Clinical trial results:
Open-Label Study of Bevacizumab (Avastin®) and Taxane Monotherapy for the First-Line Treatment of Patients With Advanced Triple Negative Breast Cancer

Summary

EudraCT number	2009-014279-37
Trial protocol	GB
Global end of trial date	02 December 2015

Results information

Result version number	v1 (current)
This version publication date	04 January 2017
First version publication date	04 January 2017

Trial information

Trial identification

Sponsor protocol code	ML22780

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01094184
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, 41 61 6878333, global.trial_information@roche.com
Scientific contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, 41 61 6878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 August 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the tolerability and safety profile of bevacizumab when combined with taxane monotherapy (weekly paclitaxel) as first line treatment of participants with triple-negative metastatic breast cancer.

Protection of trial subjects:

The study was conducted in accordance with the principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP). Approval from the Independent Ethics Committee/Institutional Review Board (IEC/IRB) was obtained before study start and was documented in a letter to the Investigator specifying the date on which the committee met and granted the approval. The Sponsor also obtained approval from the relevant Competent Authority prior to starting the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 March 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	37
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 53 participants were screened; 49 participants were eligible for the study and assigned to study treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Bevacizumab 10 mg/kg Q2W

Arm description:

Participants received bevacizumab at a dose of 10 milligram per kilogram (mg/kg) every 2 weeks (Q2W) as intravenous infusion along with paclitaxel every week (Q1W) or docetaxel every 3 weeks (Q3W) as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Bevacizumab 10 mg/kg Q2W
Investigational medicinal product code	
Other name	Avastin
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bevacizumab was administered at a dose of 10 mg/kg Q2W as intravenous infusion.

Arm title	Bevacizumab 15 mg/kg Q3W

Arm description:

Participants received bevacizumab at a dose of 15 mg/kg Q3W as intravenous infusion along with paclitaxel Q1W or docetaxel Q3W as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Bevacizumab 15 mg/kg Q3W
Investigational medicinal product code	
Other name	Avastin
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bevacizumab was administered at a dose of 15 mg/kg Q3W as intravenous infusion.

Number of subjects in period 1	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W
Started	36	13
Completed	1	2
Not completed	35	11
Death	35	11

Baseline characteristics

Reporting groups	
Reporting group title	Bevacizumab 10 mg/kg Q2W
Reporting group description:	
Participants received bevacizumab at a dose of 10 milligram per kilogram (mg/kg) every 2 weeks (Q2W) as intravenous infusion along with paclitaxel every week (Q1W) or docetaxel every 3 weeks (Q3W) as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.	
Reporting group title	Bevacizumab 15 mg/kg Q3W
Reporting group description:	
Participants received bevacizumab at a dose of 15 mg/kg Q3W as intravenous infusion along with paclitaxel Q1W or docetaxel Q3W as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.	

Reporting group values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W	Total
Number of subjects	36	13	49
Age categorical			
Units: Subjects			
Age continuous			
Safety analysis population included all participants who received at least one dose of study medication (taxane [paclitaxel/ docetaxel] or bevacizumab).			
Units: years			
arithmetic mean	52.8	58.4	
standard deviation	± 14.74	± 9.22	-
Gender categorical			
Safety analysis population			
Units: Subjects			
Female	36	13	49
Male	0	0	0

End points

End points reporting groups

Reporting group title	Bevacizumab 10 mg/kg Q2W

Reporting group description:

Participants received bevacizumab at a dose of 10 milligram per kilogram (mg/kg) every 2 weeks (Q2W) as intravenous infusion along with paclitaxel every week (Q1W) or docetaxel every 3 weeks (Q3W) as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Reporting group title	Bevacizumab 15 mg/kg Q3W

Reporting group description:

Participants received bevacizumab at a dose of 15 mg/kg Q3W as intravenous infusion along with paclitaxel Q1W or docetaxel Q3W as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Primary: Change From Baseline in Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B) Score at Cycle 2

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Breast Cancer (FACT-B) Score at Cycle 2[1]

End point description:

FACT-B is used for assessment of health-related quality of life (QoL) in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. Intent-to-treat (ITT) analysis population included all participants who received at least one dose of all study medication (taxane and bevacizumab). Here, 'Number of subject analysed' signifies the number of participants evaluable for this outcome measure and 'n' signifies the number of participants evaluable at specified time point for different arms, respectively.

End point type	Primary

End point timeframe:

Baseline, Cycle 2 (Cycle length=2 and 3 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	12		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=31,12)	98.3 (± 21.342)	102.21 (± 21.036)		
Change at Cycle 2 (n=25,6)	5.83 (± 17.027)	-2.48 (± 14.697)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 3

End point title	Change From Baseline in FACT-B Score at Cycle 3[2]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subject analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 3 (Cycle length=2 and 3 weeks)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	3		
Units: units on a scale				
arithmetic mean (standard deviation)	()	14.56 (± 13.961)		

Notes:

[3] - No participant was evaluable in the indicated arm for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 4

End point title	Change From Baseline in FACT-B Score at Cycle 4[4]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subject analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 4 (Cycle length=2 and 3 weeks)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	6		
Units: units on a scale				
arithmetic mean (standard deviation)	1.29 (± 16.304)	0.09 (± 12.275)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 5

End point title	Change From Baseline in FACT-B Score at Cycle 5[5]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0=‘Not at all’ to 4=‘Very much’. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 5 (Cycle length=2 and 3 weeks)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	2		
Units: units on a scale				
arithmetic mean (standard deviation)	-10.77 (± 11.677)	4.5 (± 27.577)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 6

End point title	Change From Baseline in FACT-B Score at Cycle 6[6]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of

participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 6 (Cycle length=2 and 3 weeks)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: units on a scale				
arithmetic mean (standard deviation)	9.47 (± 16.356)	10.08 (± 21.868)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 7

End point title	Change From Baseline in FACT-B Score at Cycle 7[7]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 7 (Cycle length=2 and 3 weeks)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-6.24 (± 13.22)	1.83 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 8

