	15.15	33.33
SD	22.918	33.333
MEDIAN	0.00	33.33
Q1, Q3	0.00, 33.33	0.00, 66.67
MIN, MAX	0.0, 66.7	0.0, 66.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 324 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 40		
N	11	3
MEAN	-9.09	-11.11
SD	39.696	19.245
MEDIAN	0.00	0.00
Q1, Q3	0.00, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 33.3	-33.3, 0.0
CYCLE 41		
N	9	0
MEAN	18.52	
SD	24.216	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 66.7	
CHANGE FROM BASELINE AT CYCLE 41		
N	9	0
MEAN	-3.70	
SD	38.889	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	-100.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 325 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 42		
N	6	1
MEAN	22.22	0.00
SD	27.217	N.A.
MEDIAN	16.67	0.00
Q1, Q3	0.00, 33.33	0.00, 0.00
MIN, MAX	0.0, 66.7	0.0, 0.0
CHANGE FROM BASELINE AT CYCLE 42		
N	6	1
MEAN	5.56	-66.67
SD	25.092	N.A.
MEDIAN	0.00	-66.67
Q1, Q3	0.00, 33.33	-66.67, -66.67
MIN, MAX	-33.3, 33.3	-66.7, -66.7
CYCLE 43		
N	4	0
MEAN	16.67	
SD	19.245	
MEDIAN	16.67	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 326 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 43		
N	4	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 44		
N	3	0
MEAN	22.22	
SD	19.245	
MEDIAN	33.33	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 44		
N	3	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 327 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 45		
N	5	0
MEAN	13.33	
SD	18.257	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	
CHANGE FROM BASELINE AT CYCLE 45		
N	5	0
MEAN	0.00	
SD	0.000	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 46		
N	3	0
MEAN	11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	0.00, 33.33	
MIN, MAX	0.0, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 328 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naive subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 46		
N	3	0
MEAN	-11.11	
SD	19.245	
MEDIAN	0.00	
Q1, Q3	-33.33, 0.00	
MIN, MAX	-33.3, 0.0	
CYCLE 47		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 47		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire
Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor.
Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 329 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CYCLE 48		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	
CHANGE FROM BASELINE AT CYCLE 48		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
CYCLE 49		
N	1	0
MEAN	33.33	
SD	N.A.	
MEDIAN	33.33	
Q1, Q3	33.33, 33.33	
MIN, MAX	33.3, 33.3	

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 330 of 330

Table P.3.1
Summary of EORTC QLQ-LC13 by Cycle
Safety Set for ROS1+
Subjects from Phase 2 Portion of the Trial

	EXP-1 TKI-naïve subjects N = 113	EXP-4 TKI-pretreated subjects N = 104
CHANGE FROM BASELINE AT CYCLE 49		
N	1	0
MEAN	0.00	
SD	N.A.	
MEDIAN	0.00	
Q1, Q3	0.00, 0.00	
MIN, MAX	0.0, 0.0	
END OF TREATMENT		
N	32	43
MEAN	27.08	21.71
SD	36.355	29.888
MEDIAN	0.00	0.00
Q1, Q3	0.00, 50.00	0.00, 33.33
MIN, MAX	0.0, 100.0	0.0, 100.0
CHANGE FROM BASELINE AT END OF TREATMENT		
N	31	43
MEAN	-2.15	-4.65
SD	40.309	35.323
MEDIAN	0.00	0.00
Q1, Q3	-33.33, 0.00	-33.33, 0.00
MIN, MAX	-100.0, 100.0	-66.7, 100.0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer QoL Questionnaire Supplement for Patients With Lung Cancer; QoL = Quality of Life; TKI = tyrosine kinase inhibitor. Restricted to patients from Phase 2 portion of the trial.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-sy-proqlqlc13-ebr2365-b2.sas

17JUL2024:09:52:50

Anhang 4-G 3: Endpunkte Verträglichkeit: Weitere Analysen

Anhang 4-G 3.1: Unerwünschte Ereignisse von besonderem Interesse (UESI)

Anhang 4-G 3.1.1: Jegliche UESI

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 1

Table S.2.1
Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for ROS1+

Medical Concept	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
SUBJECTS WITH ANY AESI	114 (98.3)	98 (92.5)
Ataxia	40 (34.5)	33 (31.1)
Cognitive Disorders	29 (25.0)	28 (26.4)
Dizziness	88 (75.9)	63 (59.4)
Dysgeusia	77 (66.4)	61 (57.5)
Hepatic Enzyme Elevation	44 (37.9)	35 (33.0)
Mood Disorders	9 (7.8)	12 (11.3)
Muscular Weakness	33 (28.4)	26 (24.5)
Paraesthesia	56 (48.3)	47 (44.3)
Peripheral Sensory Neuropathy	24 (20.7)	27 (25.5)
Pneumonitis	5 (4.3)	4 (3.8)
QT Prolongation	1 (0.9)	2 (1.9)
Skeletal Fractures	5 (4.3)	5 (4.7)
Sleep Disorders	21 (18.1)	23 (21.7)
Vision Disorders	14 (12.1)	12 (11.3)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

All Medical Concepts are included, irrespective of their frequency, and sorted alphabetically.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summc-ebr2365.sas

28MAY2024:10:41:54

Anhang 4-G 3.1.2: Schwere UESI (UESI mit einem Schweregrad von ≥ 3 nach CTCAE)

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 1

Table S.3.1
Severe Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for ROS1+

Medical Concept	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
SUBJECTS WITH ANY SEVERE AESI	21 (18.1)	16 (15.1)
Ataxia	1 (0.9)	2 (1.9)
Cognitive Disorders	0	3 (2.8)
Dizziness	2 (1.7)	4 (3.8)
Hepatic Enzyme Elevation	6 (5.2)	1 (0.9)
Mood Disorders	1 (0.9)	0
Muscular Weakness	3 (2.6)	2 (1.9)
Paraesthesia	3 (2.6)	0
Peripheral Sensory Neuropathy	0	4 (3.8)
Pneumonitis	3 (2.6)	0
Skeletal Fractures	2 (1.7)	0
Vision Disorders	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

All Medical Concepts are included, irrespective of their frequency, and sorted

alphabetically. Program Path:

/projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-summc-ebr2365.sas

28MAY2024:10:42:00

Anhang 4-G 3.1.3: Schwerwiegende UESI

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 1

Table S.4.1
Serious Treatment-Emergent Adverse Events of Special Interest by Medical Concept
Safety Set for ROS1+

Medical Concept	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
SUBJECTS WITH ANY SERIOUS AESI	11 (9.5)	5 (4.7)
Ataxia	2 (1.7)	0
Cognitive Disorders	0	2 (1.9)
Dizziness	0	2 (1.9)
Mood Disorders	1 (0.9)	0
Muscular Weakness	1 (0.9)	0
Peripheral Sensory Neuropathy	0	1 (0.9)
Pneumonitis	4 (3.4)	0
Skeletal Fractures	4 (3.4)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: AESI = Treatment-Emergent Adverse Event of Special Interest.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

All Medical Concepts are included, irrespective of their frequency, and sorted alphabetically.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-summc-ebr2365.sas