End point title	Change From Baseline in FACT-B Score at Cycle 8[8]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 8 (Cycle length=2 and 3 weeks)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	4		
Units: units on a scale				
arithmetic mean (standard deviation)	15.01 (± 9.805)	15.44 (± 19.979)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 9

End point title	Change From Baseline in FACT-B Score at Cycle 9[9]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 9 (Cycle length=2 and 3 weeks)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-2.43 (± 7.762)	7 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 10

End point title	Change From Baseline in FACT-B Score at Cycle 10[10]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 10 (Cycle length=2 and 3 weeks)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	5		
Units: units on a scale				
arithmetic mean (standard deviation)	2.71 (± 20.075)	4.61 (± 13.968)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 11

End point title	Change From Baseline in FACT-B Score at Cycle 11[11]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of

participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 11 (Cycle length=2 and 3 weeks)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: units on a scale				
arithmetic mean (standard deviation)	6.67 (± 11.889)	8.17 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 12

End point title	Change From Baseline in FACT-B Score at Cycle 12[12]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 12 (Cycle length=2 and 3 weeks)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: units on a scale				
arithmetic mean (standard deviation)	9.22 (± 8.72)	21.89 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 13

End point title	Change From Baseline in FACT-B Score at Cycle 13[13]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 13 (Cycle length=2 and 3 weeks)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[14]		
Units: units on a scale				
arithmetic mean (standard deviation)	-8 (± 9.899)	()		

Notes:

[14] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 14

End point title	Change From Baseline in FACT-B Score at Cycle 14[15]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 14 (Cycle length=2 and 3 weeks)

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	1		
Units: units on a scale				
arithmetic mean (standard deviation)	6.83 (± 5.897)	2.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 15

End point title	Change From Baseline in FACT-B Score at Cycle 15[16]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 15 (Cycle length=2 and 3 weeks)

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[17]		
Units: units on a scale				
arithmetic mean (standard deviation)	-6.67 (± 8.25)	()		

Notes:

[17] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 16

End point title	Change From Baseline in FACT-B Score at Cycle 16[18]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 16 (Cycle length=2 and 3 weeks)

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[19]		
Units: units on a scale				
arithmetic mean (standard deviation)	11.83 (± 12.79)	()		

Notes:

[19] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 17

End point title	Change From Baseline in FACT-B Score at Cycle 17[20]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 17 (Cycle length=2 and 3 weeks)

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[21]		
Units: units on a scale				
arithmetic mean (standard deviation)	22.63 (± 13.157)	()		

Notes:

[21] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 18

End point title	Change From Baseline in FACT-B Score at Cycle 18[22]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 18 (Cycle length=2 and 3 weeks)

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	10.28 (± 19.878)	5.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 20

End point title	Change From Baseline in FACT-B Score at Cycle 20[23]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 20 (Cycle length=2 and 3 weeks)

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[24]		
Units: units on a scale				
arithmetic mean (standard deviation)	20.06 (± 12.787)	()		

Notes:

[24] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 21

End point title	Change From Baseline in FACT-B Score at Cycle 21[25]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 21 (Cycle length=2 and 3 weeks)

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	25.75 (± 5.303)	10.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 22

End point title	Change From Baseline in FACT-B Score at Cycle 22[26]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from

0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 22 (Cycle length=2 and 3 weeks)

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[27]		
Units: units on a scale				
arithmetic mean (standard deviation)	13.67 (± 99999)	()		

Notes:

[27] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 23

End point title	Change From Baseline in FACT-B Score at Cycle 23[28]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 23 (Cycle length=2 and 3 weeks)

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	9.67 (± 20.742)	7.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 24

End point title	Change From Baseline in FACT-B Score at Cycle 24[29]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 24 (Cycle length=2 and 3 weeks)

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[30]		
Units: units on a scale				
arithmetic mean (standard deviation)	6 (± 99999)	()		

Notes:

[30] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 25

End point title	Change From Baseline in FACT-B Score at Cycle 25[31]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 25 (Cycle length=2 and 3 weeks)

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[32]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	11.33 (± 99999)		

Notes:

[32] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 26

End point title	Change From Baseline in FACT-B Score at Cycle 26[33]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 26 (Cycle length=2 and 3 weeks)

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[34]		
Units: units on a scale				
arithmetic mean (standard deviation)	3.22 (± 99999)	()		

Notes:

[34] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 27

End point title	Change From Baseline in FACT-B Score at Cycle 27[35]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 27 (Cycle length=2 and 3 weeks)

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-26.78 (± 99999)	12.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 28

End point title	Change From Baseline in FACT-B Score at Cycle 28[36]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 28 (Cycle length=2 and 3 weeks)

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[37]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	16.33 (± 99999)		

Notes:

[37] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 29

End point title	Change From Baseline in FACT-B Score at Cycle 29[38]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 29 (Cycle length=2 and 3 weeks)

Notes:

[38] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-3 (± 99999)	9.78 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 30

End point title	Change From Baseline in FACT-B Score at Cycle 30[39]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of

participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 30 (Cycle length=2 and 3 weeks)

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[40]		
Units: units on a scale				
arithmetic mean (standard deviation)	-3.11 (± 99999)	()		

Notes:

[40] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 32

End point title	Change From Baseline in FACT-B Score at Cycle 32[41]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 32 (Cycle length=2 and 3 weeks)

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[42]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	10.33 (± 99999)		

Notes:

[42] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 36

End point title	Change From Baseline in FACT-B Score at Cycle 36[43]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 36 (Cycle length=2 and 3 weeks)

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[44]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	3.33 (± 99999)		

Notes:

[44] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 37

End point title	Change From Baseline in FACT-B Score at Cycle 37[45]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 37 (Cycle length=2 and 3 weeks)

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[46]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	5.33 (± 99999)		

Notes:

[46] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 39

End point title	Change From Baseline in FACT-B Score at Cycle 39[47]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 39 (Cycle length=2 and 3 weeks)

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[48]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	9.33 (± 99999)		

Notes:

[48] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 42

End point title	Change From Baseline in FACT-B Score at Cycle 42[49]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 42 (Cycle length=2 and 3 weeks)

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[50]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	10.33 (± 99999)		

Notes:

[50] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 44

End point title	Change From Baseline in FACT-B Score at Cycle 44[51]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 44 (Cycle length=2 and 3 weeks)

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[52]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	11.33 (± 99999)		

Notes:

[52] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score at Cycle 46

End point title	Change From Baseline in FACT-B Score at Cycle 46[53]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 46 (Cycle length=2 and 3 weeks)

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[54]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	13.33 (± 99999)		

Notes:

[54] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in FACT-B Score At End of Study

End point title	Change From Baseline in FACT-B Score At End of Study[55]

End point description:

FACT-B is used for assessment of health-related QoL in participants with breast cancer. It consists of 36 items, summarized to 5 subscales: physical (7 items), functional (7 items), social/family (7 items); all 3 ranged from 0 to 28, emotional (6 items) ranging from 0 to 24, and breast cancer subscale (9 items) ranging from 0 to 36; high subscale score represents a better QoL. All single-item measures range from 0='Not at all' to 4='Very much'. Total possible score ranged from 0 to 144. High scale score represents a

better QoL. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, End of study (4-6 weeks after the last bevacizumab administration) (maximum up to 5 years and 9 months)

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	7		
Units: units on a scale				
arithmetic mean (standard deviation)	-10.33 (± 13.509)	-1.01 (± 9.343)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Euro Quality of Life (EQ-5D) - Health State Questionnaire Score at Cycle 2

End point title	Change From Baseline in Euro Quality of Life (EQ-5D) - Health State Questionnaire Score at Cycle 2[56]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure and 'n' signifies the number of participants evaluable at specified time point for different arms, respectively.

End point type	Primary

End point timeframe:

Baseline, Cycle 2 (Cycle length=2 and 3 weeks)

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	10		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=31,10)	0.6391 (± 0.25595)	0.8152 (± 0.12211)		

Change at Cycle 2 (n=25,5)	0.109 (± 0.23563)	-0.2074 (± 0.19784)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 3

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 3[57]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 3 (Cycle length=2 and 3 weeks)

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[58]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	0.192 (± 99999)		

Notes:

[58] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 4

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 4[59]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility

value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 4 (Cycle length=2 and 3 weeks)

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	5		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.0105 (± 0.28263)	-0.0906 (± 0.06661)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 5

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 5[60]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 5 (Cycle length=2 and 3 weeks)

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.1164 (± 0.10045)	0.228 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 6

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 6[61]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 6 (Cycle length=2 and 3 weeks)

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0474 (± 0.23827)	-0.0735 (± 0.24131)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 7

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 7[62]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects

analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 7 (Cycle length=2 and 3 weeks)

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	0[63]		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.0331 (± 0.18865)	()		

Notes:

[63] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 8

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 8[64]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 8 (Cycle length=2 and 3 weeks)

Notes:

[64] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	3		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0627 (± 0.23917)	-0.0523 (± 0.0525)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 9

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 9[65]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 9 (Cycle length=2 and 3 weeks)

Notes:

[65] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	0[66]		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.1904 (± 0.24194)	()		

Notes:

[66] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 10

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 10[67]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 10 (Cycle length=2 and 3 weeks)

Notes:

[67] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	3		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0253 (± 0.32169)	-0.054 (± 0.2499)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 11

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 11[68]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 11 (Cycle length=2 and 3 weeks)

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	0[69]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0018 (± 0.20907)	()		

Notes:

[69] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle

12

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 12[70]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 12 (Cycle length=2 and 3 weeks)

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0997 (± 0.35679)	-0.052 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 13

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 13[71]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 13 (Cycle length=2 and 3 weeks)

Notes:

[71] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[72]		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.093 (± 0.13152)	()		

Notes:

[72] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 14

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 14[73]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 14 (Cycle length=2 and 3 weeks)

Notes:

[73] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.062 (± 0.11033)	-0.332 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 15

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 15[74]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 15 (Cycle length=2 and 3 weeks)

Notes:

[74] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[75]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0175 (± 0.19021)	()		

Notes:

[75] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 16

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 16[76]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 16 (Cycle length=2 and 3 weeks)

Notes:

[76] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[77]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.006 (± 0.21806)	()		

Notes:

[77] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 17

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 17[78]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 17 (Cycle length=2 and 3 weeks)

Notes:

[78] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[79]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.1057 (± 0.17756)	()		

Notes:

[79] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 18

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 18[80]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual

activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure."99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 18 (Cycle length=2 and 3 weeks)

Notes:

[80] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.097 (± 0.01414)	-0.157 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 20

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 20[81]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 20 (Cycle length=2 and 3 weeks)

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	0[82]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.1035 (± 0.1967)	()		

Notes:

[82] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 21

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 21[83]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 21 (Cycle length=2 and 3 weeks)

Notes:

[83] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.2955 (± 0.26658)	-0.157 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 22

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 22[84]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no

problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 22 (Cycle length=2 and 3 weeks)

Notes:

[84] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[85]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.071 (± 99999)	()		

Notes:

[85] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 23

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 23[86]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 23 (Cycle length=2 and 3 weeks)

Notes:

[86] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.0625 (± 0.06293)	-0.228 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 24

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 24[87]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 24 (Cycle length=2 and 3 weeks)

Notes:

[87] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[88]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.054 (± 99999)	()		

Notes:

[88] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 25

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 25[89]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 25 (Cycle length=2 and 3 weeks)

Notes:

[89] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[90]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.332 (± 99999)		

Notes:

[90] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 26

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 26[91]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 26 (Cycle length=2 and 3 weeks)

Notes:

[91] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[92]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.018 (± 99999)	()		

Notes:

[92] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 27

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 27[93]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 27 (Cycle length=2 and 3 weeks)

Notes:

[93] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: units on a scale				
arithmetic mean (standard deviation)	0.054 (± 99999)	-0.332 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 28

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 28[94]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 28 (Cycle length=2 and 3 weeks)

Notes:

[94] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[95]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[95] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 29

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 29[96]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 29 (Cycle length=2 and 3 weeks)

Notes:

[96] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.086 (± 99999)	-0.261 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 30

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 30[97]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 30 (Cycle length=2 and 3 weeks)

Notes:

[97] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[98]		
Units: units on a scale				
arithmetic mean (standard deviation)	0.054 (± 99999)	()		

Notes:

[98] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 32

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 32[99]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 32 (Cycle length=2 and 3 weeks)

Notes:

[99] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[100]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[100] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 36

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 36[101]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 36 (Cycle length=2 and 3 weeks)

Notes:

[101] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[102]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[102] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 37

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 37[103]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 37 (Cycle length=2 and 3 weeks)

Notes:

[103] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[104]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[104] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 39

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 39[105]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 39 (Cycle length=2 and 3 weeks)

Notes:

[105] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[106]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[106] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 40

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 40[107]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 40 (Cycle length=2 and 3 weeks)

Notes:

[107] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[108]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[108] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 42

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 42[109]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 42 (Cycle length=2 and 3 weeks)

Notes:

[109] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[110]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.261 (± 99999)		

Notes:

[110] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 44

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 44[111]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 44 (Cycle length=2 and 3 weeks)

Notes:

[111] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[112]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.332 (± 99999)		

Notes:

[112] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 46

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at Cycle 46[113]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 46 (Cycle length=2 and 3 weeks)

Notes:

[113] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[114]	1		
Units: units on a scale				
arithmetic mean (standard deviation)	()	-0.332 (± 99999)		

Notes:

[114] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D- Health State Questionnaire Score at End of Study

End point title	Change From Baseline in EQ-5D- Health State Questionnaire Score at End of Study[115]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single utility score. Health State Profile component assesses level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression; 1 indicates better health state (no problems); 3 indicates worst health state. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score is transformed and results in a total score range -0.594 to 1.000; higher score indicates a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, End of study (4-6 weeks after the last bevacizumab administration) (maximum up to 5 years and 9 months)

Notes:

[115] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	5		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.1344 (± 0.20511)	-0.1178 (± 0.14225)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D - Visual Analog Scale (VAS) Score at Cycle 2

End point title	Change From Baseline in EQ-5D - Visual Analog Scale (VAS) Score at Cycle 2[116]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value.

The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure and 'n' signifies the number of participants evaluable at specified time point for different arms, respectively.

End point type	Primary

End point timeframe:

Baseline, Cycle 2 (Cycle length=2 and 3 weeks)

Notes:

[116] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	12		
Units: mm				
arithmetic mean (standard deviation)				
Baseline (n=30,12)	64.8 (± 24.34)	60.3 (± 26.96)		
Change at Cycle 2 (n=23,6)	-1 (± 18.59)	-8.3 (± 19.41)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 3

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 3[117]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 3 (Cycle length=2 and 3 weeks)

Notes:

[117] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[118]	3		
Units: mm				
arithmetic mean (standard deviation)	()	20 (± 26.46)		

Notes:

[118] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 4

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 4[119]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 4 (Cycle length=2 and 3 weeks)

Notes:

[119] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	6		
Units: mm				
arithmetic mean (standard deviation)	-1.9 (± 18.23)	3.3 (± 29.27)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 5

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 5[120]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 5 (Cycle length=2 and 3 weeks)

Notes:

[120] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	2		
Units: mm				
arithmetic mean (standard deviation)	-8.2 (± 17.57)	7 (± 46.67)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 6

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 6[121]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 6 (Cycle length=2 and 3 weeks)

Notes:

[121] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: mm				
arithmetic mean (standard deviation)	9.8 (± 22)	21.4 (± 35.69)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 7

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 7[122]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 7 (Cycle length=2 and 3 weeks)

Notes:

[122] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: mm				
arithmetic mean (standard deviation)	-3.6 (± 12.1)	-9 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 8

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 8[123]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 8 (Cycle length=2 and 3 weeks)

Notes:

[123] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: mm				
arithmetic mean (standard deviation)	11 (± 27.6)	35 (± 22.91)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 9

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 9[124]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis

population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 9 (Cycle length=2 and 3 weeks)

Notes:

[124] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	2		
Units: mm				
arithmetic mean (standard deviation)	-5.8 (± 15.43)	27.5 (± 45.96)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 10

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 10[125]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 10 (Cycle length=2 and 3 weeks)

Notes:

[125] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	5		
Units: mm				
arithmetic mean (standard deviation)	6 (± 21.91)	14 (± 32.79)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 11

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 11[126]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 11 (Cycle length=2 and 3 weeks)

Notes:

[126] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: mm				
arithmetic mean (standard deviation)	2 (± 24.14)	40 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 12

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 12[127]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 12 (Cycle length=2 and 3 weeks)

Notes:

[127] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: mm				
arithmetic mean (standard deviation)	13.7 (± 24.19)	60 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 13

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 13[128]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 13 (Cycle length=2 and 3 weeks)

Notes:

[128] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[129]		
Units: mm				
arithmetic mean (standard deviation)	-3 (± 2.83)	()		

Notes:

[129] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 14

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 14[130]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 14 (Cycle length=2 and 3 weeks)

Notes:

[130] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: mm				
arithmetic mean (standard deviation)	-5 (± 20)	9 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 15

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 15[131]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 15 (Cycle length=2 and 3 weeks)

Notes:

[131] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[132]		
Units: mm				
arithmetic mean (standard deviation)	5 (± 7.07)	()		

Notes:

[132] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 16

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 16[133]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis

population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 16 (Cycle length=2 and 3 weeks)

Notes:

[133] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[134]		
Units: mm				
arithmetic mean (standard deviation)	7.3 (± 37.87)	()		

Notes:

[134] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 17

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 17[135]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 17 (Cycle length=2 and 3 weeks)

Notes:

[135] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	0[136]		
Units: mm				
arithmetic mean (standard deviation)	30 (± 25)	()		

Notes:

[136] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 18

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 18[137]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 18 (Cycle length=2 and 3 weeks)

Notes:

[137] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: mm				
arithmetic mean (standard deviation)	9.5 (± 55.86)	10 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 20

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 20[138]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 20 (Cycle length=2 and 3 weeks)

Notes:

[138] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	0[139]		
Units: mm				
arithmetic mean (standard deviation)	15 (± 31.36)	()		

Notes:

[139] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 21

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 21[140]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 21 (Cycle length=2 and 3 weeks)

Notes:

[140] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: mm				
arithmetic mean (standard deviation)	27.5 (± 31.82)	8 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 22

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 22[141]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 22 (Cycle length=2 and 3 weeks)

Notes:

[141] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[142]		
Units: mm				
arithmetic mean (standard deviation)	52 (± 99999)	()		

Notes:

[142] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 23

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 23[143]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 23 (Cycle length=2 and 3 weeks)

Notes:

[143] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: mm				
arithmetic mean (standard deviation)	23.5 (± 47.38)	10 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 24

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 24[144]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 24 (Cycle length=2 and 3 weeks)

Notes:

[144] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[145]		
Units: mm				
arithmetic mean (standard deviation)	-20 (± 99999)	()		

Notes:

[145] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 25

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 25[146]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 25 (Cycle length=2 and 3 weeks)

Notes:

[146] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[147]	1		
Units: mm				
arithmetic mean (standard deviation)	()	9 (± 99999)		

Notes:

[147] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 26

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 26[148]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 26 (Cycle length=2 and 3 weeks)

Notes:

[148] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[149]		
Units: mm				
arithmetic mean (standard deviation)	-20 (± 99999)	()		

Notes:

[149] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 27

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 27[150]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 27 (Cycle length=2 and 3 weeks)

Notes:

[150] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: mm				
arithmetic mean (standard deviation)	-20 (± 99999)	10 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 28

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 28[151]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 28 (Cycle length=2 and 3 weeks)

Notes:

[151] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[152]	1		
Units: mm				
arithmetic mean (standard deviation)	()	9 (± 99999)		

Notes:

[152] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 29

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 29[153]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 29 (Cycle length=2 and 3 weeks)

Notes:

[153] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: mm				
arithmetic mean (standard deviation)	-20 (± 99999)	10 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 30

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 30[154]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 30 (Cycle length=2 and 3 weeks)

Notes:

[154] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[155]		
Units: mm				
arithmetic mean (standard deviation)	-20 (± 99999)	()		

Notes:

[155] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 32

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 32[156]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.
"99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 32 (Cycle length=2 and 3 weeks)

Notes:

[156] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[157]	1		
Units: mm				
arithmetic mean (standard deviation)	()	9 (± 99999)		

Notes:

[157] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 36

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 36[158]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 36 (Cycle length=2 and 3 weeks)

Notes:

[158] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[159]	1		
Units: mm				
arithmetic mean (standard deviation)	()	8 (± 99999)		

Notes:

[159] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 37

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 37[160]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 37 (Cycle length=2 and 3 weeks)

Notes:

[160] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[161]	1		
Units: mm				
arithmetic mean (standard deviation)	()	8 (± 99999)		

Notes:

[161] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 39

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 39[162]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 39 (Cycle length=2 and 3 weeks)

Notes:

[162] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[163]	1		
Units: mm				
arithmetic mean (standard deviation)	()	8 (± 99999)		

Notes:

[163] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 40

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 40[164]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.
"99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 40 (Cycle length=2 and 3 weeks)

Notes:

[164] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[165]	1		
Units: mm				
arithmetic mean (standard deviation)	()	5 (± 99999)		

Notes:

[165] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 42

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 42[166]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value.

The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 42 (Cycle length=2 and 3 weeks)

Notes:

[166] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[167]	1		
Units: mm				
arithmetic mean (standard deviation)	()	7 (± 99999)		

Notes:

[167] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 44

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 44[168]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 44 (Cycle length=2 and 3 weeks)

Notes:

[168] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[169]	1		
Units: mm				
arithmetic mean (standard deviation)	()	13 (± 99999)		

Notes:

[169] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at Cycle 46

End point title	Change From Baseline in EQ-5D-VAS Score at Cycle 46[170]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure. "99999" in results indicate data could not be calculated because only 1 participant was evaluable in this arm for the indicated outcome measure.

End point type	Primary

End point timeframe:

Baseline, Cycle 46 (Cycle length=2 and 3 weeks)

Notes:

[170] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[171]	1		
Units: mm				
arithmetic mean (standard deviation)	()	14 (± 99999)		

Notes:

[171] - No participant was evaluable in this arm for the indicated outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in EQ-5D-VAS Score at End of Study

End point title	Change From Baseline in EQ-5D-VAS Score at End of Study[172]

End point description:

EQ-5D: participant rated questionnaire to assess health-related QoL in terms of a single index value. The VAS component rates current health state on a scale from 0 mm (worst imaginable health state) to 100 mm (best imaginable health state); higher scores indicate a better health state. ITT analysis population. Here, 'Number of subjects analysed' signifies the number of participants evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Baseline, End of study (4-6 weeks after the last bevacizumab administration) (maximum up to 5 years and 9 months)

Notes:

[172] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Results were reported descriptively and were not planned to be analyzed for statistically significant differences between groups.