28MAY2024:10:42:07

Anhang 4-G 3.2: UE auf SOC/PT-Ebene

Anhang 4-G 3.2.1: Jegliche UE auf SOC/PT-Ebene

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
SUBJECTS WITH ANY TEAE	116 (100.0)	104 (98.1)
Blood and lymphatic system disorders	57 (49.1)	46 (43.4)
Anaemia	50 (43.1)	43 (40.6)
Iron deficiency anaemia	1 (0.9)	0
Leukocytosis	1 (0.9)	0
Leukopenia	1 (0.9)	1 (0.9)
Lymphocytosis	0	1 (0.9)
Lymphopenia	1 (0.9)	2 (1.9)
Neutropenia	6 (5.2)	2 (1.9)
Thrombocytopenia	1 (0.9)	1 (0.9)
Thrombocytosis	2 (1.7)	1 (0.9)
Cardiac disorders	20 (17.2)	14 (13.2)
Acute myocardial infarction	1 (0.9)	0
Arteriosclerosis coronary artery	1 (0.9)	0
Atrial fibrillation	3 (2.6)	1 (0.9)
Bradycardia	2 (1.7)	0
Cardiac arrest	1 (0.9)	1 (0.9)
Cardiac failure	0	1 (0.9)
Cardiac septal hypertrophy	1 (0.9)	0
Cardiac tamponade	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Endocarditis noninfective	1 (0.9)	0
Left atrial enlargement	1 (0.9)	0
Left ventricular enlargement	1 (0.9)	0
Myocardial ischaemia	1 (0.9)	0
Palpitations	0	2 (1.9)
Pericardial effusion	9 (7.8)	1 (0.9)
Pericarditis	0	1 (0.9)
Sinus bradycardia	2 (1.7)	1 (0.9)
Sinus tachycardia	2 (1.7)	3 (2.8)
Supraventricular tachycardia	1 (0.9)	0
Tachycardia	0	3 (2.8)
Tricuspid valve incompetence	1 (0.9)	0
Ventricular extrasystoles	1 (0.9)	0
Congenital, familial and genetic disorders	2 (1.7)	0
Colour blindness	1 (0.9)	0
Leukodystrophy	1 (0.9)	0
Ear and labyrinth disorders	15 (12.9)	11 (10.4)
Deafness	1 (0.9)	2 (1.9)
Ear pain	0	1 (0.9)
Hyperacusis	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Hypoacusis	0	1 (0.9)
Motion sickness	1 (0.9)	0
Tinnitus	7 (6.0)	3 (2.8)
Vertigo	8 (6.9)	3 (2.8)
Endocrine disorders	3 (2.6)	1 (0.9)
Adrenal insufficiency	0	1 (0.9)
Androgen deficiency	1 (0.9)	0
Diabetes insipidus	1 (0.9)	0
Thyroid mass	1 (0.9)	0
Eye disorders	14 (12.1)	11 (10.4)
Asthenopia	0	1 (0.9)
Blepharospasm	0	1 (0.9)
Cataract	0	1 (0.9)
Cataract nuclear	0	1 (0.9)
Diplopia	1 (0.9)	0
Dry eye	3 (2.6)	1 (0.9)
Eye oedema	1 (0.9)	0
Eye pain	0	2 (1.9)
Eye swelling	0	1 (0.9)
Glaucoma	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Myopia	0	1 (0.9)
Orbital oedema	1 (0.9)	0
Periorbital oedema	0	1 (0.9)
Photophobia	0	1 (0.9)
Presbyopia	1 (0.9)	0
Vision blurred	6 (5.2)	3 (2.8)
Visual field defect	0	1 (0.9)
Visual impairment	1 (0.9)	2 (1.9)
Vitreous floaters	0	1 (0.9)
Gastrointestinal disorders	91 (78.4)	73 (68.9)
Abdominal distension	5 (4.3)	3 (2.8)
Abdominal pain	6 (5.2)	7 (6.6)
Abdominal pain lower	1 (0.9)	0
Abdominal pain upper	3 (2.6)	2 (1.9)
Abdominal tenderness	1 (0.9)	0
Anal incontinence	3 (2.6)	0
Colitis	1 (0.9)	1 (0.9)
Constipation	59 (50.9)	40 (37.7)
Diarrhoea	14 (12.1)	18 (17.0)
Dry mouth	5 (4.3)	4 (3.8)
Dyspepsia	3 (2.6)	4 (3.8)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Dysphagia	13 (11.2)	8 (7.5)
Flatulence	2 (1.7)	2 (1.9)
Food poisoning	0	1 (0.9)
Gastritis	3 (2.6)	1 (0.9)
Gastrooesophageal reflux disease	4 (3.4)	7 (6.6)
Hypoaesthesia oral	7 (6.0)	5 (4.7)
Intra-abdominal fluid collection	1 (0.9)	0
Nausea	22 (19.0)	18 (17.0)
Oral dysaesthesia	2 (1.7)	2 (1.9)
Oral pain	1 (0.9)	1 (0.9)
Paraesthesia oral	6 (5.2)	9 (8.5)
Rectal tenesmus	1 (0.9)	0
Regurgitation	1 (0.9)	0
Stomatitis	0	2 (1.9)
Tooth impacted	0	1 (0.9)
Toothache	2 (1.7)	0
Vomiting	12 (10.3)	9 (8.5)
General disorders and administration site conditions	69 (59.5)	66 (62.3)
Asthenia	15 (12.9)	6 (5.7)
Axillary pain	0	1 (0.9)
Catheter site pain	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Chest discomfort	1 (0.9)	4 (3.8)
Chest pain	4 (3.4)	3 (2.8)
Chills	2 (1.7)	2 (1.9)
Death	3 (2.6)	1 (0.9)
Drug withdrawal syndrome	0	1 (0.9)
Exercise tolerance decreased	1 (0.9)	1 (0.9)
Face oedema	2 (1.7)	2 (1.9)
Fatigue	26 (22.4)	24 (22.6)
Feeling abnormal	2 (1.7)	0
Feeling hot	1 (0.9)	1 (0.9)
Gait disturbance	4 (3.4)	8 (7.5)
Generalised oedema	1 (0.9)	2 (1.9)
Influenza like illness	4 (3.4)	4 (3.8)
Localised oedema	2 (1.7)	1 (0.9)
Malaise	1 (0.9)	2 (1.9)
Mucosal inflammation	3 (2.6)	1 (0.9)
Non-cardiac chest pain	1 (0.9)	1 (0.9)
Oedema	1 (0.9)	2 (1.9)
Oedema peripheral	9 (7.8)	19 (17.9)
Pain	5 (4.3)	8 (7.5)
Peripheral swelling	1 (0.9)	2 (1.9)
Pyrexia	11 (9.5)	10 (9.4)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Sensation of foreign body	2 (1.7)	0
Serositis	1 (0.9)	0
Soft tissue inflammation	0	1 (0.9)
Sudden death	0	1 (0.9)
Temperature intolerance	0	1 (0.9)
Vessel puncture site bruise	0	1 (0.9)
Hepatobiliary disorders	7 (6.0)	2 (1.9)
Hepatic cytolysis	1 (0.9)	0
Hepatic function abnormal	2 (1.7)	1 (0.9)
Hepatic pain	1 (0.9)	0
Hepatitis	1 (0.9)	0
Hypertransaminasaemia	2 (1.7)	1 (0.9)
Immune system disorders	3 (2.6)	1 (0.9)
Contrast media allergy	1 (0.9)	0
Haemophagocytic lymphohistiocytosis	1 (0.9)	0
Seasonal allergy	1 (0.9)	1 (0.9)
Infections and infestations	58 (50.0)	47 (44.3)
Appendicitis	1 (0.9)	0
Asymptomatic bacteriuria	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 8 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Bacterial vaginosis	1 (0.9)	0
Bacteriuria	2 (1.7)	2 (1.9)
Bronchiolitis	1 (0.9)	0
Bronchitis	3 (2.6)	3 (2.8)
COVID-19	27 (23.3)	13 (12.3)
COVID-19 pneumonia	1 (0.9)	0
Cellulitis	1 (0.9)	1 (0.9)
Conjunctivitis	0	2 (1.9)
Cystitis	1 (0.9)	2 (1.9)
Cytomegalovirus infection	1 (0.9)	0
Device related infection	1 (0.9)	0
Ear infection	1 (0.9)	0
Enteritis infectious	1 (0.9)	0
Erysipelas	0	1 (0.9)
Furuncle	0	1 (0.9)
Gastroenteritis viral	1 (0.9)	0
Gingivitis	1 (0.9)	1 (0.9)
Herpes virus infection	0	1 (0.9)
Herpes zoster	1 (0.9)	0
Influenza	1 (0.9)	0
Intervertebral discitis	1 (0.9)	2 (1.9)
Laryngopharyngitis	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 9 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Lower respiratory tract infection	2 (1.7)	1 (0.9)
Lower respiratory tract infection bacterial	0	1 (0.9)
Lymphangitis	0	1 (0.9)
Nasopharyngitis	2 (1.7)	0
Onychomycosis	0	1 (0.9)
Paronychia	0	1 (0.9)
Pelvic abscess	1 (0.9)	0
Pelvic infection	1 (0.9)	0
Peritonitis	1 (0.9)	0
Pneumonia	12 (10.3)	10 (9.4)
Pneumonia aspiration	0	2 (1.9)
Pneumonia bacterial	0	1 (0.9)
Pneumonia klebsiella	0	1 (0.9)
Pneumonia viral	1 (0.9)	0
Rash pustular	0	1 (0.9)
Respiratory tract infection	2 (1.7)	1 (0.9)
Rhinitis	1 (0.9)	2 (1.9)
Sepsis	2 (1.7)	0
Sinusitis	1 (0.9)	1 (0.9)
Staphylococcal infection	1 (0.9)	0
Tooth infection	1 (0.9)	0
Upper respiratory tract infection	9 (7.8)	6 (5.7)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 10 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Urinary tract infection	5 (4.3)	11 (10.4)
Vaginal infection	0	1 (0.9)
Viral upper respiratory tract infection	0	2 (1.9)
Injury, poisoning and procedural complications	19 (16.4)	17 (16.0)
Acetabulum fracture	0	1 (0.9)
Ankle fracture	1 (0.9)	0
Arthropod sting	0	1 (0.9)
Contusion	2 (1.7)	4 (3.8)
Dental restoration failure	0	1 (0.9)
Extradural haematoma	0	1 (0.9)
Fall	4 (3.4)	5 (4.7)
Femur fracture	1 (0.9)	0
Foot fracture	0	1 (0.9)
Infusion related reaction	1 (0.9)	0
Ligament rupture	0	1 (0.9)
Ligament sprain	3 (2.6)	0
Limb injury	0	1 (0.9)
Meniscus injury	1 (0.9)	0
Muscle injury	1 (0.9)	1 (0.9)
Muscle rupture	1 (0.9)	0
Post procedural discomfort	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 11 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Post procedural fever	0	1 (0.9)
Procedural pain	1 (0.9)	0
Procedural pneumothorax	0	1 (0.9)
Radiation skin injury	0	1 (0.9)
Rib fracture	1 (0.9)	1 (0.9)
Spinal compression fracture	1 (0.9)	1 (0.9)
Sternal fracture	0	1 (0.9)
Subdural haematoma	0	1 (0.9)
Thermal burn	1 (0.9)	0
Traumatic ulcer	1 (0.9)	0
Upper limb fracture	1 (0.9)	0
Investigations	79 (68.1)	66 (62.3)
5'nucleotidase increased	0	1 (0.9)
Activated partial thromboplastin time prolonged	2 (1.7)	0
Activated partial thromboplastin time shortened	1 (0.9)	0
Alanine aminotransferase increased	32 (27.6)	32 (30.2)
Alpha hydroxybutyrate dehydrogenase increased	0	1 (0.9)
Apolipoprotein A-I increased	1 (0.9)	0
Apolipoprotein B increased	1 (0.9)	0
Aspartate aminotransferase decreased	0	1 (0.9)
Aspartate aminotransferase increased	38 (32.8)	21 (19.8)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 12 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Bilirubin conjugated increased	0	1 (0.9)
Blood alkaline phosphatase increased	9 (7.8)	11 (10.4)
Blood bilirubin decreased	1 (0.9)	0
Blood cholesterol increased	4 (3.4)	5 (4.7)
Blood creatine phosphokinase MB increased	1 (0.9)	0
Blood creatine phosphokinase decreased	0	1 (0.9)
Blood creatine phosphokinase increased	29 (25.0)	22 (20.8)
Blood creatinine increased	7 (6.0)	2 (1.9)
Blood fibrinogen decreased	1 (0.9)	0
Blood fibrinogen increased	1 (0.9)	0
Blood folate decreased	0	1 (0.9)
Blood follicle stimulating hormone increased	0	1 (0.9)
Blood glucose increased	2 (1.7)	1 (0.9)
Blood lactate dehydrogenase increased	6 (5.2)	5 (4.7)
Blood luteinising hormone increased	0	1 (0.9)
Blood magnesium increased	2 (1.7)	0
Blood methaemoglobin present	1 (0.9)	0
Blood phosphorus decreased	1 (0.9)	0
Blood potassium decreased	1 (0.9)	0
Blood potassium increased	1 (0.9)	0
Blood pressure increased	1 (0.9)	0
Blood prolactin abnormal	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 13 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Blood prolactin increased	2 (1.7)	1 (0.9)
Blood testosterone decreased	1 (0.9)	0
Blood testosterone increased	1 (0.9)	0
Blood triglycerides increased	0	1 (0.9)
Blood urea increased	1 (0.9)	0
Blood uric acid increased	1 (0.9)	0
Blood urine present	1 (0.9)	0
Breath sounds abnormal	1 (0.9)	0
C-reactive protein increased	0	2 (1.9)
Carcinoembryonic antigen increased	0	1 (0.9)
Coagulation factor increased	0	1 (0.9)
Ejection fraction decreased	1 (0.9)	0
Electrocardiogram QT prolonged	1 (0.9)	2 (1.9)
Electrocardiogram T wave inversion	0	1 (0.9)
Eosinophil count increased	0	1 (0.9)
Fibrin D dimer increased	0	1 (0.9)
Gamma-glutamyltransferase increased	9 (7.8)	8 (7.5)
Glutathione s-transferase increased	1 (0.9)	2 (1.9)
Haematocrit decreased	1 (0.9)	0
Haemoglobin decreased	2 (1.7)	2 (1.9)
Heart rate increased	0	1 (0.9)
International normalised ratio decreased	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 14 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
International normalised ratio increased	2 (1.7)	1 (0.9)
Lipase increased	0	1 (0.9)
Low density lipoprotein increased	1 (0.9)	0
Lymphocyte count decreased	4 (3.4)	6 (5.7)
Monocyte count increased	0	1 (0.9)
Myocardial necrosis marker increased	0	1 (0.9)
Myoglobin blood increased	0	1 (0.9)
N-terminal prohormone brain natriuretic peptide increased	0	1 (0.9)
Neurological examination abnormal	0	1 (0.9)
Neutrophil count decreased	17 (14.7)	11 (10.4)
Neutrophil count increased	1 (0.9)	2 (1.9)
Platelet count decreased	0	1 (0.9)
Platelet count increased	9 (7.8)	4 (3.8)
Protein total decreased	0	3 (2.8)
Protein urine present	0	1 (0.9)
Prothrombin time prolonged	2 (1.7)	0
Prothrombin time shortened	1 (0.9)	0
Red blood cell count decreased	1 (0.9)	0
Red blood cells urine positive	1 (0.9)	0
Renal scan abnormal	0	1 (0.9)
SARS-CoV-2 test positive	0	2 (1.9)