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	7		
Units: mm				
arithmetic mean (standard deviation)	-2.7 (± 13.17)	-1.4 (± 22.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Died Due to Any Cause

End point title	Percentage of Participants Who Died Due to Any Cause

End point description:

ITT analysis population

End point type	Secondary

End point timeframe:

Baseline up to death (overall approximately 5 years and 9 months)

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: percentage of participants				
number (not applicable)	97.1	84.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival

End point description:

Overall survival was defined as the time from start of taxane plus bevacizumab therapy to death due to any cause. Overall survival was calculated in months as (date of death from any cause - date of first administration of taxane or bevacizumab + 1) / 30.4375 and rounded to 1 decimal place. Participants for whom no death was captured on the clinical database were censored at the last date they were known to be alive. ITT analysis population.

End point type	Secondary

End point timeframe:

Baseline up to death (overall approximately 5 years and 9 months)

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: months				
median (confidence interval 95%)	11.6 (8.5 to 16.9)	18.9 (12.8 to 33.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Disease Progression

End point title	Percentage of Participants With Disease Progression

End point description:

Disease progression was defined as greater than or equal to (>/=) 20 percent (%) relative increase and >/=5 mm of absolute increase in the sum of diameters (SD) of target lesions (TLs), taking as reference the smallest SD recorded since treatment started, or appearance of 1 or more new lesions. ITT analysis population.

End point type	Secondary

End point timeframe:

Baseline up to disease progression (overall approximately 5 years and 9 months)

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: percentage of participants				
number (not applicable)	74.3	69.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Disease Progression

End point title	Time to Disease Progression

End point description:

Time to disease progression was defined as the time from the start of taxane plus bevacizumab therapy to investigator assessed disease progression and was calculated in months as (date of Investigator assessed disease progression - date of first administration of taxane or bevacizumab + 1) / 30.4375 and rounded to 1 decimal place. Participants who had not progressed at the time of study completion (including participants who had died before progressive disease) or who were lost to follow-up were censored at the last bevacizumab administration date. Disease progression was defined as >/=20% relative increase and >/=5 mm of absolute increase in the SD of TLs, taking as reference the smallest SD recorded since treatment started, or appearance of 1 or more new lesions. ITT analysis population.

End point type	Secondary

End point timeframe:

Baseline up to disease progression (overall approximately 5 years and 9 months)

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: months				
median (confidence interval 95%)	6.7 (4.5 to 14.1)	7.9 (3.2 to 9.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants by Karnofsky Performance Status Scale Scores

End point title	Percentage of Participants by Karnofsky Performance Status Scale Scores

End point description:

Karnofsky performance score is used to quantify participant's general well-being and activities of daily life and participants are classified based on their functional impairment. Karnofsky performance score is 11 level score which range between 0% (death) to 100% (no evidence of disease). Higher score means higher ability to perform daily tasks. Percentage of participants with different level scores is reported. ITT analysis population. Here, 'Number of subjects analysed' signifies overall number of participants evaluable for this outcome measure and 'n' signifies number of participants evaluable at specified time points for different arms, respectively. No data reported for Cycles 35, 41, 44 as no participant was evaluable at these time points.

End point type	Secondary

End point timeframe:

Baseline, Cycle 1 thereafter every cycle up to Cycle 47 (Cycle length=2 and 3 weeks), end of study (4-6 weeks after the last bevacizumab infusion) (maximum up to 5 years and 9 months)

End point values	Bevacizumab 10 mg/kg Q2W	Bevacizumab 15 mg/kg Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: percentage of participants				
number (not applicable)				
Baseline, 60% (n=33,12)	3	8		
Baseline, 70% (n=33,12)	9	8		
Baseline, 80% (n=33,12)	27	25		
Baseline, 90% (n=33,12)	30	25		
Baseline, 100% (n=33,12)	30	33		
Cycle 1, 60% (n=31,12)	6	0		
Cycle 1, 70% (n=31,12)	6	25		
Cycle 1, 80% (n=31,12)	26	25		

Cycle 1, 90% (n=31,12)	32	25		
Cycle 1, 100% (n=31,12)	29	25		
Cycle 2, 60% (n=31,10)	0	10		
Cycle 2, 70% (n=31,10)	13	30		
Cycle 2, 80% (n=31,10)	23	20		
Cycle 2, 90% (n=31,10)	35	30		
Cycle 2, 100% (n=31,10)	29	10		
Cycle 3, 70% (n=28,10)	4	30		
Cycle 3, 80% (n=28,10)	43	30		
Cycle 3, 90% (n=28,10)	32	30		
Cycle 3, 100% (n=28,10)	21	10		
Cycle 4, 60% (n=24,8)	0	13		
Cycle 4, 70% (n=24,8)	8	13		
Cycle 4, 80% (n=24,8)	29	38		
Cycle 4, 90% (n=24,8)	42	25		
Cycle 4, 100% (n=24,8)	21	13		
Cycle 5, 60% (n=19,9)	0	11		
Cycle 5, 70% (n=19,9)	5	11		
Cycle 5, 80% (n=19,9)	37	33		
Cycle 5, 90% (n=19,9)	42	33		
Cycle 5, 100% (n=19,9)	16	11		
Cycle 6, 80% (n=15,8)	33	50		
Cycle 6, 90% (n=15,8)	47	38		
Cycle 6, 100% (n=15,8)	20	13		
Cycle 7, 80% (n=14,7)	14	43		
Cycle 7, 90% (n=14,7)	64	29		
Cycle 7, 100% (n=14,7)	21	29		
Cycle 8, 70% (n=10,7)	0	14		
Cycle 8, 80% (n=10,7)	20	29		
Cycle 8, 90% (n=10,7)	60	43		
Cycle 8, 100% (n=10,7)	20	14		
Cycle 9, 60% (n=10,6)	0	17		
Cycle 9, 70% (n=10,6)	10	0		
Cycle 9, 80% (n=10,6)	10	17		
Cycle 9, 90% (n=10,6)	60	50		
Cycle 9, 100% (n=10,6)	20	17		
Cycle 10, 70% (n=11,5)	0	20		
Cycle 10, 80% (n=11,5)	9	40		
Cycle 10, 90% (n=11,5)	73	20		
Cycle 10, 100% (n=11,5)	18	20		
Cycle 11, 70% (n=10,4)	0	25		
Cycle 11, 80% (n=10,4)	0	25		
Cycle 11, 90% (n=10,4)	80	25		
Cycle 11, 100% (n=10,4)	20	25		
Cycle 12, 70% (n=10,4)	0	25		
Cycle 12, 80% (n=10,4)	0	25		
Cycle 12, 90% (n=10,4)	80	25		
Cycle 12, 100% (n=10,4)	20	25		
Cycle 13, 90% (n=8,2)	88	100		
Cycle 13, 100% (n=8,2)	13	0		
Cycle 14, 80% (n=8,1)	13	0		
Cycle 14, 90% (n=8,1)	75	100		

Cycle 14, 100% (n=8,1)	13	0		
Cycle 15, 80% (n=7,1)	14	0		
Cycle 15, 90% (n=7,1)	71	100		
Cycle 15, 100% (n=7,1)	14	0		
Cycle 16, 80% (n=4,1)	25	0		
Cycle 16, 90% (n=4,1)	75	100		
Cycle 16, 100% (n=4,1)	0	0		
Cycle 17, 90% (n=4,1)	75	100		
Cycle 17, 100% (n=4,1)	25	0		
Cycle 18, 90% (n=4,1)	75	100		
Cycle 18, 100% (n=4,1)	25	0		
Cycle 19, 90% (n=4,1)	75	0		
Cycle 19, 100% (n=4,1)	25	100		
Cycle 20, 80% (n=4,1)	0	100		
Cycle 20, 90% (n=4,1)	75	0		
Cycle 20, 100% (n=4,1)	25	0		
Cycle 21, 90% (n=4,1)	50	100		
Cycle 21, 100% (n=4,1)	50	0		
Cycle 22, 90% (n=2,1)	50	100		
Cycle 22, 100% (n=2,1)	50	0		
Cycle 23, 90% (n=3,1)	67	100		
Cycle 23, 100% (n=3,1)	33	0		
Cycle 24, 90% (n=3,1)	67	100		
Cycle 24, 100% (n=3,1)	33	0		
Cycle 25, 90% (n=3,1)	67	100		
Cycle 25, 100% (n=3,1)	33	0		
Cycle 26, 90% (n=4,1)	75	100		
Cycle 26, 100% (n=4,1)	25	0		
Cycle 27, 90% (n=2,1)	50	100		
Cycle 27, 100% (n=2,1)	50	0		
Cycle 28, 90% (n=1,1)	100	100		
Cycle 28, 100% (n=1,1)	0	0		
Cycle 29, 90% (n=1,0)	100	0		
Cycle 30, 80% (n=1,0)	100	0		
Cycle 31, 90% (n=0,1)	0	100		
Cycle 32, 90% (n=0,1)	0	100		
Cycle 33, 90% (n=0,1)	0	100		
Cycle 34, 90% (n=0,1)	0	100		
Cycle 36, 90% (n=0,1)	0	100		
Cycle 37, 90% (n=0,1)	0	100		
Cycle 38, 90% (n=0,1)	0	100		
Cycle 39, 90% (n=0,1)	0	100		
Cycle 40, 90% (n=0,1)	0	100		
Cycle 42, 100% (n=0,1)	0	100		
Cycle 43, 100% (n=0,1)	0	100		
Cycle 45, 100% (n=0,1)	0	100		
Cycle 46, 100% (n=0,1)	0	100		
Cycle 47, 100% (n=0,1)	0	100		
End of Study, 50% (n=19,8)	5	0		
End of Study, 60% (n=19,8)	0	13		
End of Study, 70% (n=19,8)	16	25		
End of Study, 80% (n=19,8)	32	25		

End of Study, 90% (n=19,8)	42	38		
End of Study, 100% (n=19,8)	5	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to 6 months after last dose (overall approximately 5 years and 9 months)

Adverse event reporting additional description:

Treatment-emergent are events between first dose of study drug and up to 6 months after last dose that were absent before treatment or that worsened relative to pretreatment state. Safety analysis population.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Bevacizumab 15 mg/kg Q3W

Reporting group description:

Participants received bevacizumab at a dose of 15 mg/kg Q3W as intravenous infusion along with paclitaxel Q1W or docetaxel Q3W as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Reporting group title	Bevacizumab 10 mg/kg Q2W

Reporting group description:

Participants received bevacizumab at a dose of 10 mg/kg Q2W as intravenous infusion along with paclitaxel Q1W or docetaxel Q3W as per discretion of the treating physician until disease progression, unacceptable toxicity or withdrawal of consent.

Serious adverse events	Bevacizumab 15 mg/kg Q3W	Bevacizumab 10 mg/kg Q2W	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)	15 / 36 (41.67%)	
number of deaths (all causes)	11	35	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lung			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			

subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Catheter site dermatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum perforation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Procedural pneumothorax			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative wound infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 13 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Bevacizumab 15 mg/kg Q3W	Bevacizumab 10 mg/kg Q2W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	35 / 36 (97.22%)	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Hot flush			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Hypertension			
subjects affected / exposed	4 / 13 (30.77%)	9 / 36 (25.00%)	
occurrences (all)	4	11	
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Lymphoedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Orthostatic hypotension			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Phlebitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Catheter site inflammation			
subjects affected / exposed	2 / 13 (15.38%)	0 / 36 (0.00%)	
occurrences (all)	4	0	