Sex hormone binding globulin increased	1 (0.9)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 15 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Transferrin decreased	1 (0.9)	0
Tri-iodothyronine decreased	1 (0.9)	0
Troponin T increased	1 (0.9)	0
Troponin increased	1 (0.9)	0
Urinary occult blood positive	0	1 (0.9)
Weight decreased	4 (3.4)	2 (1.9)
Weight increased	28 (24.1)	16 (15.1)
White blood cell count	0	1 (0.9)
White blood cell count decreased	15 (12.9)	14 (13.2)
White blood cell count increased	1 (0.9)	1 (0.9)
White blood cells urine positive	1 (0.9)	0
Metabolism and nutrition disorders	43 (37.1)	29 (27.4)
Acidosis	1 (0.9)	0
Decreased appetite	13 (11.2)	8 (7.5)
Dehydration	3 (2.6)	0
Fluid retention	2 (1.7)	0
Hypercalcaemia	3 (2.6)	1 (0.9)
Hyperchloraemia	0	1 (0.9)
Hypercholesterolaemia	3 (2.6)	3 (2.8)
Hyperglycaemia	4 (3.4)	1 (0.9)
Hyperkalaemia	4 (3.4)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 16 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Hyperlipidaemia	2 (1.7)	1 (0.9)
Hypermagnesaemia	6 (5.2)	3 (2.8)
Hypernatraemia	5 (4.3)	4 (3.8)
Hyperphosphataemia	3 (2.6)	3 (2.8)
Hypertriglyceridaemia	4 (3.4)	2 (1.9)
Hyperuricaemia	5 (4.3)	6 (5.7)
Hypoalbuminaemia	5 (4.3)	3 (2.8)
Hypocalcaemia	7 (6.0)	2 (1.9)
Hypokalaemia	2 (1.7)	6 (5.7)
Hypomagnesaemia	1 (0.9)	1 (0.9)
Hyponatraemia	6 (5.2)	0
Hypophosphataemia	3 (2.6)	8 (7.5)
Increased appetite	0	1 (0.9)
Vitamin B12 deficiency	0	1 (0.9)
Weight loss poor	1 (0.9)	0
Musculoskeletal and connective tissue disorders	77 (66.4)	65 (61.3)
Arthralgia	22 (19.0)	25 (23.6)
Back pain	13 (11.2)	9 (8.5)
Bone pain	2 (1.7)	2 (1.9)
Flank pain	0	2 (1.9)
Groin pain	2 (1.7)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 17 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Intervertebral disc protrusion	1 (0.9)	0
Joint effusion	1 (0.9)	0
Joint instability	0	1 (0.9)
Joint range of motion decreased	0	1 (0.9)
Joint stiffness	1 (0.9)	0
Limb discomfort	2 (1.7)	1 (0.9)
Muscle atrophy	1 (0.9)	0
Muscle spasms	2 (1.7)	1 (0.9)
Muscle tightness	1 (0.9)	1 (0.9)
Muscle twitching	2 (1.7)	0
Muscular weakness	33 (28.4)	26 (24.5)
Musculoskeletal chest pain	4 (3.4)	2 (1.9)
Musculoskeletal discomfort	1 (0.9)	0
Musculoskeletal pain	3 (2.6)	2 (1.9)
Musculoskeletal stiffness	2 (1.7)	0
Myalgia	17 (14.7)	11 (10.4)
Myopathy	2 (1.7)	1 (0.9)
Myositis	1 (0.9)	0
Neck pain	7 (6.0)	6 (5.7)
Nuchal rigidity	1 (0.9)	0
Osteoarthritis	1 (0.9)	1 (0.9)
Osteochondritis	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 18 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Osteonecrosis	0	1 (0.9)
Osteoporosis	2 (1.7)	1 (0.9)
Pain in extremity	14 (12.1)	17 (16.0)
Rheumatoid arthritis	0	1 (0.9)
Scoliosis	1 (0.9)	0
Spinal ligament ossification	1 (0.9)	0
Spinal osteoarthritis	0	1 (0.9)
Spinal pain	2 (1.7)	0
Synovial cyst	1 (0.9)	0
Torticollis	1 (0.9)	0
Neoplasms benign, malignant and unspecified (incl cysts andolyps)	7 (6.0)	6 (5.7)
Basal cell carcinoma	1 (0.9)	0
Fibroadenoma of breast	1 (0.9)	0
Intraductal proliferative breast lesion	1 (0.9)	0
Lipoma	1 (0.9)	0
Paraneoplastic syndrome	1 (0.9)	0
Skin papilloma	0	1 (0.9)
Squamous cell carcinoma	0	1 (0.9)
Tumour associated fever	1 (0.9)	1 (0.9)
Tumour pain	3 (2.6)	3 (2.8)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort. Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 19 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Nervous system disorders	107 (92.2)	95 (89.6)
Ageusia	3 (2.6)	0
Altered state of consciousness	0	1 (0.9)
Amnesia	1 (0.9)	2 (1.9)
Anaesthesia	1 (0.9)	0
Aphasia	0	1 (0.9)
Ataxia	34 (29.3)	22 (20.8)
Balance disorder	5 (4.3)	3 (2.8)
Brain injury	0	1 (0.9)
Brain oedema	0	1 (0.9)
Burning sensation	2 (1.7)	1 (0.9)
Carpal tunnel syndrome	1 (0.9)	1 (0.9)
Cerebral haemorrhage	0	1 (0.9)
Cerebral infarction	2 (1.7)	1 (0.9)
Cervical radiculopathy	1 (0.9)	0
Cognitive disorder	8 (6.9)	9 (8.5)
Coordination abnormal	0	1 (0.9)
Depressed level of consciousness	0	1 (0.9)
Disturbance in attention	12 (10.3)	16 (15.1)
Dizziness	82 (70.7)	62 (58.5)
Dizziness exertional	1 (0.9)	0
Dizziness postural	3 (2.6)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 20 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Dysaesthesia	2 (1.7)	2 (1.9)
Dysarthria	1 (0.9)	2 (1.9)
Dysgeusia	71 (61.2)	55 (51.9)
Dyskinesia	2 (1.7)	2 (1.9)
Dystonia	1 (0.9)	0
Embolic stroke	1 (0.9)	0
Epilepsy	1 (0.9)	1 (0.9)
Extrapyramidal disorder	3 (2.6)	2 (1.9)
Formication	1 (0.9)	0
Head discomfort	0	3 (2.8)
Headache	21 (18.1)	29 (27.4)
Hydrocephalus	0	1 (0.9)
Hyperaesthesia	6 (5.2)	2 (1.9)
Hypersomnia	2 (1.7)	1 (0.9)
Hypoaesthesia	5 (4.3)	8 (7.5)
Hypogeusia	1 (0.9)	0
Hypoxic-ischaemic encephalopathy	1 (0.9)	0
Lethargy	2 (1.7)	0
Leukoencephalopathy	1 (0.9)	0
Memory impairment	19 (16.4)	15 (14.2)
Monoparesis	0	1 (0.9)
Myasthenic syndrome	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 21 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Neuralgia	17 (14.7)	18 (17.0)
Neuropathy peripheral	4 (3.4)	4 (3.8)
Neurotoxicity	0	1 (0.9)
Nystagmus	0	1 (0.9)
Paraesthesia	50 (43.1)	38 (35.8)
Paraneoplastic neurological syndrome	1 (0.9)	0
Peripheral motor neuropathy	0	2 (1.9)
Peripheral sensory neuropathy	4 (3.4)	5 (4.7)
Polyneuropathy	0	1 (0.9)
Quadriparesis	1 (0.9)	0
Sciatica	1 (0.9)	0
Seizure	0	2 (1.9)
Sensory disturbance	1 (0.9)	2 (1.9)
Sensory loss	0	1 (0.9)
Slow speech	1 (0.9)	1 (0.9)
Somnolence	9 (7.8)	14 (13.2)
Speech disorder	0	1 (0.9)
Syncope	3 (2.6)	5 (4.7)
Taste disorder	3 (2.6)	5 (4.7)
Transient ischaemic attack	1 (0.9)	0
Tremor	4 (3.4)	2 (1.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort. Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 22 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Product issues	0	2 (1.9)
Device occlusion	0	2 (1.9)
Psychiatric disorders	21 (18.1)	21 (19.8)
Abnormal dreams	1 (0.9)	0
Affective disorder	0	1 (0.9)
Agitation	0	1 (0.9)
Anxiety	4 (3.4)	6 (5.7)
Attention deficit hyperactivity disorder	2 (1.7)	1 (0.9)
Bradyphrenia	0	1 (0.9)
Confusional state	1 (0.9)	3 (2.8)
Delirium	1 (0.9)	1 (0.9)
Delusion	0	1 (0.9)
Depressed mood	3 (2.6)	0
Depression	1 (0.9)	3 (2.8)
Enuresis	0	1 (0.9)
Hallucination	1 (0.9)	0
Insomnia	6 (5.2)	8 (7.5)
Irritability	1 (0.9)	2 (1.9)
Libido decreased	1 (0.9)	0
Mania	1 (0.9)	0
Mental status changes	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 23 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Mood altered	1 (0.9)	1 (0.9)
Pressure of speech	1 (0.9)	0
Psychotic disorder	1 (0.9)	0
Sleep disorder	0	1 (0.9)
Renal and urinary disorders	16 (13.8)	13 (12.3)
Chromaturia	1 (0.9)	0
Dysuria	3 (2.6)	1 (0.9)
Haematuria	1 (0.9)	1 (0.9)
Micturition urgency	1 (0.9)	0
Neurogenic bladder	0	1 (0.9)
Proteinuria	2 (1.7)	2 (1.9)
Renal failure	0	1 (0.9)
Renal impairment	0	1 (0.9)
Strangury	1 (0.9)	0
Ureteric dilatation	0	1 (0.9)
Urinary hesitation	1 (0.9)	0
Urinary incontinence	5 (4.3)	3 (2.8)
Urinary retention	1 (0.9)	2 (1.9)
Urinary tract obstruction	0	1 (0.9)
Urinary tract pain	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort. Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 24 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Reproductive system and breast disorders	9 (7.8)	2 (1.9)
Benign prostatic hyperplasia	2 (1.7)	0
Breast enlargement	0	1 (0.9)
Breast mass	1 (0.9)	0
Dysmenorrhoea	1 (0.9)	0
Genital haemorrhage	1 (0.9)	0
Heavy menstrual bleeding	1 (0.9)	0
Intermenstrual bleeding	2 (1.7)	0
Menopausal symptoms	0	1 (0.9)
Testicular atrophy	1 (0.9)	0
Vaginal discharge	1 (0.9)	0
Vaginal haemorrhage	1 (0.9)	0
Respiratory, thoracic and mediastinal disorders	65 (56.0)	66 (62.3)
Acute respiratory failure	1 (0.9)	1 (0.9)
Asphyxia	0	1 (0.9)
Aspiration	1 (0.9)	0
Asthma	1 (0.9)	2 (1.9)
Atelectasis	1 (0.9)	0
Chronic obstructive pulmonary disease	2 (1.7)	1 (0.9)
Cough	23 (19.8)	19 (17.9)
Dysphonia	5 (4.3)	3 (2.8)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent
Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug
are considered treatment emergent.System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms
are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 25 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Dyspnoea	37 (31.9)	31 (29.2)
Dyspnoea exertional	3 (2.6)	3 (2.8)
Epistaxis	1 (0.9)	3 (2.8)
Haemoptysis	4 (3.4)	1 (0.9)
Hiccups	1 (0.9)	0
Hypercapnia	1 (0.9)	0
Hypoxia	6 (5.2)	6 (5.7)
Nasal congestion	1 (0.9)	3 (2.8)
Nasal turbinate hypertrophy	0	1 (0.9)
Obstructive sleep apnoea syndrome	1 (0.9)	0
Oropharyngeal discomfort	0	1 (0.9)
Oropharyngeal pain	4 (3.4)	3 (2.8)
Orthopnoea	1 (0.9)	0
Pharyngeal oedema	0	1 (0.9)
Pharyngeal swelling	0	1 (0.9)
Pleural effusion	8 (6.9)	9 (8.5)
Pleuritic pain	0	1 (0.9)
Pneumonitis	5 (4.3)	4 (3.8)
Productive cough	8 (6.9)	5 (4.7)
Pulmonary arterial hypertension	1 (0.9)	1 (0.9)
Pulmonary embolism	9 (7.8)	6 (5.7)
Pulmonary granuloma	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 26 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Pulmonary hypertension	0	1 (0.9)
Pulmonary pain	0	1 (0.9)
Pulmonary toxicity	1 (0.9)	0
Rales	1 (0.9)	0
Respiratory acidosis	0	1 (0.9)
Respiratory failure	2 (1.7)	1 (0.9)
Rhinitis allergic	0	2 (1.9)
Rhinorrhoea	1 (0.9)	3 (2.8)
Sleep apnoea syndrome	2 (1.7)	1 (0.9)
Sneezing	1 (0.9)	0
Tachypnoea	4 (3.4)	1 (0.9)
Throat irritation	1 (0.9)	0
Upper-airway cough syndrome	1 (0.9)	1 (0.9)
Wheezing	3 (2.6)	3 (2.8)
Skin and subcutaneous tissue disorders	29 (25.0)	28 (26.4)
Acne	1 (0.9)	1 (0.9)
Alopecia	0	4 (3.8)
Angioedema	0	1 (0.9)
Blister	0	1 (0.9)
Decubitus ulcer	0	1 (0.9)
Dermatitis acneiform	0	2 (1.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 27 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Dermatitis allergic	1 (0.9)	1 (0.9)
Dermatitis contact	1 (0.9)	0
Dry skin	3 (2.6)	5 (4.7)
Ecchymosis	1 (0.9)	0
Erosive pustular dermatosis	0	1 (0.9)
Erythema	1 (0.9)	1 (0.9)
Hyperhidrosis	0	1 (0.9)
Hyperkeratosis	1 (0.9)	1 (0.9)
Nail discolouration	0	1 (0.9)
Nail dystrophy	1 (0.9)	0
Pain of skin	5 (4.3)	2 (1.9)
Palmar-plantar erythrodysaesthesia syndrome	1 (0.9)	1 (0.9)
Photosensitivity reaction	1 (0.9)	0
Pruritus	6 (5.2)	2 (1.9)
Psoriasis	1 (0.9)	0
Rash	5 (4.3)	5 (4.7)
Rash erythematous	0	1 (0.9)
Rash maculo-papular	1 (0.9)	0
Scab	1 (0.9)	0
Skin burning sensation	1 (0.9)	1 (0.9)
Skin discomfort	1 (0.9)	0
Skin exfoliation	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 28 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Skin fissures	1 (0.9)	0
Skin hyperpigmentation	0	1 (0.9)
Skin lesion	1 (0.9)	1 (0.9)
Skin tightness	1 (0.9)	0
Urticaria	1 (0.9)	1 (0.9)
Surgical and medical procedures	1 (0.9)	0
Therapeutic hypothermia	1 (0.9)	0
Vascular disorders	18 (15.5)	20 (18.9)
Deep vein thrombosis	0	2 (1.9)
Embolism	0	1 (0.9)
Embolism venous	1 (0.9)	0
Flushing	3 (2.6)	1 (0.9)
Haemorrhage	0	1 (0.9)
Hot flush	2 (1.7)	1 (0.9)
Hypertension	3 (2.6)	5 (4.7)
Hypotension	7 (6.0)	4 (3.8)
Lymphoedema	0	1 (0.9)
Orthostatic hypotension	4 (3.4)	3 (2.8)
Phlebitis	1 (0.9)	0
Superficial vein thrombosis	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsoptsaf-ebr2365.sas

29MAY2024:01:07:41

Ergänzende Analysen

Protocol: TPX-0005-01

Page 29 of 29

Table S.5.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

System Organ Class (%) Preferred Term (%)	TKI-naïve subjects (N = 116)	TKI-pretreated subjects (N = 106)
Superior vena cava syndrome	0	1 (0.9)
Thrombosis	0	1 (0.9)
Vasoconstriction	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent

Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency. Program Path:

/projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocptsaf-ebr2365.sas

29MAY2024:01:07:41

Anhang 4-G 3.2.2: Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE) auf SOC/PT-Ebene

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
SUBJECTS WITH ANY SEVERE TEAE	74 (63.8)	51 (48.1)
Blood and lymphatic system disorders	7 (6.0)	7 (6.6)
Anaemia	5 (4.3)	6 (5.7)
Lymphocytosis	0	1 (0.9)
Lymphopenia	0	1 (0.9)
Neutropenia	1 (0.9)	0
Thrombocytopenia	1 (0.9)	0
Cardiac disorders	7 (6.0)	4 (3.8)
Acute myocardial infarction	1 (0.9)	0
Cardiac arrest	1 (0.9)	1 (0.9)
Cardiac tamponade	0	1 (0.9)
Endocarditis noninfective	1 (0.9)	0
Pericardial effusion	5 (4.3)	1 (0.9)
Pericarditis	0	1 (0.9)
Eye disorders	0	1 (0.9)
Periorbital oedema	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Gastrointestinal disorders	5 (4.3)	3 (2.8)
Abdominal pain	1 (0.9)	0
Colitis	1 (0.9)	0
Diarrhoea	1 (0.9)	0
Dysphagia	1 (0.9)	0
Gastritis	0	1 (0.9)
Nausea	0	3 (2.8)
Vomiting	1 (0.9)	0
General disorders and administration site conditions	6 (5.2)	3 (2.8)
Death	3 (2.6)	1 (0.9)
Fatigue	2 (1.7)	0
Gait disturbance	0	1 (0.9)
Generalised oedema	1 (0.9)	0
Sudden death	0	1 (0.9)
Hepatobiliary disorders	3 (2.6)	0
Hepatic cytolysis	1 (0.9)	0
Hepatic function abnormal	1 (0.9)	0
Hepatic pain	1 (0.9)	0
Immune system disorders	1 (0.9)	0
Haemophagocytic lymphohistiocytosis	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Infections and infestations	17 (14.7)	10 (9.4)
Appendicitis	1 (0.9)	0
COVID-19	2 (1.7)	2 (1.9)
COVID-19 pneumonia	1 (0.9)	0
Cytomegalovirus infection	1 (0.9)	0
Device related infection	1 (0.9)	0
Enteritis infectious	1 (0.9)	0
Intervertebral discitis	1 (0.9)	1 (0.9)
Lower respiratory tract infection	1 (0.9)	0
Lower respiratory tract infection bacterial	0	1 (0.9)
Lymphangitis	0	1 (0.9)
Pelvic abscess	1 (0.9)	0
Pelvic infection	1 (0.9)	0
Peritonitis	1 (0.9)	0
Pneumonia	7 (6.0)	2 (1.9)
Pneumonia aspiration	0	2 (1.9)
Pneumonia bacterial	0	1 (0.9)
Pneumonia viral	1 (0.9)	0
Respiratory tract infection	1 (0.9)	0
Sepsis	2 (1.7)	0
Upper respiratory tract infection	0	1 (0.9)
Urinary tract infection	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Injury, poisoning and procedural complications	5 (4.3)	1 (0.9)
Fall	2 (1.7)	0
Femur fracture	1 (0.9)	0
Muscle injury	0	1 (0.9)
Muscle rupture	1 (0.9)	0
Spinal compression fracture	1 (0.9)	0
Investigations	31 (26.7)	8 (7.5)
Alanine aminotransferase increased	4 (3.4)	1 (0.9)
Aspartate aminotransferase increased	4 (3.4)	0
Blood alkaline phosphatase increased	1 (0.9)	0
Blood cholesterol increased	1 (0.9)	1 (0.9)
Blood creatine phosphokinase increased	9 (7.8)	3 (2.8)
Blood methaemoglobin present	1 (0.9)	0
Ejection fraction decreased	1 (0.9)	0
Gamma-glutamyltransferase increased	2 (1.7)	1 (0.9)
Haemoglobin decreased	1 (0.9)	0
Lymphocyte count decreased	1 (0.9)	0
Neutrophil count decreased	5 (4.3)	1 (0.9)
Platelet count increased	1 (0.9)	0
Weight increased	8 (6.9)	3 (2.8)
White blood cell count decreased	2 (1.7)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Metabolism and nutrition disorders	4 (3.4)	5 (4.7)
Acidosis	1 (0.9)	0
Decreased appetite	0	1 (0.9)
Hypercholesterolaemia	1 (0.9)	0
Hypermagnesaemia	0	1 (0.9)
Hypertriglyceridaemia	2 (1.7)	0
Hypoalbuminaemia	0	1 (0.9)
Hypokalaemia	0	1 (0.9)
Hyponatraemia	1 (0.9)	0
Hypophosphataemia	0	2 (1.9)
Musculoskeletal and connective tissue disorders	8 (6.9)	6 (5.7)
Arthralgia	1 (0.9)	0
Back pain	0	1 (0.9)
Intervertebral disc protrusion	1 (0.9)	0
Muscular weakness	3 (2.6)	2 (1.9)
Myalgia	1 (0.9)	0
Myopathy	0	1 (0.9)
Osteonecrosis	0	1 (0.9)
Spinal ligament ossification	1 (0.9)	0
Spinal osteoarthritis	0	1 (0.9)
Synovial cyst	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.7)	0
Paraneoplastic syndrome	1 (0.9)	0
Tumour associated fever	1 (0.9)	0
Nervous system disorders	13 (11.2)	17 (16.0)
Altered state of consciousness	0	1 (0.9)
Ataxia	1 (0.9)	1 (0.9)
Cerebral infarction	1 (0.9)	0
Depressed level of consciousness	0	1 (0.9)
Dizziness	2 (1.7)	4 (3.8)
Embolic stroke	1 (0.9)	0
Head discomfort	0	1 (0.9)
Hydrocephalus	0	1 (0.9)
Hypoaesthesia	1 (0.9)	0
Hypoxic-ischaemic encephalopathy	1 (0.9)	0
Neuralgia	0	1 (0.9)
Neuropathy peripheral	0	1 (0.9)
Paraesthesia	2 (1.7)	0
Peripheral motor neuropathy	0	1 (0.9)
Peripheral sensory neuropathy	0	1 (0.9)
Seizure	0	1 (0.9)
Syncope	3 (2.6)	4 (3.8)
Transient ischaemic attack	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Product issues	0	1 (0.9)
Device occlusion	0	1 (0.9)
Psychiatric disorders	1 (0.9)	1 (0.9)
Confusional state	0	1 (0.9)
Mania	1 (0.9)	0
Renal and urinary disorders	0	3 (2.8)
Renal failure	0	1 (0.9)
Urinary retention	0	2 (1.9)
Urinary tract obstruction	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 8 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Respiratory, thoracic and mediastinal disorders	20 (17.2)	18 (17.0)
Acute respiratory failure	1 (0.9)	1 (0.9)
Asphyxia	0	1 (0.9)
Aspiration	1 (0.9)	0
Asthma	0	1 (0.9)
Atelectasis	1 (0.9)	0
Chronic obstructive pulmonary disease	2 (1.7)	0
Dyspnoea	4 (3.4)	6 (5.7)
Hypercapnia	1 (0.9)	0
Hypoxia	2 (1.7)	4 (3.8)
Pharyngeal oedema	0	1 (0.9)
Pleural effusion	2 (1.7)	5 (4.7)
Pneumonitis	3 (2.6)	0
Pulmonary embolism	6 (5.2)	4 (3.8)
Respiratory acidosis	0	1 (0.9)
Respiratory failure	2 (1.7)	1 (0.9)
Skin and subcutaneous tissue disorders	0	2 (1.9)
Decubitus ulcer	0	1 (0.9)
Urticaria	0	1 (0.9)
Surgical and medical procedures	1 (0.9)	0
Therapeutic hypothermia	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Ergänzende Analysen

Protocol: TPX-0005-01

Page 9 of 9

Table S.7.1
Severe Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Vascular disorders	0	1 (0.9)
Superior vena cava syndrome	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. Severe TEAE are TEAE CTCAE Grade ≥3.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms

are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:29

Anhang 4-G 3.2.3: Schwerwiegende UE auf SOC/PT-Ebene

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 7

Table S.8.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
SUBJECTS WITH ANY SERIOUS TEAE	51 (44.0)	37 (34.9)
Blood and lymphatic system disorders	2 (1.7)	2 (1.9)
Anaemia	1 (0.9)	2 (1.9)
Thrombocytopenia	1 (0.9)	0
Cardiac disorders	5 (4.3)	3 (2.8)
Acute myocardial infarction	1 (0.9)	0
Cardiac arrest	1 (0.9)	1 (0.9)
Cardiac tamponade	0	1 (0.9)
Endocarditis noninfective	1 (0.9)	0
Pericardial effusion	3 (2.6)	1 (0.9)
Endocrine disorders	0	1 (0.9)
Adrenal insufficiency	0	1 (0.9)
Gastrointestinal disorders	2 (1.7)	1 (0.9)
Abdominal pain	1 (0.9)	0
Colitis	1 (0.9)	0
Nausea	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 7

Table S.8.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
General disorders and administration site conditions	5 (4.3)	3 (2.8)
Asthenia	1 (0.9)	0
Death	3 (2.6)	1 (0.9)
Oedema peripheral	0	1 (0.9)
Pyrexia	1 (0.9)	0
Sudden death	0	1 (0.9)
Hepatobiliary disorders	1 (0.9)	0
Hepatic pain	1 (0.9)	0
Immune system disorders	1 (0.9)	0
Haemophagocytic lymphohistiocytosis	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 7

Table S.8.1
 Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
 Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Infections and infestations	15 (12.9)	13 (12.3)
Appendicitis	1 (0.9)	0
COVID-19	2 (1.7)	3 (2.8)
COVID-19 pneumonia	1 (0.9)	0
Cytomegalovirus infection	1 (0.9)	0
Device related infection	1 (0.9)	0
Erysipelas	0	1 (0.9)
Intervertebral discitis	0	1 (0.9)
Lower respiratory tract infection	1 (0.9)	0
Lower respiratory tract infection bacterial	0	1 (0.9)
Lymphangitis	0	1 (0.9)
Pelvic abscess	1 (0.9)	0
Pelvic infection	1 (0.9)	0
Peritonitis	1 (0.9)	0
Pneumonia	6 (5.2)	3 (2.8)
Pneumonia aspiration	0	2 (1.9)
Pneumonia bacterial	0	1 (0.9)
Pneumonia viral	1 (0.9)	0
Sepsis	2 (1.7)	0
Staphylococcal infection	1 (0.9)	0
Upper respiratory tract infection	1 (0.9)	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 7

Table S.8.1
 Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
 Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Injury, poisoning and procedural complications	4 (3.4)	2 (1.9)
Ankle fracture	1 (0.9)	0
Fall	1 (0.9)	1 (0.9)
Femur fracture	1 (0.9)	0
Procedural pneumothorax	0	1 (0.9)
Rib fracture	1 (0.9)	0
Spinal compression fracture	1 (0.9)	0
Investigations	1 (0.9)	0
Blood creatine phosphokinase increased	1 (0.9)	0
Metabolism and nutrition disorders	1 (0.9)	1 (0.9)
Decreased appetite	0	1 (0.9)
Hyponatraemia	1 (0.9)	0
Musculoskeletal and connective tissue disorders	4 (3.4)	2 (1.9)
Back pain	0	1 (0.9)
Intervertebral disc protrusion	1 (0.9)	0
Muscular weakness	1 (0.9)	0
Spinal ligament ossification	1 (0.9)	0
Spinal osteoarthritis	0	1 (0.9)
Synovial cyst	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 7

Table S.8.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (2.6)	0
Intraductal proliferative breast lesion	1 (0.9)	0
Paraneoplastic syndrome	1 (0.9)	0
Tumour associated fever	1 (0.9)	0
Nervous system disorders	5 (4.3)	10 (9.4)
Altered state of consciousness	0	1 (0.9)
Ataxia	2 (1.7)	0
Cerebral infarction	1 (0.9)	0
Dizziness	0	2 (1.9)
Embolic stroke	1 (0.9)	0
Hydrocephalus	0	1 (0.9)
Monoparesis	0	1 (0.9)
Peripheral motor neuropathy	0	1 (0.9)
Seizure	0	2 (1.9)
Syncope	0	2 (1.9)
Transient ischaemic attack	1 (0.9)	0
Product issues	0	1 (0.9)
Device occlusion	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 7

Table S.8.1
 Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
 Safety Set for ROS1+

SOC PT	EXP-1 TKI-naive subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Psychiatric disorders	1 (0.9)	1 (0.9)
Confusional state	0	1 (0.9)
Mania	1 (0.9)	0
Renal and urinary disorders	0	2 (1.9)
Renal failure	0	1 (0.9)
Urinary retention	0	1 (0.9)
Urinary tract obstruction	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 7

Table S.8.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116	EXP-4 TKI-pretreated subjects N = 106
Respiratory, thoracic and mediastinal disorders	17 (14.7)	15 (14.2)
Acute respiratory failure	1 (0.9)	0
Asphyxia	0	1 (0.9)
Aspiration	1 (0.9)	0
Asthma	0	1 (0.9)
Chronic obstructive pulmonary disease	2 (1.7)	0
Dyspnoea	2 (1.7)	4 (3.8)
Hypoxia	3 (2.6)	2 (1.9)
Pharyngeal oedema	0	1 (0.9)
Pleural effusion	2 (1.7)	6 (5.7)
Pneumonitis	4 (3.4)	0
Pulmonary embolism	3 (2.6)	2 (1.9)
Respiratory acidosis	0	1 (0.9)
Respiratory failure	2 (1.7)	1 (0.9)
Wheezing	1 (0.9)	0
Vascular disorders	0	2 (1.9)
Hypotension	0	1 (0.9)
Superior vena cava syndrome	0	1 (0.9)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

System Organ Classes are sorted alphabetically, and then within each System Organ Class, Preferred Terms are sorted alphabetically as well.

All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocpt-ebr2365-b2.sas

20JUN2024:04:33:18

Anhang 4-G 3.2.4: Zum Therapieabbruch führende UE auf SOC/PT-Ebene

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table S.9.1
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class, Preferred Term and Grade
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116			EXP-4 TKI-pretreated subjects N = 106		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
SUBJECTS WITH ANY EVENT	17 (14.7)	6 (5.2)	5 (4.3)	12 (11.3)	8 (7.5)	1 (0.9)
Cardiac disorders	3 (2.6)	1 (0.9)	2 (1.7)	1 (0.9)	1 (0.9)	0
Acute myocardial infarction	1 (0.9)	0	1 (0.9)	0	0	0
Cardiac arrest	1 (0.9)	0	1 (0.9)	0	0	0
Cardiac septal hypertrophy	1 (0.9)	0	0	0	0	0
Pericardial effusion	1 (0.9)	1 (0.9)	0	0	0	0
Pericarditis	0	0	0	1 (0.9)	1 (0.9)	0
Congenital, familial and genetic disorders	1 (0.9)	0	0	0	0	0
Colour blindness	1 (0.9)	0	0	0	0	0
General disorders and administration site conditions	1 (0.9)	0	1 (0.9)	1 (0.9)	0	1 (0.9)
Death	1 (0.9)	0	1 (0.9)	1 (0.9)	0	1 (0.9)
Hepatobiliary disorders	1 (0.9)	1 (0.9)	0	0	0	0
Hepatic pain	1 (0.9)	1 (0.9)	0	0	0	0
Infections and infestations	1 (0.9)	1 (0.9)	0	0	0	0
Lower respiratory tract infection	1 (0.9)	1 (0.9)	0	0	0	0
Injury, poisoning and procedural complications	1 (0.9)	0	1 (0.9)	0	0	0
Femur fracture	1 (0.9)	0	1 (0.9)	0	0	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug

are considered treatment emergent. If a subject reported one or more adverse events, the subject is counted

only once at each level reported based on the maximum grade reported for each coded term.

System Organ Classes are sorted alphabetically, and within each System Organ Class, Preferred Terms are sorted

alphabetically as well. All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocptgr12d-ebr2365-b2.sas

20JUN2024:04:34:07

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table S.9.1
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
by System Organ Class, Preferred Term and Grade
Safety Set for ROS1+

SOC PT	EXP-1 TKI-naïve subjects N = 116			EXP-4 TKI-pretreated subjects N = 106		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
Investigations	1 (0.9)	1 (0.9)	0	0	0	0
Neutrophil count decreased	1 (0.9)	1 (0.9)	0	0	0	0
Musculoskeletal and connective tissue disorders	3 (2.6)	1 (0.9)	0	0	0	0
Muscular weakness	3 (2.6)	1 (0.9)	0	0	0	0
Nervous system disorders	0	0	0	5 (4.7)	3 (2.8)	0
Balance disorder	0	0	0	1 (0.9)	0	0
Depressed level of consciousness	0	0	0	1 (0.9)	1 (0.9)	0
Head discomfort	0	0	0	1 (0.9)	1 (0.9)	0
Peripheral motor neuropathy	0	0	0	1 (0.9)	0	0
Syncope	0	0	0	1 (0.9)	1 (0.9)	0
Respiratory, thoracic and mediastinal disorders	6 (5.2)	2 (1.7)	1 (0.9)	4 (3.8)	3 (2.8)	0
Dyspnoea	1 (0.9)	0	0	2 (1.9)	2 (1.9)	0
Hypoxia	1 (0.9)	0	1 (0.9)	0	0	0
Pleural effusion	1 (0.9)	1 (0.9)	0	1 (0.9)	1 (0.9)	0
Pneumonitis	3 (2.6)	1 (0.9)	0	1 (0.9)	0	0
Vascular disorders	0	0	0	1 (0.9)	1 (0.9)	0
Superior vena cava syndrome	0	0	0	1 (0.9)	1 (0.9)	0

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the corresponding cohort.

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent. If a subject reported one or more adverse events, the subject is counted only once at each level reported based on the maximum grade reported for each coded term.

System Organ Classes are sorted alphabetically, and within each System Organ Class, Preferred Terms are sorted alphabetically as well. All System Organ Classes and Preferred Terms are included, irrespective of their frequency.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sumsocptgrl2d-ebr2365-b2.sas

20JUN2024:04:34:07

Anhang 4-G 4: Subgruppenanalysen

Anhang 4-G 4.1: Endpunkt Mortalität – Gesamtüberleben (OS)

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table E.10.1
Overall Survival
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	Median (1) (95% CI) (2) (months)	N	Events n (%)	Median (1) (95% CI) (2) (months)
AGE (YEARS)						
>= 12 TO < 18	0	0	N.M.E.	0	0	N.M.E.
>= 18 TO < 65	90	23 (25.6)	44.42 (N.A., N.A.)	75	31 (41.3)	26.38 (15.15, N.A.)
>= 65 TO < 75	20	4 (20.0)	N.M.E.	22	9 (40.9)	N.M.E.
>= 75	6	4 (66.7)	N.M.E.	9	4 (44.4)	N.M.E.
SEX						
MALE	51	14 (27.5)	N.A. (37.32, N.A.)	28	13 (46.4)	17.77 (9.03, N.A.)
FEMALE	65	17 (26.2)	44.42 (31.61, N.A.)	78	31 (39.7)	26.38 (17.87, N.A.)
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	2	0	N.M.E.	0	0	N.M.E.
ASIAN	68	18 (26.5)	N.A. (31.61, N.A.)	45	12 (26.7)	31.38 (26.38, N.A.)
WHITE	36	12 (33.3)	44.42 (22.60, N.A.)	51	25 (49.0)	17.87 (12.81, N.A.)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	0	N.M.E.	2	2 (100.0)	N.M.E.
BLACK OR AFRICAN AMERICAN	3	0	N.M.E.	4	4 (100.0)	N.M.E.
OTHER	0	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	6	1 (16.7)	N.M.E.	4	1 (25.0)	N.M.E.
REGION						
US	18	4 (22.2)	N.M.E.	25	13 (52.0)	25.13 (14.98, N.A.)
ASIA	58	14 (24.1)	N.A. (31.61, N.A.)	37	10 (27.0)	N.A. (15.84, N.A.)
OTHER	40	13 (32.5)	N.A. (20.11, N.A.)	44	21 (47.7)	19.35 (12.88, 31.38)
ECOG PERFORMANCE STATUS						
0	44	5 (11.4)	N.M.E.	36	11 (30.6)	55.66 (27.43, N.A.)
1	72	26 (36.1)	37.32 (24.71, N.A.)	70	33 (47.1)	19.35 (14.55, 31.38)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Overall survival (OS) is defined as the time from the first dose of repotrectinib to the date of death due to any cause + 1 day.

(1) Median computed using Kaplan-Meier method.

(2) 95% CIs are based on Kaplan-Meier methodology using the Greenwood variance estimate.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ef-ossafros-ebr2365-b4.sas

28AUG2024:07:28:56

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table E.10.1
Overall Survival
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naïve subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	Median (1) (95% CI) (2) (months)	N	Events n (%)	Median (1) (95% CI) (2) (months)
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	11	4 (36.4)	N.M.E.
NO	116	31 (26.7)	44.42 (37.32, N.A.)	95	40 (42.1)	26.38 (15.84, N.A.)
BRAIN METASTASIS BY INVESTIGATOR						
YES	33	13 (39.4)	31.61 (21.19, N.A.)	50	22 (44.0)	25.13 (15.15, N.A.)
NO	83	18 (21.7)	44.42 (N.A., N.A.)	56	22 (39.3)	27.43 (14.65, N.A.)
BRAIN METASTASIS BY BICR						
YES	28	9 (32.1)	N.M.E.	43	20 (46.5)	18.04 (11.07, N.A.)
NO	88	22 (25.0)	44.42 (37.32, N.A.)	63	24 (38.1)	27.43 (17.87, N.A.)
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	21	10 (47.6)	19.35 (12.81, N.A.)
NO	116	31 (26.7)	44.42 (37.32, N.A.)	85	34 (40.0)	26.38 (15.84, N.A.)
ANY PRIOR TREATMENT WITH CRIZOTINIB						
YES	0	0	N.M.E.	82	34 (41.5)	25.13 (15.15, N.A.)
NO	116	31 (26.7)	44.42 (37.32, N.A.)	24	10 (41.7)	31.38 (14.65, N.A.)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Overall survival (OS) is defined as the time from the first dose of repotrectinib to the date of death due to any cause + 1 day.

(1) Median computed using Kaplan-Meier method.

(2) 95% CIs are based on Kaplan-Meier methodology using the Greenwood variance estimate.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ef-ossafros-ebr2365-b4.sas

28AUG2024:07:28:56

Anhang 4-G 4.2: Endpunkte Verträglichkeit

Anhang 4-G 4.2.1: Schwere UE (UE mit einem Schweregrad von ≥ 3 nach CTCAE)

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table S.11.1
Severe Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naïve subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
AGE (YEARS)						
>= 18 TO < 65	90	59 (65.6)	54.8, 75.3	75	33 (44.0)	32.5, 55.9
>= 65 TO < 75	20	10 (50.0)	27.2, 72.8	22	14 (63.6)	40.7, 82.8
>= 75	6	5 (83.3)	N.M.E.	9	4 (44.4)	N.M.E.
SEX						
MALE	51	39 (76.5)	62.5, 87.2	28	16 (57.1)	37.2, 75.5
FEMALE	65	35 (53.8)	41.0, 66.3	78	35 (44.9)	33.6, 56.6
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	2	1 (50.0)	N.M.E.	0	0	N.M.E.
ASIAN	68	42 (61.8)	49.2, 73.3	45	18 (40.0)	25.7, 55.7
WHITE	36	24 (66.7)	49.0, 81.4	51	26 (51.0)	36.6, 65.2
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	1 (100.0)	N.M.E.	2	2 (100.0)	N.M.E.
BLACK OR AFRICAN AMERICAN	3	3 (100.0)	N.M.E.	4	2 (50.0)	N.M.E.
OTHER	0	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	6	3 (50.0)	N.M.E.	4	3 (75.0)	N.M.E.
REGION						
US	18	12 (66.7)	41.0, 86.7	25	10 (40.0)	21.1, 61.3
ASIA	58	33 (56.9)	43.2, 69.8	37	15 (40.5)	24.8, 57.9
OTHER	40	29 (72.5)	56.1, 85.4	44	26 (59.1)	43.2, 73.7

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Severe TEAE are TEAE CTCAE Grade ≥3.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:50:50

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table S.11.1
Severe Treatment-Emergent Adverse Events
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naïve subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	44	26 (59.1)	43.2, 73.7	36	14 (38.9)	23.1, 56.5
1	72	48 (66.7)	54.6, 77.3	70	37 (52.9)	40.6, 64.9
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	11	5 (45.5)	N.M.E.
NO	116	74 (63.8)	54.4, 72.5	95	46 (48.4)	38.0, 58.9
BRAIN METASTASIS BY INVESTIGATOR						
YES	33	20 (60.6)	42.1, 77.1	50	25 (50.0)	35.5, 64.5
NO	83	54 (65.1)	53.8, 75.2	56	26 (46.4)	33.0, 60.3
BRAIN METASTASIS BY BICR						
YES	28	18 (64.3)	44.1, 81.4	43	21 (48.8)	33.3, 64.5
NO	88	56 (63.6)	52.7, 73.6	63	30 (47.6)	34.9, 60.6
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	21	12 (57.1)	34.0, 78.2
NO	116	74 (63.8)	54.4, 72.5	85	39 (45.9)	35.0, 57.0
ANY PRIOR TREATMENT WITH CRIZOTINIB						
YES	0	0	N.M.E.	82	38 (46.3)	35.3, 57.7
NO	116	74 (63.8)	54.4, 72.5	24	13 (54.2)	32.8, 74.4

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Abbreviations: TEAE = Treatment-Emergent Adverse Event.

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Severe TEAE are TEAE CTCAE Grade ≥3.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:50:50

Anhang 4-G 4.2.2: Schwerwiegende UE

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table S.12.1
 Serious Treatment-Emergent Adverse Events
 Subgroup Analysis
 Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
AGE (YEARS)						
>= 18 TO < 65	90	38 (42.2)	31.9, 53.1	75	24 (32.0)	21.7, 43.8
>= 65 TO < 75	20	8 (40.0)	N.M.E.	22	7 (31.8)	N.M.E.
>= 75	6	5 (83.3)	N.M.E.	9	6 (66.7)	N.M.E.
SEX						
MALE	51	28 (54.9)	40.3, 68.9	28	12 (42.9)	24.5, 62.8
FEMALE	65	23 (35.4)	23.9, 48.2	78	25 (32.1)	21.9, 43.6
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	2	1 (50.0)	N.M.E.	0	0	N.M.E.
ASIAN	68	25 (36.8)	25.4, 49.3	45	16 (35.6)	21.9, 51.2
WHITE	36	18 (50.0)	32.9, 67.1	51	16 (31.4)	19.1, 45.9
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	1 (100.0)	N.M.E.	2	2 (100.0)	N.M.E.
BLACK OR AFRICAN AMERICAN	3	3 (100.0)	N.M.E.	4	1 (25.0)	N.M.E.
OTHER	0	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	6	3 (50.0)	N.M.E.	4	2 (50.0)	N.M.E.
REGION						
US	18	12 (66.7)	41.0, 86.7	25	8 (32.0)	N.M.E.
ASIA	58	16 (27.6)	16.7, 40.9	37	14 (37.8)	22.5, 55.2
OTHER	40	23 (57.5)	40.9, 73.0	44	15 (34.1)	20.5, 49.9

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:50:57

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table S.12.1
 Serious Treatment-Emergent Adverse Events
 Subgroup Analysis
 Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	44	18 (40.9)	26.3, 56.8	36	7 (19.4)	N.M.E.
1	72	33 (45.8)	34.0, 58.0	70	30 (42.9)	31.1, 55.3
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	11	4 (36.4)	N.M.E.
NO	116	51 (44.0)	34.8, 53.5	95	33 (34.7)	25.3, 45.2
BRAIN METASTASIS BY INVESTIGATOR						
YES	33	13 (39.4)	22.9, 57.9	50	18 (36.0)	22.9, 50.8
NO	83	38 (45.8)	34.8, 57.1	56	19 (33.9)	21.8, 47.8
BRAIN METASTASIS BY BICR						
YES	28	13 (46.4)	27.5, 66.1	43	18 (41.9)	27.0, 57.9
NO	88	38 (43.2)	32.7, 54.2	63	19 (30.2)	19.2, 43.0
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	21	10 (47.6)	25.7, 70.2
NO	116	51 (44.0)	34.8, 53.5	85	27 (31.8)	22.1, 42.8
ANY PRIOR TREATMENT WITH CRIZOTINIB						
YES	0	0	N.M.E.	82	26 (31.7)	21.9, 42.9
NO	116	51 (44.0)	34.8, 53.5	24	11 (45.8)	25.6, 67.2

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:50:57

Table S.11.1

Anhang 4-G 4.2.3: Zum Therapieabbruch führende UE

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table S.13.1
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
AGE (YEARS)						
>= 18 TO < 65	90	10 (11.1)	5.5, 19.5	75	8 (10.7)	N.M.E.
>= 65 TO < 75	20	5 (25.0)	N.M.E.	22	2 (9.1)	N.M.E.
>= 75	6	2 (33.3)	N.M.E.	9	2 (22.2)	N.M.E.
SEX						
MALE	51	10 (19.6)	9.8, 33.1	28	3 (10.7)	N.M.E.
FEMALE	65	7 (10.8)	N.M.E.	78	9 (11.5)	N.M.E.
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	2	1 (50.0)	N.M.E.	0	0	N.M.E.
ASIAN	68	8 (11.8)	N.M.E.	45	3 (6.7)	N.M.E.
WHITE	36	7 (19.4)	N.M.E.	51	7 (13.7)	N.M.E.
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	0	N.M.E.	2	2 (100.0)	N.M.E.
BLACK OR AFRICAN AMERICAN	3	1 (33.3)	N.M.E.	4	0	N.M.E.
OTHER	0	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	6	0	N.M.E.	4	0	N.M.E.
REGION						
US	18	4 (22.2)	N.M.E.	25	4 (16.0)	N.M.E.
ASIA	58	5 (8.6)	N.M.E.	37	3 (8.1)	N.M.E.
OTHER	40	8 (20.0)	N.M.E.	44	5 (11.4)	N.M.E.

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

Protocol: TPX-0005-01

28AUG2024:08:51:04

Page 2 of 2

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table S.13.1
Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	44	6 (13.6)	N.M.E.	36	3 (8.3)	N.M.E.
1	72	11 (15.3)	7.9, 25.7	70	9 (12.9)	N.M.E.
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	11	2 (18.2)	N.M.E.
NO	116	17 (14.7)	8.8, 22.4	95	10 (10.5)	5.2, 18.5
BRAIN METASTASIS BY INVESTIGATOR						
YES	33	4 (12.1)	N.M.E.	50	6 (12.0)	N.M.E.
NO	83	13 (15.7)	8.6, 25.3	56	6 (10.7)	N.M.E.
BRAIN METASTASIS BY BICR						
YES	28	5 (17.9)	N.M.E.	43	5 (11.6)	N.M.E.
NO	88	12 (13.6)	7.2, 22.6	63	7 (11.1)	N.M.E.
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	21	2 (9.5)	N.M.E.
NO	116	17 (14.7)	8.8, 22.4	85	10 (11.8)	5.8, 20.6
ANY PRIOR TREATMENT WITH CRIZOTINIB						
YES	0	0	N.M.E.	82	10 (12.2)	6.0, 21.3
NO	116	17 (14.7)	8.8, 22.4	24	2 (8.3)	N.M.E.

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:51:04

Anhang 4-G 4.2.4: Jegliche UESI

Ergänzende Analysen

Protocol: TPX-0005-01

Page 1 of 2

Table S.14.1
Treatment-Emergent Adverse Events of Special Interest
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
AGE (YEARS)						
>= 18 TO < 65	90	88 (97.8)	92.2, 99.7	75	69 (92.0)	83.4, 97.0
>= 65 TO < 75	20	20 (100.0)	83.2,100.0	22	20 (90.9)	70.8, 98.9
>= 75	6	6 (100.0)	N.M.E.	9	9 (100.0)	N.M.E.
SEX						
MALE	51	51 (100.0)	93.0,100.0	28	24 (85.7)	67.3, 96.0
FEMALE	65	63 (96.9)	89.3, 99.6	78	74 (94.9)	87.4, 98.6
RACE						
AMERICAN INDIAN OR ALASKAN NATIVE	2	2 (100.0)	N.M.E.	0	0	N.M.E.
ASIAN	68	66 (97.1)	89.8, 99.6	45	41 (91.1)	78.8, 97.5
WHITE	36	36 (100.0)	90.3,100.0	51	47 (92.2)	81.1, 97.8
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	1 (100.0)	N.M.E.	2	2 (100.0)	N.M.E.
BLACK OR AFRICAN AMERICAN	3	3 (100.0)	N.M.E.	4	4 (100.0)	N.M.E.
OTHER	0	0	N.M.E.	0	0	N.M.E.
NOT REPORTED OR UNKNOWN	6	6 (100.0)	N.M.E.	4	4 (100.0)	N.M.E.
REGION						
US	18	18 (100.0)	81.5,100.0	25	24 (96.0)	79.6, 99.9
ASIA	58	56 (96.6)	88.1, 99.6	37	33 (89.2)	74.6, 97.0
OTHER	40	40 (100.0)	91.2,100.0	44	41 (93.2)	81.3, 98.6

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:51:10

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 2

Table S.14.1
Treatment-Emergent Adverse Events of Special Interest
Subgroup Analysis
Safety Set for ROS1+

Parameter	EXP-1 TKI-naive subjects			EXP-4 TKI-pretreated subjects		
	N	Events n (%)	95% CI	N	Events n (%)	95% CI
ECOG PERFORMANCE STATUS						
0	44	44 (100.0)	92.0, 100.0	36	35 (97.2)	85.5, 99.9
1	72	70 (97.2)	90.3, 99.7	70	63 (90.0)	80.5, 95.9
SOLVENT MUTATION STATUS						
YES	0	0	N.M.E.	11	10 (90.9)	58.7, 99.8
NO	116	114 (98.3)	93.9, 99.8	95	88 (92.6)	85.4, 97.0
BRAIN METASTASIS BY INVESTIGATOR						
YES	33	33 (100.0)	89.4, 100.0	50	47 (94.0)	83.5, 98.7
NO	83	81 (97.6)	91.6, 99.7	56	51 (91.1)	80.4, 97.0
BRAIN METASTASIS BY BICR						
YES	28	27 (96.4)	81.7, 99.9	43	39 (90.7)	77.9, 97.4
NO	88	87 (98.9)	93.8, 100.0	63	59 (93.7)	84.5, 98.2
ANY PRIOR TREATMENT WITH ENTRECTINIB						
YES	0	0	N.M.E.	21	18 (85.7)	63.7, 97.0
NO	116	114 (98.3)	93.9, 99.8	85	80 (94.1)	86.8, 98.1
ANY PRIOR TREATMENT WITH CRIZOTINIB						
YES	0	0	N.M.E.	82	77 (93.9)	86.3, 98.0
NO	116	114 (98.3)	93.9, 99.8	24	21 (87.5)	67.6, 97.3

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Percentages are based on the total number of subjects in the respective subgroup (within the corresponding cohort).

Adverse events were coded using the MedDRA dictionary, Version 25.0.

Adverse events occurring on or after the first dose date through 28 days after last dose of study drug are considered treatment emergent.

Program Path: /pic/projects5/blinded/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

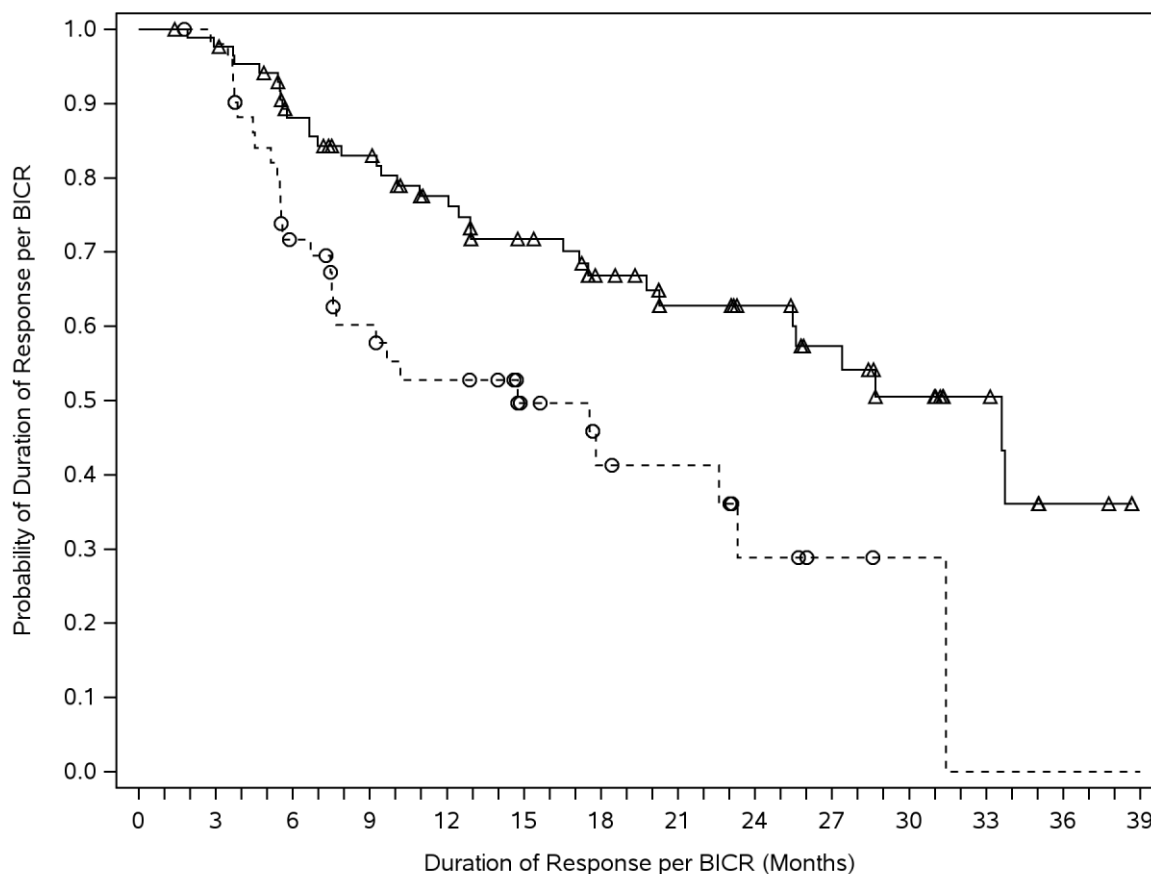
Program Name: rt-ae-sum-ebr2365.sas

28AUG2024:08:51:10

Anhang 4-G 5: Kaplan-Meier-Kurven

Anhang 4-G 5.1: Kaplan-Meier-Kurven für den Endpunkt Dauer des Ansprechens (DOR) gemäß BICR

Figure E.3.1
Kaplan-Meier Plot of Duration of Response per BICR , AMNOG definition - Full Analysis Set for ROS1+ - Subjects with Confirmed Objective Tumor Response (PR or CR)



Number of Subjects at Risk

EXP-1 TKI-naïve subjects

87 84 70 63 54 45 36 28 24 18 13 8 3 0

EXP-4 TKI-pretreated subjects

52 50 33 25 21 14 9 8 4 2 1 0 0 0

—▲— EXP-1 TKI-naïve subjects (events: 33/87), median and 95% CI: 33.61 (25.46, N.A.)

--○-- EXP-4 TKI-pretreated subjects (events: 28/52), median and 95% CI: 14.75 (7.56, 23.33)

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Symbols represent censored observations.

Duration of response (DOR) is only calculated for the subgroup of subjects with a confirmed objective tumor response (PR or CR). CR/PR must be confirmed with a repeat radiological assessment ≥ 4 weeks immediately after first reported CR/PR.

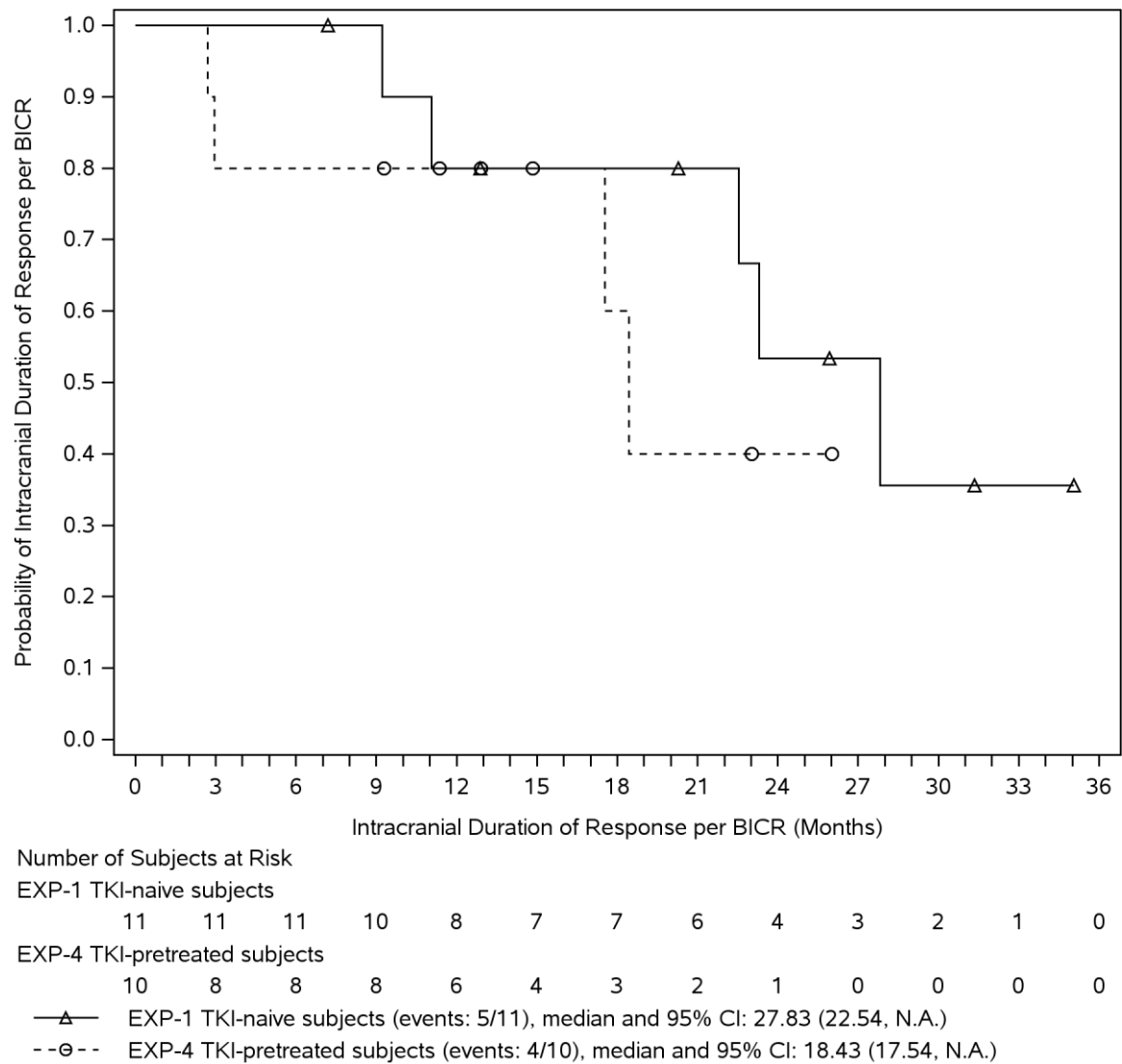
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures

Program Name: rg-ef-kmplot-eb2365.sas

16JUL2024:13:40:47

**Anhang 4-G 5.2: Kaplan-Meier-Kurven für den Endpunkt Dauer des
intrakraniellen Ansprechens (IC-DOR) gemäß BICR**

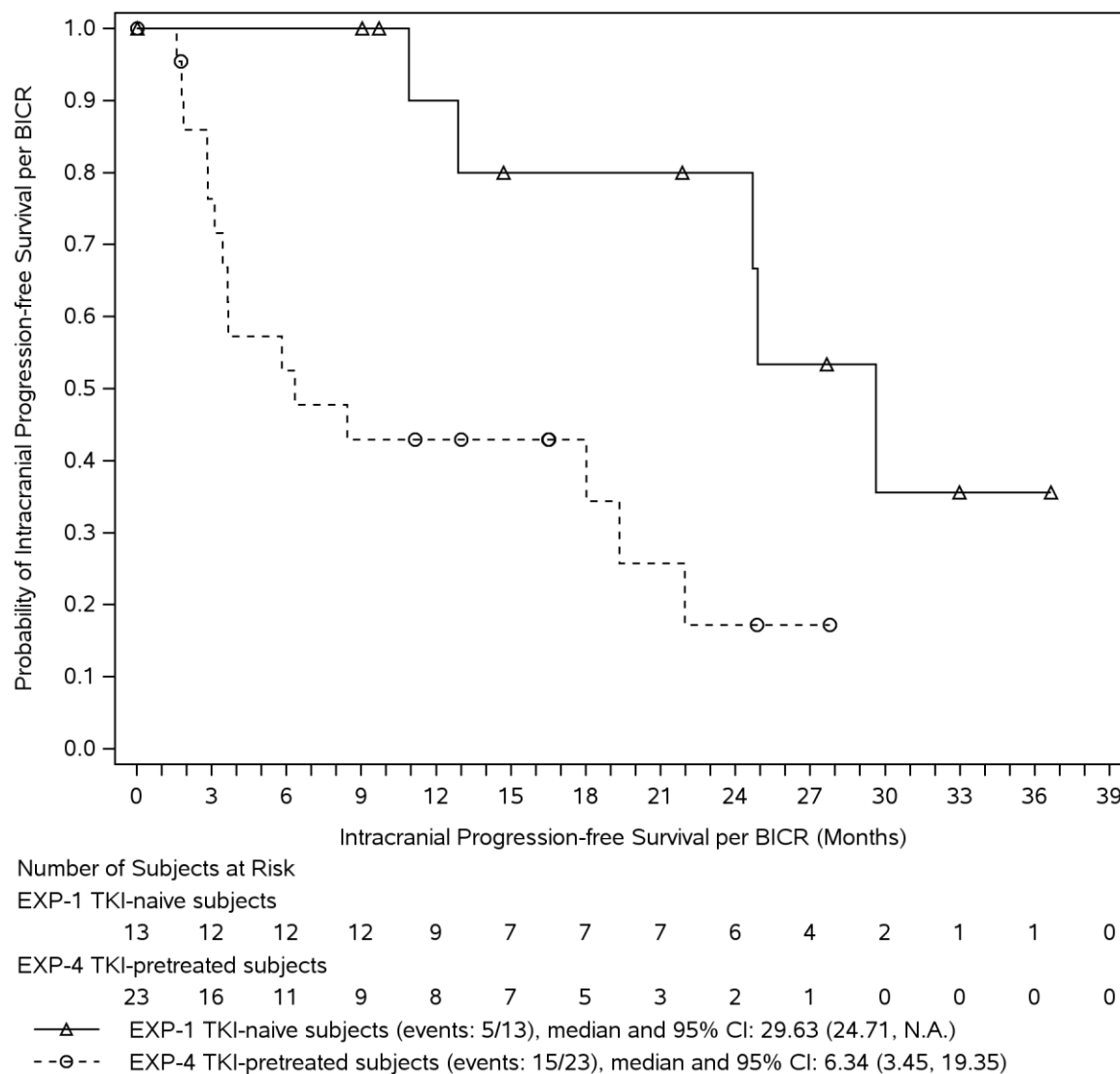
Figure E.4.1
Kaplan-Meier Plot of Intracranial Duration of Response per BICR, AMNOG definition - Full Analysis Set for ROS1+ - Subjects from Phase 2 Portion of the Trial with Measurable Brain Metastasis at Baseline - and Confirmed Objective Tumor Response (PR or CR)



DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023
Symbols represent censored observations.
Duration of intracranial response (IC-DOR) is only calculated for the subgroup of patients in the corresponding cohort of the Phase 2 portion of the trial with measurable baseline brain metastasis per BICR for tumor assessment per modified RECIST v1.1 criteria.
Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures
Program Name: rg-ef-kmplot-ebr2365.sas
16JUL2024:13:41:12

**Anhang 4-G 5.3: Kaplan-Meier-Kurven für den Endpunkt intrakranielles
progressionsfreies Überleben (IC-PFS) gemäß BICR**

Figure E.5.1
Kaplan-Meier Plot of Intracranial Progression-free Survival per BICR, AMNOG definition - Full Analysis Set for ROS1+ -
Subjects from Phase 2 Portion of the Trial with Measurable Brain Metastasis at Baseline



DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Intracranial Progression-free survival (IC-PFS) is only calculated for the subgroup of patients in the corresponding cohort of the Phase 2 portion of the trial with measurable baseline brain metastasis per BICR for tumor assessment per modified RECIST v1.1 criteria.

IC-PFS is defined as the time from the first dose of repotrectinib to first evidence of radiographic intracranial disease progression per modified RECIST v1.1 or death due to any cause (whichever occurs first) + 1 day.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/figures

Program Name: rg-ef-kmplot-ebr2365.sas

25JUL2024:15:46:47

Anhang 4-G 6: Übersicht der den UESI zugrundeliegenden MedDRA-Terme

Protocol: TPX-0005-01

Page 1 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Ataxia	Higher Level Term: Coordination and balance disturbances Preferred Term: Gait disturbance
Cognitive disorders	Preferred Term: Altered state of consciousness Preferred Term: Amnesia Preferred Term: Aphasia Preferred Term: Attention deficit hyperactivity disorder Preferred Term: Bradyphrenia Preferred Term: Cognitive disorder Preferred Term: Confusional state Preferred Term: Delirium Preferred Term: Delusion Preferred Term: Depressed level of consciousness Preferred Term: Disorientation Preferred Term: Disturbance in attention Preferred Term: Dysgraphia Preferred Term: Hallucination Preferred Term: Hallucination, visual Preferred Term: Intellectual disability Preferred Term: Memory impairment Preferred Term: Mental disorder Preferred Term: Mental status changes Preferred Term: Neurological decompensation

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 2 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Dizziness	Preferred Term: Dizziness Preferred Term: Dizziness exertional Preferred Term: Dizziness postural Preferred Term: Vertigo Preferred Term: Vertigo positional
Dysgeusia	Higher Level Term: Sensory abnormalities NEC Remove the Preferred Term: Neuralgia
Hepatic enzyme elevation	Preferred Term: Alanine aminotransferase increased Preferred Term: Aspartate aminotransferase increased Preferred Term: Hepatic cytolysis Preferred Term: Hypertransaminasaemia Preferred Term: Liver function test increased Preferred Term: Transaminases increased
Mood disorders	Preferred Term: Affect lability Preferred Term: Affective disorder Preferred Term: Aggression Preferred Term: Agitated depression Preferred Term: Agitation Preferred Term: Anxiety Preferred Term: Anxiety disorder Preferred Term: Depressed mood

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 3 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Mood disorders	Preferred Term: Depression Preferred Term: Euphoric mood Preferred Term: Irritability Preferred Term: Mania Preferred Term: Mood altered Preferred Term: Mood swings Preferred Term: Persistent depressive disorder Preferred Term: Personality change Preferred Term: Personality disorder Preferred Term: Psychomotor retardation Preferred Term: Stress Preferred Term: Suicidal ideation
Muscular weakness	Preferred Term: Muscle fatigue Preferred Term: Muscular weakness
Paraesthesia	Higher Level Term: Paraesthesias and dysaesthesias
Peripheral Sensory Neuropathy	Higher Level Term: Peripheral neuropathies NEC Preferred Term: Neuralgia
Pneumonitis	Preferred Term: Interstitial lung disease Preferred Term: Pneumonitis

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 4 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
QT prolongation	Preferred Term: Electrocardiogram qt prolonged Preferred Term: Torsade de pointes Preferred Term: Ventricular arrhythmia Preferred Term: Ventricular fibrillation Preferred Term: Ventricular flutter Preferred Term: Ventricular tachycardia
Skeletal fractures	Preferred Term: Acetabulum fracture Preferred Term: Ankle fracture Preferred Term: Atypical femur fracture Preferred Term: Atypical fracture Preferred Term: Avulsion fracture Preferred Term: Bone fragmentation Preferred Term: Cervical vertebral fracture Preferred Term: Chance fracture Preferred Term: Clavicle fracture Preferred Term: Comminuted fracture Preferred Term: Complicated fracture Preferred Term: Compression fracture Preferred Term: Costal cartilage fracture Preferred Term: Craniofacial fracture Preferred Term: Epiphyseal fracture Preferred Term: Facial bones fracture Preferred Term: Femoral neck fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 5 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Femur fracture Preferred Term: Fibula fracture Preferred Term: Flail chest Preferred Term: Foot fracture Preferred Term: Forearm fracture Preferred Term: Fracture Preferred Term: Fracture blisters Preferred Term: Fracture delayed union Preferred Term: Fracture displacement Preferred Term: Fracture malunion Preferred Term: Fracture nonunion Preferred Term: Fractured coccyx Preferred Term: Fractured sacrum Preferred Term: Fractured skull depressed Preferred Term: Greenstick fracture Preferred Term: Hand fracture Preferred Term: Hip fracture Preferred Term: Humerus fracture Preferred Term: Ilium fracture Preferred Term: Impacted fracture Preferred Term: Jaw fracture Preferred Term: Limb fracture Preferred Term: Lisfranc fracture Preferred Term: Lower limb fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 6 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Lumbar vertebral fracture Preferred Term: Maisonneuve fracture Preferred Term: Metaphyseal corner fracture Preferred Term: Multiple fractures Preferred Term: Open fracture Preferred Term: Osteochondral fracture Preferred Term: Osteophyte fracture Preferred Term: Osteoporotic fracture Preferred Term: Patella fracture Preferred Term: Pathological fracture Preferred Term: Pelvic fracture Preferred Term: Periprosthetic fracture Preferred Term: Radius fracture Preferred Term: Rib fracture Preferred Term: Sacroiliac fracture Preferred Term: Scapula fracture Preferred Term: Skull fracture Preferred Term: Skull fractured base Preferred Term: Spinal compression fracture Preferred Term: Spinal fracture Preferred Term: Spinal fusion fracture Preferred Term: Sternal fracture Preferred Term: Stress fracture Preferred Term: Subchondral insufficiency fracture

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 7 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Skeletal fractures	Preferred Term: Thoracic vertebral fracture Preferred Term: Tibia fracture Preferred Term: Torus fracture Preferred Term: Traumatic fracture Preferred Term: Ulna fracture Preferred Term: Upper limb fracture Preferred Term: Wrist fracture
Sleep disorders	Preferred Term: Abnormal dreams Preferred Term: Abnormal sleep-related event Preferred Term: Advanced sleep phase Preferred Term: Behavioural induced insufficient sleep syndrome Preferred Term: Behavioural insomnia of childhood Preferred Term: Breathing-related sleep disorder Preferred Term: Cataplexy Preferred Term: Central sleep apnoea syndrome Preferred Term: Circadian rhythm sleep disorder Preferred Term: Confusional arousal Preferred Term: Delayed sleep phase Preferred Term: Dyssomnia Preferred Term: Hypersomnia Preferred Term: Hyposomnia Preferred Term: Initial insomnia Preferred Term: Insomnia

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_dbl03/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 8 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Sleep disorders	Preferred Term: Irregular sleep phase Preferred Term: Irregular sleep wake rhythm disorder Preferred Term: Loss of dreaming Preferred Term: Middle insomnia Preferred Term: Narcolepsy Preferred Term: Nightmare Preferred Term: Non-24-hour sleep-wake disorder Preferred Term: Obstructive sleep apnoea syndrome Preferred Term: Paradoxical insomnia Preferred Term: Parasomnia Preferred Term: Poor quality sleep Preferred Term: Psychophysiologic insomnia Preferred Term: Rapid eye movement sleep behaviour disorder Preferred Term: Rapid eye movements sleep abnormal Preferred Term: Sleep apnoea syndrome Preferred Term: Sleep attacks Preferred Term: Sleep disorder Preferred Term: Sleep disorder due to a general medical condition Preferred Term: Sleep disorder due to general medical condition, hypersomnia type Preferred Term: Sleep disorder due to general medical condition, insomnia type Preferred Term: Sleep disorder due to general medical condition, mixed type Preferred Term: Sleep disorder due to general medical condition, parasomnia type Preferred Term: Sleep inertia Preferred Term: Sleep paralysis

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 9 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Sleep disorders	Preferred Term: Sleep talking Preferred Term: Sleep terror Preferred Term: Snoring Preferred Term: Somnambulism Preferred Term: Somnolence Preferred Term: Sopor Preferred Term: Stupor Preferred Term: Terminal insomnia Preferred Term: Upper airway resistance syndrome
Vision disorders	Preferred Term: Asthenopia Preferred Term: Blepharospasm Preferred Term: Cataract Preferred Term: Cataract nuclear Preferred Term: Colour blindness Preferred Term: Conjunctivitis Preferred Term: Diplopia Preferred Term: Dry eye Preferred Term: Eye haematoma Preferred Term: Eye infection Preferred Term: Eye oedema Preferred Term: Eye pain Preferred Term: Eye swelling Preferred Term: Eyelid disorder

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

31MAY2024:04:29:42

Ergänzende Analysen

Protocol: TPX-0005-01

Page 10 of 10

Table S.6
Summary of MedDRA terms for Treatment-Emergent Adverse Events of Special Interest classification

Medical Concept	MedDRA Terms Included
Vision disorders	Preferred Term: Eyelid injury Preferred Term: Eyelids pruritus Preferred Term: Glaucoma Preferred Term: Hemianopia homonymous Preferred Term: Iridocyclitis Preferred Term: Myopia Preferred Term: Night blindness Preferred Term: Ophthalmic herpes zoster Preferred Term: Orbital oedema Preferred Term: Periorbital oedema Preferred Term: Photophobia Preferred Term: Photosensitivity reaction Preferred Term: Vision blurred Preferred Term: Visual acuity reduced Preferred Term: Visual field defect Preferred Term: Visual impairment Preferred Term: Vitreous floaters

DCO date: 15-OCT-2023 / DBL date: 15-DEC-2023

Based on MedDRA dictionary, Version 25.0.

Program Path: /projects/bms227017/stats/secpub/sp127p1024/dec2023_db103/prog/tables

Program Name: rt-ae-summedra.sas

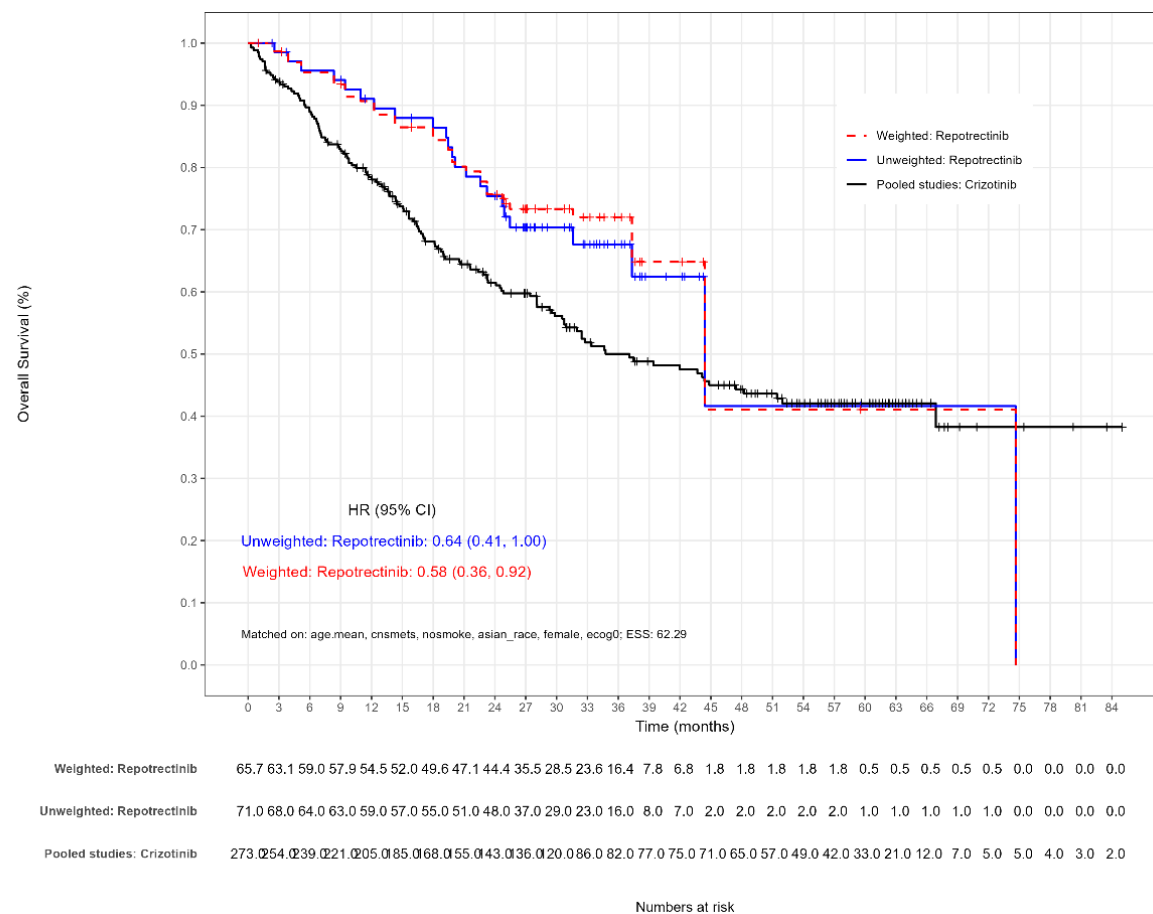
31MAY2024:04:29:42

Anhang 4-G 7: Indirekter Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA

Anhang 4-G 7.1: Kaplan-Meier-Kurven für den Endpunkt Gesamtüberleben für den indirekten Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA¹

¹ Siehe Modul 4B, Quelle Nr. 2: Bristol Myers Squibb. Repotrectinib. Non-interventional Study Report for Study CA127-1036. Indirect treatment comparisons of Repotrectinib among patients with ROS1+ NSCLC; Version 3.1; Report Date: 22.10.2024; 2024.

Ergänzende Analysen



Anhang 4-G 7.2: Kaplan-Meier-Kurven für den Endpunkt progressionsfreies Überleben für den indirekten Vergleich von Repotrectinib versus Crizotinib basierend auf TRIDENT-1 und POMEA²

² Siehe Modul 4B, Quelle Nr. 2: Bristol Myers Squibb. Repotrectinib. Non-interventional Study Report for Study CA127-1036. Indirect treatment comparisons of Repotrectinib among patients with ROS1+ NSCLC; Version 3.1; Report Date: 22.10.2024; 2024.

Ergänzende Analysen