Chills			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	9 / 13 (69.23%)	26 / 36 (72.22%)	
occurrences (all)	11	28	
Oedema peripheral			
subjects affected / exposed	2 / 13 (15.38%)	3 / 36 (8.33%)	
occurrences (all)	2	4	
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Mucosal inflammation			
subjects affected / exposed	2 / 13 (15.38%)	11 / 36 (30.56%)	
occurrences (all)	3	12	
Pain			
subjects affected / exposed	3 / 13 (23.08%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Ulcer			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Vulvovaginal dryness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 13 (23.08%)	9 / 36 (25.00%)	
occurrences (all)	3	10	
Cough			
subjects affected / exposed	4 / 13 (30.77%)	10 / 36 (27.78%)	
occurrences (all)	4	11	
Hiccups			

subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	4 / 13 (30.77%)	14 / 36 (38.89%)	
occurrences (all)	5	15	
Nasal congestion			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Rhinalgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Rhinorrhoea			
subjects affected / exposed	2 / 13 (15.38%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Insomnia			
subjects affected / exposed	1 / 13 (7.69%)	4 / 36 (11.11%)	
occurrences (all)	1	4	
Mood altered			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Blood bilirubin increased			

subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 13 (7.69%)	3 / 36 (8.33%)	
occurrences (all)	1	3	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Neutrophil count decreased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Weight increased			
subjects affected / exposed	1 / 13 (7.69%)	2 / 36 (5.56%)	
occurrences (all)	1	4	
Weight decreased			
subjects affected / exposed	0 / 13 (0.00%)	5 / 36 (13.89%)	
occurrences (all)	0	5	
White blood cells urine positive			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	8	
White blood cell count decreased			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Ligament sprain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Wound decomposition			

subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Headache			
subjects affected / exposed	3 / 13 (23.08%)	11 / 36 (30.56%)	
occurrences (all)	4	12	
Dysgeusia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Neuralgia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Lethargy			
subjects affected / exposed	2 / 13 (15.38%)	5 / 36 (13.89%)	
occurrences (all)	2	5	
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Syncope			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Neuropathy peripheral			
subjects affected / exposed	8 / 13 (61.54%)	17 / 36 (47.22%)	
occurrences (all)	11	23	
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 13 (15.38%)	2 / 36 (5.56%)	
occurrences (all)	2	2	
Tremor			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Neutropenia			
subjects affected / exposed	3 / 13 (23.08%)	2 / 36 (5.56%)	
occurrences (all)	4	3	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Dry eye			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Eye irritation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Eye pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hyphaema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Eyelid ptosis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Vision blurred			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Lacrimation increased			
subjects affected / exposed	3 / 13 (23.08%)	0 / 36 (0.00%)	
occurrences (all)	3	0	
Gastrointestinal disorders			

Constipation			
subjects affected / exposed	5 / 13 (38.46%)	14 / 36 (38.89%)	
occurrences (all)	5	15	
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Diarrhoea			
subjects affected / exposed	5 / 13 (38.46%)	11 / 36 (30.56%)	
occurrences (all)	11	11	
Dyspepsia			
subjects affected / exposed	2 / 13 (15.38%)	2 / 36 (5.56%)	
occurrences (all)	2	3	
Mouth ulceration			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Dry mouth			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Oral pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	4 / 13 (30.77%)	13 / 36 (36.11%)	
occurrences (all)	6	17	
Toothache			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Stomatitis			
subjects affected / exposed	3 / 13 (23.08%)	4 / 36 (11.11%)	
occurrences (all)	3	4	
Vomiting			
subjects affected / exposed	1 / 13 (7.69%)	5 / 36 (13.89%)	
occurrences (all)	2	5	
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	3 / 13 (23.08%)	11 / 36 (30.56%)		
occurrences (all)	4	11		
Dermatitis acneiform				
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)		
occurrences (all)	0	2		
Dry skin				
subjects affected / exposed	1 / 13 (7.69%)	7 / 36 (19.44%)		
occurrences (all)	1	8		
Nail disorder				
subjects affected / exposed	3 / 13 (23.08%)	4 / 36 (11.11%)		
occurrences (all)	3	4		
Dermatitis allergic				
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)		
occurrences (all)	0	2		
Erythema				
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)		
occurrences (all)	1	1		
Onycholysis				
subjects affected / exposed	2 / 13 (15.38%)	6 / 36 (16.67%)		
occurrences (all)	2	6		
Onychomadesis				
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)		
occurrences (all)	0	2		
Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	2 / 13 (15.38%)	2 / 36 (5.56%)		
occurrences (all)	2	2		
Pruritus				
subjects affected / exposed	3 / 13 (23.08%)	3 / 36 (8.33%)		
occurrences (all)	3	3		
Rash maculo-papular				
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)		
occurrences (all)	0	3		
Rash				
subjects affected / exposed	4 / 13 (30.77%)	6 / 36 (16.67%)		
occurrences (all)	6	8		

Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	2 / 13 (15.38%)	3 / 36 (8.33%)	
occurrences (all)	9	6	
Haematuria			
subjects affected / exposed	1 / 13 (7.69%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	6 / 36 (16.67%)	
occurrences (all)	1	8	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Back pain			
subjects affected / exposed	1 / 13 (7.69%)	5 / 36 (13.89%)	
occurrences (all)	1	5	
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Musculoskeletal pain			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Pain in extremity			
subjects affected / exposed	1 / 13 (7.69%)	5 / 36 (13.89%)	
occurrences (all)	1	6	
Infections and infestations			
Catheter site infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	

Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Fungal infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Herpes simplex			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	3 / 13 (23.08%)	2 / 36 (5.56%)	
occurrences (all)	3	2	
Nail infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Nasopharyngitis			
subjects affected / exposed	2 / 13 (15.38%)	5 / 36 (13.89%)	
occurrences (all)	3	6	
Paronychia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Oral herpes			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	3	1	
Tooth abscess			
subjects affected / exposed	2 / 13 (15.38%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Urinary tract infection			
subjects affected / exposed	3 / 13 (23.08%)	8 / 36 (22.22%)	
occurrences (all)	3	12	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	

Vulvovaginal candidiasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 13 (15.38%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Hyperglycaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 February 2011	Docetaxel was removed as a treatment combination option, following the decision by the European Medicines Agency (EMA) to follow the recommendation of the Committee for Medicinal Products for Human Use (CHMP) to remove docetaxel from the Avastin product licence.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported