EU Clinical Trials Register

Clinical trial results:
A 52-Week, Open-Label, Single-Arm Study to Evaluate the Safety and Tolerability of 24-Hour Daily Exposure of Continuous Subcutaneous Infusion of ABBV-951 in Subjects with Parkinson's Disease

Summary

EudraCT number	2018-002144-85
Trial protocol	GB DK NL ES BE DE IT
Global end of trial date	17 August 2022

Results information

Result version number	v2 (current)
This version publication date	10 November 2023
First version publication date	30 August 2023
Version creation reason	• Correction of full data set Minor clarifying edits to related to units of measure and an endpoint title.

Trial information

Trial identification

Sponsor protocol code	M15-741

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03781167
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.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	17 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to assess the safety and tolerability of ABBV-951 (Foslevodopa/Foscarbidopa) in participants with Parkinson's disease (PD).

This was a single-arm study with preplanned analyses conducted by dose subgroup (Low Dose or High Dose) based on the modal total daily dose (most frequent dose) over the treatment period.

Protection of trial subjects:	
Subject read and understood the information provided about the study and gave written permission.	
Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	29 April 2019
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	Belgium: 7
Country: Number of subjects enrolled	Canada: 9
Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Denmark: 9
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Japan: 27
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Russian Federation: 8
Country: Number of subjects enrolled	Spain: 28
Country: Number of subjects enrolled	Sweden: 8
Country: Number of subjects enrolled	United Kingdom: 13
Country: Number of subjects enrolled	United States: 81
Worldwide total number of subjects	244
EEA total number of subjects	79

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)	119
From 65 to 84 years	124
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study had a 10 to 42-day Screening Period, during which a 6-day Monitoring Period was completed.

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	ABBV-951 Low Dose Subgroup

Arm description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was < 2530 mg of Foslevodopa/day were analyzed as the Low Dose Subgroup.

Arm type	Experimental
Investigational medicinal product name	ABBV-951
Investigational medicinal product code	
Other name	Foslevodopa/Foscarbidopa
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Solution for continuous subcutaneous infusion (CSCI)

Arm title	ABBV-951 High Dose Subgroup

Arm description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was ≥ 2530 mg of Foslevodopa/day were analyzed as the High Dose Subgroup.

Arm type	Experimental
Investigational medicinal product name	ABBV-951
Investigational medicinal product code	
Other name	Foslevodopa/Foscarbidopa
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Solution for continuous subcutaneous infusion (CSCI)

Number of subjects in period 1	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup
Started	131	113
Completed	84	65
Not completed	47	48
Adverse event, non-fatal	23	25
Other, not specified	2	2
Withdrew consent	16	12
Lost to follow-up	-	1
Difficulty with drug delivery system	2	3
Lack of efficacy	4	5

Baseline characteristics

Reporting groups

Reporting group title	ABBV-951 Low Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was < 2530 mg of Foslevodopa/day were analyzed as the Low Dose Subgroup.

Reporting group title	ABBV-951 High Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was ≥ 2530 mg of Foslevodopa/day were analyzed as the High Dose Subgroup.

Reporting group values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	Total
Number of subjects	131	113	244
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	63.5	64.4	
standard deviation	± 8.87	± 9.54	-
Gender categorical			
Units: Subjects			
Female	66	32	98
Male	65	81	146
Ethnicity			
Units: Subjects			
Hispanic or Latino	8	12	20
Not Hispanic or Latino	123	101	224
Unknown or Not Reported	0	0	0
Race			
Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	27	7	34
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	102	105	207
More than one race	1	0	1
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	ABBV-951 Low Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was < 2530 mg of Foslevodopa/day were analyzed as the Low Dose Subgroup.

Reporting group title	ABBV-951 High Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was ≥ 2530 mg of Foslevodopa/day were analyzed as the High Dose Subgroup.

Subject analysis set title	ABBV-951 Low Dose Subgroup
Subject analysis set type	Per protocol

Subject analysis set description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was < 2530 mg of Foslevodopa/day were analyzed as the Low Dose Subgroup.

Subject analysis set title	ABBV-951 High Dose Subgroup
Subject analysis set type	Per protocol

Subject analysis set description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was ≥ 2530 mg of Foslevodopa/day were analyzed as the High Dose Subgroup.

Subject analysis set title	ABBV-951 All Participants
Subject analysis set type	Per protocol

Subject analysis set description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period.

Primary: Number of Participants With Adverse Events

End point title	Number of Participants With Adverse Events[1]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product which does not necessarily have a causal relationship with this treatment. The investigator assesses the relationship of each event to the use of study drug. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent adverse events/treatment-emergent serious adverse events (TEAEs/TESAEs) are defined as any event that began or worsened in severity on or after the first dose of study drug.

End point type	Primary

End point timeframe:

From first dose of study drug until 30 days following last dose of study drug (up to 480 days)

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: Descriptive data are summarized for this end point per protocol.

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[2]	113[3]	244[4]	
Units: participants				
Any TEAE	121	109	230	
TESAE	32	31	63	

Notes:

[2] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[3] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[4] - Safety Analysis Set: all participants who received any ABBV-951 infusion

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Adverse Events of Special Interest

End point title	Number of Participants With Adverse Events of Special

End point description:

Treatment emergent adverse events of special interest are defined as any adverse event of infusion site infections, infusion site reactions, hallucinations/psychosis, falls and associated injuries, polyneuropathy (peripheral neuropathy), weight loss, or somnolence from the first dose of study drug until 30 days following last dose of study drug.

End point type	Primary

End point timeframe:

From first dose of study drug until 30 days following last dose of study drug (up to 480 days)

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: Descriptive data are summarized for this end point per protocol.

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[6]	113[7]	244[8]	
Units: participants				
Infusion site infections	42	44	86	
Infusion site reactions	103	97	200	
Hallucinations/psychosis	32	29	61	
Falls and associated injuries	37	37	74	
Polyneuropathy (peripheral neuropathy)	14	13	27	
Weight loss	12	15	27	
Somnolence	9	3	12	

Notes:

[6] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[7] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[8] - Safety Analysis Set: all participants who received any ABBV-951 infusion

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Numeric Grade Equal to or Higher Than 5 and With Letter Grade Equal to or Higher Than D on the Infusion Site Evaluation Scale

End point title	Number of Participants With Numeric Grade Equal to or Higher Than 5 and With Letter Grade Equal to or Higher Than D on the Infusion Site Evaluation Scale[9]

End point description:

Skin tolerability was assessed using the Infusion Site Evaluation Scale, a 2-part numeric (0-7) and letter (A-G) grade scale, where a notable skin reaction is defined as a reaction with a numeric grade of 6 or 7 or a letter grade of D, E, F, or G. Any observation of infusion site reaction with irritation criteria > 2 or > C was recorded as an adverse event (AE).

End point type	Primary

End point timeframe:

Day 1, Day 2, Week 1, Week 2, Week 3, Week 4, Week 6, Week 13, Week 26, Week 39, and Week 52

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: Descriptive data are summarized for this end point per protocol.

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[10]	113[11]	244[12]	
Units: participants	10	15	25	

Notes:

[10] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[11] - Safety Analysis Set: all participants who received any ABBV-951 infusion

[12] - Safety Analysis Set: all participants who received any ABBV-951 infusion

Statistical analyses

No statistical analyses for this end point

Primary: Hematocrit (Hematology): Change From Baseline to End of Study

End point title	Hematocrit (Hematology): Change From Baseline to End of Study[13]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol.

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	128[14]	113[15]	241[16]	
Units: proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week 6 (n=94, 91, 185)	-0.02 (± 0.031)	-0.02 (± 0.029)	-0.02 (± 0.030)	
Week 26 (n=69, 61, 130)	-0.01 (± 0.030)	-0.02 (± 0.026)	-0.02 (± 0.028)	
Week 39 (n=61, 53, 114)	-0.02 (± 0.028)	-0.02 (± 0.029)	-0.02 (± 0.028)	
Week 52 (n=62, 56, 118)	-0.02 (± 0.029)	-0.02 (± 0.028)	-0.02 (± 0.029)	

Notes:

[14] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[15] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[16] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Hemoglobin (Hematology): Change From Baseline to End of Study

End point title	Hemoglobin (Hematology): Change From Baseline to End of Study[17]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[17] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[18]	113[19]	243[20]	
Units: g/L				
arithmetic mean (standard deviation)				
Week 6 (n=98, 93, 191)	-5.00 (± 8.308)	-6.82 (± 9.222)	-5.89 (± 8.789)	
Week 26 (n=71, 63, 134)	-5.42 (± 9.296)	-4.48 (± 7.502)	-4.98 (± 8.482)	

Week 39 (n=68, 53, 121)	-5.74 (± 8.430)	-6.58 (± 8.601)	-6.11 (± 8.480)	
Week 52 (n=69, 56, 125)	-7.96 (± 8.862)	-5.80 (± 9.308)	-6.99 (± 9.091)	

Notes:

[18] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[19] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[20] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Red Blood Cell (RBC) Count (Hematology): Change From Baseline to End of Study

End point title	Red Blood Cell (RBC) Count (Hematology): Change From Baseline to End of Study[21]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[21] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[22]	113[23]	243[24]	
Units: cells*10^12/L				
arithmetic mean (standard deviation)				
Week 6 (n=96, 93, 189)	-0.15 (± 0.261)	-0.21 (± 0.296)	-0.18 (± 0.280)	
Week 26 (n=71, 63, 134)	-0.12 (± 0.295)	-0.13 (± 0.273)	-0.13 (± 0.284)	
Week 39 (n=68, 53, 121)	-0.14 (± 0.271)	-0.19 (± 0.290)	-0.17 (± 0.279)	
Week 52 (n=69, 56, 125)	-0.21 (± 0.291)	-0.16 (± 0.293)	-0.19 (± 0.292)	

Notes:

[22] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[23] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[24] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: White Blood Cell (WBC) Count (Hematology): Change From Baseline to End of Study

End point title	White Blood Cell (WBC) Count (Hematology): Change From

	Baseline to End of Study[25]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[26]	113[27]	243[28]	
Units: cells*10^9/L				
arithmetic mean (standard deviation)				
Week 6 (n=98, 93, 191)	0.02 (± 1.705)	0.32 (± 2.120)	0.17 (± 1.919)	
Week 26 (n=71, 63, 134)	0.12 (± 1.892)	0.22 (± 2.990)	0.17 (± 2.460)	
Week 39 (n=69, 53, 122)	0.35 (± 4.014)	0.38 (± 1.670)	0.36 (± 3.202)	
Week 52 (n=69, 56, 125)	-0.08 (± 2.027)	-0.04 (± 1.568)	-0.06 (± 1.829)	

Notes:

[26] - The statistical analysis results are presented in the endpoint data table, per protocol

[27] - The statistical analysis results are presented in the endpoint data table, per protocol

[28] - The statistical analysis results are presented in the endpoint data table, per protocol

Statistical analyses

No statistical analyses for this end point

Primary: Neutrophils (Hematology): Change From Baseline to End of Study

End point title	Neutrophils (Hematology): Change From Baseline to End of Study[29]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[30]	113[31]	243[32]	
Units: cells*10^9/L				
arithmetic mean (standard deviation)				
Week 6 (n=97, 92, 189)	0.01 (± 1.720)	0.33 (± 2.102)	0.17 (± 1.917)	
Week 26 (n=71, 63, 134)	-0.03 (± 1.813)	143.08 (± 1133.988)	67.25 (± 777.558)	
Week 39 (n=68, 53, 121)	-0.23 (± 2.380)	0.18 (± 1.635)	-0.05 (± 2.089)	
Week 52 (n=69, 56, 125)	-0.14 (± 1.986)	-0.04 (± 1.498)	-0.10 (± 1.778)	

Notes:

[30] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[31] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[32] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Lymphocytes (Hematology): Change From Baseline to End of Study

End point title	Lymphocytes (Hematology): Change From Baseline to End of Study[33]
End point description:	
Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.	
End point type	Primary
End point timeframe:	
Baseline, Weeks 6, 26, 39, and 52	

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[34]	113[35]	243[36]	
Units: cells*10^9/L				
arithmetic mean (standard deviation)				
Week 6 (n=97, 92, 189)	0.06 (± 0.305)	-0.07 (± 0.326)	0.00 (± 0.321)	
Week 26 (n=71, 63, 134)	0.09 (± 0.331)	13.92 (± 110.588)	6.59 (± 75.823)	
Week 39 (n=68, 53, 121)	0.03 (± 0.394)	0.04 (± 0.312)	0.03 (± 0.359)	
Week 52 (n=69, 56, 125)	0.04 (± 0.394)	-0.05 (± 0.294)	0.00 (± 0.354)	

Notes:

[34] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[35] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Monocytes (Hematology): Change From Baseline to End of Study

End point title	Monocytes (Hematology): Change From Baseline to End of Study[37]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[37] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[38]	113[39]	243[40]	
Units: cells*10^9/L				
arithmetic mean (standard deviation)				
Week 6 (n=96, 92, 188)	0.01 (± 0.127)	0.01 (± 0.123)	0.01 (± 0.125)	
Week 26 (n=71, 63, 134)	0.02 (± 0.095)	17.43 (± 138.498)	8.21 (± 94.963)	
Week 39 (n=68, 53, 121)	0.02 (± 0.120)	0.03 (± 0.122)	0.02 (± 0.120)	
Week 52 (n=69, 56, 125)	0.00 (± 0.109)	0.01 (± 0.132)	0.00 (± 0.119)	

Notes:

[38] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[39] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[40] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Absolute Platelet Count (Hematology): Change From Baseline to End of Study

End point title	Absolute Platelet Count (Hematology): Change From Baseline to End of Study[41]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[42]	112[43]	242[44]	
Units: cells*10^9/L				
arithmetic mean (standard deviation)				
Week 6 (n=96, 92, 188)	4.59 (± 36.489)	0.39 (± 40.844)	2.54 (± 38.635)	
Week 26 (n=71, 62, 133)	-1.68 (± 43.279)	-10.39 (± 43.757)	-5.74 (± 43.556)	
Week 39 (n=68, 52, 120)	-3.90 (± 43.848)	-7.29 (± 49.222)	-5.37 (± 46.084)	
Week 52 (n=69, 54, 123)	-3.41 (± 41.120)	-10.63 (± 44.537)	-6.58 (± 42.628)	

Notes:

[42] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[43] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[44] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Mean Corpuscular Hemoglobin (Hematology): Change From Baseline to End of Study

End point title	Mean Corpuscular Hemoglobin (Hematology): Change From Baseline to End of Study[45]
End point description:	

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process
the samples and provide results.

End point type	Primary
End point timeframe:	

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[46]	113[47]	243[48]	
Units: picograms				
arithmetic mean (standard deviation)				

Week 6 (n=96, 92, 188)	-0.09 (± 0.822)	-0.15 (± 0.825)	-0.12 (± 0.821)	
Week 26 (n=71, 62, 133)	-0.38 (± 1.033)	0.05 (± 1.078)	-0.18 (± 1.072)	
Week 39 (n=68, 53, 121)	-0.34 (± 1.205)	-0.08 (± 0.978)	-0.22 (± 1.114)	
Week 52 (n=69, 56, 125)	-0.36 (± 1.124)	-0.07 (± 1.142)	-0.23 (± 1.137)	

Notes:

[46] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[47] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[48] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Mean Corpuscular Volume Concentration (MCHC) (Hematology): Change From Baseline to End of Study

End point title	Mean Corpuscular Volume Concentration (MCHC) (Hematology): Change From Baseline to End of Study[49]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process
the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	128[50]	113[51]	241[52]	
Units: g/L				
arithmetic mean (standard deviation)				
Week 6 (n=93, 90, 183)	2.15 (± 11.689)	1.78 (± 10.870)	1.97 (± 11.264)	
Week 26 (n=69, 60, 129)	-1.30 (± 14.844)	2.17 (± 15.741)	0.31 (± 15.306)	
Week 39 (n=61, 53, 114)	-2.13 (± 13.677)	-2.64 (± 14.826)	-2.37 (± 14.161)	
Week 52 (n=62, 56, 118)	-0.16 (± 12.609)	0.18 (± 13.684)	0.00 (± 13.074)	

Notes:

[50] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[51] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[52] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Prothrombin Time (PT) (Hematology): Change From Baseline to End of Study

End point title	Prothrombin Time (PT) (Hematology): Change From Baseline to End of Study[53]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[54]	113[55]	244[56]	
Units: seconds				
arithmetic mean (standard deviation)				
Week 6 (n=100, 93, 193)	0.03 (± 0.480)	-0.09 (± 2.556)	-0.03 (± 1.803)	
Week 26 (n=70, 57, 127)	-0.08 (± 1.026)	-0.36 (± 3.187)	-0.20 (± 2.261)	
Week 39 (n=70, 51, 121)	0.10 (± 0.569)	-0.21 (± 3.396)	-0.03 (± 2.239)	
Week 52 (n=72, 52, 124)	0.10 (± 0.889)	-0.22 (± 3.703)	-0.04 (± 2.483)	

Notes:

[54] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[55] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[56] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Activated Partial Thromboplastin Time (Hematology): Change From Baseline to End of Study

End point title	Activated Partial Thromboplastin Time (Hematology): Change From Baseline to End of Study[57]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[58]	113[59]	244[60]	
Units: seconds				
arithmetic mean (standard deviation)				
Week 6 (n=100, 93, 193)	-0.27 (± 2.151)	0.55 (± 2.483)	0.13 (± 2.347)	
Week 26 (n=70, 57, 127)	-0.02 (± 1.898)	0.48 (± 1.932)	0.20 (± 1.922)	
Week 39 (n=70, 51, 121)	0.14 (± 1.556)	0.67 (± 3.672)	0.36 (± 2.661)	
Week 52 (n=71, 51, 122)	-0.09 (± 2.156)	0.88 (± 2.992)	0.32 (± 2.573)	

Notes:

[58] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[59] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[60] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Blood Urea Nitrogen (BUN) (Clinical Chemistry): Change From Baseline to End of Study

End point title	Blood Urea Nitrogen (BUN) (Clinical Chemistry): Change From Baseline to End of Study[61]
End point description:	

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary
End point timeframe:	

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[62]	113[63]	244[64]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	0.02 (± 1.348)	-0.01 (± 1.560)	0.00 (± 1.450)	
Week 26 (n=75, 62, 137)	0.21 (± 1.489)	0.17 (± 1.600)	0.19 (± 1.535)	
Week 39 (n=72, 55, 127)	0.41 (± 1.852)	0.05 (± 1.659)	0.25 (± 1.773)	
Week 52 (n=74, 56, 130)	0.16 (± 1.836)	0.15 (± 1.342)	0.16 (± 1.636)	

Notes:

[62] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[63] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[64] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Creatinine (Clinical Chemistry): Change From Baseline to End of Study

End point title	Creatinine (Clinical Chemistry): Change From Baseline to End of Study[65]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[66]	113[67]	244[68]	
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=104, 96, 200)	-4.45 (± 9.227)	-5.67 (± 10.725)	-5.04 (± 9.968)	
Week 26 (n=75, 63, 138)	-2.71 (± 10.478)	-4.07 (± 12.074)	-3.33 (± 11.213)	
Week 39 (n=72, 55, 127)	-1.47 (± 12.414)	-4.02 (± 10.182)	-2.58 (± 11.527)	
Week 52 (n=74, 56, 130)	-4.78 (± 11.446)	-5.21 (± 9.941)	-4.96 (± 10.785)	

Notes:

[66] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[67] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[68] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Creatine Phosphokinase (Clinical Chemistry): Change From Baseline to End of Study

End point title	Creatine Phosphokinase (Clinical Chemistry): Change From Baseline to End of Study[69]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[69] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[70]	113[71]	244[72]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	2.52 (± 56.209)	-11.01 (± 94.662)	-4.01 (± 77.285)	
Week 26 (n=75, 61, 136)	5.61 (± 51.627)	-15.44 (± 62.435)	-3.83 (± 57.480)	
Week 39 (n=72, 54, 126)	8.40 (± 96.021)	-9.67 (± 75.655)	0.66 (± 88.002)	
Week 52 (n=74, 56, 130)	30.39 (± 125.044)	-16.55 (± 85.305)	10.17 (± 111.783)	

Notes:

[70] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[71] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[72] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Total Bilirubin (Clinical Chemistry): Change From Baseline to End of Study

End point title	Total Bilirubin (Clinical Chemistry): Change From Baseline to End of Study[73]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[74]	113[75]	244[76]	
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-0.85 (± 3.420)	-0.15 (± 3.167)	-0.51 (± 3.311)	
Week 26 (n=75, 61, 136)	-0.43 (± 3.535)	0.28 (± 2.814)	-0.11 (± 3.240)	
Week 39 (n=72, 55, 127)	-0.71 (± 2.881)	0.31 (± 3.754)	-0.27 (± 3.313)	
Week 52 (n=74, 56, 130)	-0.30 (± 3.673)	-0.15 (± 3.250)	-0.24 (± 3.485)	

Notes:

[74] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[75] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[76] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Serum Alanine Aminotransferase (Clinical Chemistry): Change From Baseline to End of Study

End point title	Serum Alanine Aminotransferase (Clinical Chemistry): Change From Baseline to End of Study[77]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[77] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[78]	113[79]	244[80]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-8.94 (± 8.928)	-11.28 (± 10.053)	-10.07 (± 9.535)	
Week 26 (n=75, 61, 136)	-8.95 (± 9.869)	-11.66 (± 11.294)	-10.16 (± 10.579)	
Week 39 (n=71, 54, 125)	-9.70 (± 9.145)	-10.09 (± 13.476)	-9.87 (± 11.175)	
Week 52 (n=73, 56, 129)	-9.37 (± 10.347)	-12.11 (± 9.947)	-10.56 (± 10.227)	

Notes:

[78] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[79] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[80] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Serum Aspartate Aminotransferase (Clinical Chemistry): Change From Baseline to End of Study

End point title	Serum Aspartate Aminotransferase (Clinical Chemistry): Change From Baseline to End of Study[81]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[82]	113[83]	244[84]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=102, 95, 197)	-1.89 (± 4.881)	-2.21 (± 6.163)	-2.05 (± 5.524)	
Week 26 (n=74, 59, 133)	-0.69 (± 8.569)	-2.56 (± 7.013)	-1.52 (± 7.943)	
Week 39 (n=72, 54, 126)	-1.38 (± 6.714)	-1.17 (± 7.036)	-1.29 (± 6.827)	
Week 52 (n=73, 55, 128)	-0.81 (± 6.576)	-0.82 (± 7.794)	-0.81 (± 7.095)	

Notes:

[82] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[83] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[84] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Serum Lactate Dehydrogenase (LDH) (Clinical Chemistry): Change From Baseline to End of Study

End point title	Serum Lactate Dehydrogenase (LDH) (Clinical Chemistry): Change From Baseline to End of Study[85]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[85] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	129[86]	109[87]	238[88]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=93, 89, 182)	-6.57 (± 26.734)	-8.58 (± 23.626)	-7.55 (± 25.213)	
Week 26 (n=67, 56, 123)	-1.66 (± 23.894)	-4.91 (± 23.613)	-3.14 (± 23.725)	
Week 39 (n=59, 47, 106)	-2.17 (± 25.010)	-2.02 (± 26.431)	-2.10 (± 25.526)	

Week 52 (n=71, 47, 118)	0.14 (± 22.788)	3.32 (± 26.413)	1.41 (± 24.237)	

Notes:

[86] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[87] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[88] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Gamma-glutamyl Transferase (Clinical Chemistry): Change From Baseline to End of Study

End point title	Gamma-glutamyl Transferase (Clinical Chemistry): Change From Baseline to End of Study[89]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[90]	113[91]	244[92]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-1.07 (± 9.516)	-3.13 (± 9.393)	-2.06 (± 9.489)	
Week 26 (n=75, 62, 137)	-1.47 (± 11.487)	-5.02 (± 15.370)	-3.07 (± 13.450)	
Week 39 (n=72, 54, 126)	-1.92 (± 10.860)	-4.67 (± 12.516)	-3.10 (± 11.631)	
Week 52 (n=74, 56, 130)	1.69 (± 23.235)	-3.09 (± 14.538)	-0.37 (± 20.031)	

Notes:

[90] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[91] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[92] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Alkaline Phosphatase (Clinical Chemistry): Change From Baseline to End of Study

End point title	Alkaline Phosphatase (Clinical Chemistry): Change From Baseline to End of Study[93]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was

used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[94]	113[95]	244[96]	
Units: U/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-1.91 (± 12.394)	-4.56 (± 12.340)	-3.19 (± 12.408)	
Week 26 (n=75, 63, 138)	1.68 (± 18.995)	-2.86 (± 14.157)	-0.39 (± 17.051)	
Week 39 (n=72, 55, 127)	-2.28 (± 12.252)	-5.02 (± 16.088)	-3.46 (± 14.049)	
Week 52 (n=74, 56, 130)	0.55 (± 18.637)	-1.54 (± 13.796)	-0.35 (± 16.697)	

Notes:

[94] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[95] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[96] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Sodium (Clinical Chemistry): Change From Baseline to End of Study

End point title	Sodium (Clinical Chemistry): Change From Baseline to End of Study[97]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[98]	113[99]	244[100]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 95, 198)	-0.52 (± 3.168)	-1.06 (± 2.592)	-0.78 (± 2.911)	

Week 26 (n=74, 61, 135)	-0.35 (± 3.173)	-1.26 (± 2.744)	-0.76 (± 3.010)	
Week 39 (n=72, 53, 125)	-0.90 (± 2.984)	-0.68 (± 2.772)	-0.81 (± 2.887)	
Week 52 (n=73, 56, 129)	-0.55 (± 2.774)	-0.84 (± 2.164)	-0.67 (± 2.522)	

Notes:

[98] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[99] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[100] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Potassium (Clinical Chemistry): Change From Baseline to End of Study

End point title	Potassium (Clinical Chemistry): Change From Baseline to End of Study[101]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[102]	113[103]	244[104]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-0.02 (± 0.335)	-0.08 (± 0.330)	-0.05 (± 0.333)	
Week 26 (n=74, 61, 135)	0.01 (± 0.367)	0.00 (± 0.373)	0.00 (± 0.368)	
Week 39 (n=72, 52, 124)	-0.01 (± 0.389)	-0.09 (± 0.382)	-0.04 (± 0.387)	
Week 52 (n=73, 56, 129)	-0.10 (± 0.369)	-0.03 (± 0.338)	-0.07 (± 0.357)	

Notes:

[102] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[103] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[104] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Calcium (Clinical Chemistry): Change From Baseline to End of Study

End point title	Calcium (Clinical Chemistry): Change From Baseline to End of Study[105]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[106]	113[107]	244[108]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-0.02 (± 0.079)	-0.04 (± 0.086)	-0.03 (± 0.083)	
Week 26 (n=75, 63, 138)	-0.03 (± 0.080)	-0.04 (± 0.091)	-0.03 (± 0.085)	
Week 39 (n=72, 55, 127)	-0.04 (± 0.091)	-0.05 (± 0.087)	-0.05 (± 0.089)	
Week 52 (n=74, 56, 130)	-0.06 (± 0.084)	-0.04 (± 0.092)	-0.05 (± 0.088)	

Notes:

[106] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[107] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[108] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Inorganic Phosphorus (Clinical Chemistry): Change From Baseline to End of Study

End point title	Inorganic Phosphorus (Clinical Chemistry): Change From Baseline to End of Study[109]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[110]	113[111]	244[112]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	0.08 (± 0.173)	0.08 (± 0.168)	0.08 (± 0.170)	
Week 26 (n=75, 62, 137)	0.09 (± 0.182)	0.09 (± 0.170)	0.09 (± 0.176)	
Week 39 (n=72, 55, 127)	0.07 (± 0.165)	0.08 (± 0.155)	0.08 (± 0.160)	
Week 52 (n=74, 56, 130)	0.09 (± 0.169)	0.08 (± 0.172)	0.08 (± 0.170)	

Notes:

[110] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[111] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[112] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Uric Acid (Clinical Chemistry): Change From Baseline to End of Study

End point title	Uric Acid (Clinical Chemistry): Change From Baseline to End of Study[113]
End point description:	
Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.	
End point type	Primary
End point timeframe:	
Baseline, Weeks 6, 26, 39, and 52	

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[114]	113[115]	244[116]	
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-28.36 (± 51.219)	-37.43 (± 37.302)	-32.73 (± 45.163)	
Week 26 (n=75, 62, 137)	-16.66 (± 60.922)	-32.91 (± 34.446)	-24.01 (± 51.163)	
Week 39 (n=72, 55, 127)	-13.55 (± 57.830)	-35.80 (± 40.965)	-23.18 (± 52.213)	
Week 52 (n=74, 56, 130)	-15.27 (± 56.459)	-31.23 (± 29.780)	-22.15 (± 47.380)	

Notes:

[114] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[115] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[116] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Total Cholesterol (Clinical Chemistry): Change From Baseline to End of Study

End point title	Total Cholesterol (Clinical Chemistry): Change From Baseline to End of Study[117]
End point description:	
Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.	
End point type	Primary
End point timeframe:	
Baseline, Weeks 6, 26, 39, and 52	
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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[118]	113[119]	244[120]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=102, 95, 197)	-0.37 (± 0.688)	-0.57 (± 0.556)	-0.47 (± 0.634)	
Week 26 (n=74, 62, 136)	-0.19 (± 0.657)	-0.31 (± 0.661)	-0.25 (± 0.659)	
Week 39 (n=72, 53, 125)	-0.33 (± 0.565)	-0.41 (± 0.552)	-0.36 (± 0.559)	
Week 52 (n=73, 56, 129)	-0.31 (± 0.660)	-0.25 (± 0.594)	-0.29 (± 0.630)	

Notes:

[118] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[119] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[120] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Albumin (Clinical Chemistry): Change From Baseline to End of Study

End point title	Albumin (Clinical Chemistry): Change From Baseline to End of Study[121]
End point description:	
Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.	
End point type	Primary
End point timeframe:	
Baseline, Weeks 6, 26, 39, and 52	
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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[122]	113[123]	244[124]	
Units: g/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 96, 199)	-1.65 (± 2.782)	-1.95 (± 2.885)	-1.79 (± 2.829)	
Week 26 (n=75, 63, 138)	-1.31 (± 2.541)	-1.14 (± 2.558)	-1.23 (± 2.541)	
Week 39 (n=72, 55, 127)	-1.75 (± 2.782)	-1.56 (± 2.507)	-1.67 (± 2.658)	
Week 52 (n=74, 56, 130)	-1.96 (± 2.949)	-1.02 (± 3.205)	-1.55 (± 3.086)	

Notes:

[122] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[123] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[124] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Glucose (Clinical Chemistry): Change From Baseline to End of Study

End point title	Glucose (Clinical Chemistry): Change From Baseline to End of Study[125]
End point description:	

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary
End point timeframe:	

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[126]	113[127]	244[128]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 97, 200)	-0.39 (± 1.186)	-0.39 (± 1.438)	-0.39 (± 1.311)	
Week 26 (n=75, 63, 138)	-0.37 (± 1.271)	-0.14 (± 1.486)	-0.27 (± 1.373)	
Week 39 (n=72, 55, 127)	-0.33 (± 1.181)	-0.60 (± 1.327)	-0.45 (± 1.249)	
Week 52 (n=74, 56, 130)	-0.32 (± 1.917)	-0.55 (± 1.479)	-0.42 (± 1.740)	

Notes:

[126] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[127] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[128] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Sodium Bicarbonate/CO2 (Clinical Chemistry): Change From Baseline to End of Study

End point title	Sodium Bicarbonate/CO2 (Clinical Chemistry): Change From Baseline to End of Study[129]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[129] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[130]	113[131]	243[132]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=100, 94, 194)	1.19 (± 2.372)	0.97 (± 2.518)	1.09 (± 2.440)	
Week 26 (n=71, 60, 131)	0.77 (± 2.418)	0.28 (± 2.744)	0.55 (± 2.574)	
Week 39 (n=67, 50, 117)	0.90 (± 2.240)	0.63 (± 2.874)	0.78 (± 2.522)	
Week 52 (n=72, 55, 127)	0.78 (± 2.374)	0.57 (± 2.304)	0.69 (± 2.337)	

Notes:

[130] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[131] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[132] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Magnesium (Clinical Chemistry): Change From Baseline to End of Study

End point title	Magnesium (Clinical Chemistry): Change From Baseline to End of Study[133]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[134]	113[135]	244[136]	
Units: mmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=103, 95, 198)	-0.03 (± 0.067)	-0.03 (± 0.058)	-0.03 (± 0.063)	
Week 26 (n=74, 61, 135)	-0.03 (± 0.064)	-0.02 (± 0.062)	-0.02 (± 0.063)	
Week 39 (n=72, 53, 125)	-0.02 (± 0.076)	-0.01 (± 0.073)	-0.02 (± 0.075)	
Week 52 (n=73, 56, 129)	-0.03 (± 0.078)	-0.01 (± 0.057)	-0.02 (± 0.070)	

Notes:

[134] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[135] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[136] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Creatinine Clearance (Clinical Chemistry): Change From Baseline to End of Study

End point title	Creatinine Clearance (Clinical Chemistry): Change From Baseline to End of Study[137]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results. "99999" indicates values that could not be estimated due to low number of participants.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	1[138]	1[139]	2[140]	
Units: mL/sec/1.73m^2				
arithmetic mean (standard deviation)				
Week 6 (n=1, 1, 2)	-0.08 (± 99999)	0.00 (± 99999)	-0.04 (± 0.059)	
Week 26 (n=0, 1, 1)	99999 (± 99999)	-0.17 (± 99999)	-0.17 (± 99999)	
Week 39 (n=0, 0, 0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	
Week 52 (n=0, 0, 0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	

Notes:

[138] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Homocysteine (Clinical Chemistry): Change From Baseline to End of Study

End point title	Homocysteine (Clinical Chemistry): Change From Baseline to End of Study[141]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[142]	113[143]	244[144]	
Units: µmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=105, 95, 200)	3.07 (± 5.301)	6.70 (± 11.040)	4.79 (± 8.692)	
Week 26 (n=76, 61, 137)	4.22 (± 7.549)	6.69 (± 6.306)	5.32 (± 7.106)	
Week 52 (n=73, 52, 125)	4.88 (± 6.103)	7.24 (± 8.687)	5.86 (± 7.351)	

Notes:

[142] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[143] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[144] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Vitamin B6 (Clinical Chemistry): Change From Baseline to End of Study

End point title	Vitamin B6 (Clinical Chemistry): Change From Baseline to End of Study[145]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[146]	113[147]	244[148]	
Units: nmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=104, 94, 198)	0.30 (± 129.306)	4.68 (± 87.199)	2.38 (± 111.069)	
Week 26 (n=76, 62, 138)	-4.50 (± 89.013)	14.10 (± 103.462)	3.86 (± 95.865)	
Week 52 (n=71, 54, 125)	-0.32 (± 124.059)	44.30 (± 124.456)	18.95 (± 125.703)	

Notes:

[146] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[147] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[148] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Vitamin B12 (Clinical Chemistry): Change From Baseline to End of Study

End point title	Vitamin B12 (Clinical Chemistry): Change From Baseline to End of Study[149]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, and 52

Notes:

[149] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[150]	113[151]	244[152]	
Units: pmol/L				
arithmetic mean (standard deviation)				
Week 6 (n=104, 94, 198)	-229.58 (± 1349.008)	-206.30 (± 2217.016)	-218.53 (± 1808.859)	
Week 26 (n=76, 63, 139)	-147.38 (± 845.662)	-143.30 (± 1033.488)	-145.53 (± 931.955)	
Week 52 (n=74, 54, 128)	-268.44 (± 1684.785)	-212.84 (± 1096.656)	-244.98 (± 1460.902)	

Notes:

[150] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[151] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[152] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: pH (Urinalysis): Change From Baseline to End of Study

End point title	pH (Urinalysis): Change From Baseline to End of Study[153]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[154]	113[155]	244[156]	
Units: no units				
arithmetic mean (standard deviation)				
Week 6 (n=98, 88, 186)	0.07 (± 0.601)	0.19 (± 0.575)	0.13 (± 0.590)	
Week 26 (n=69, 61, 130)	0.20 (± 0.537)	0.24 (± 0.560)	0.22 (± 0.546)	
Week 39 (n=67, 54, 121)	0.13 (± 0.566)	0.31 (± 0.617)	0.21 (± 0.594)	
Week 52 (n=71, 56, 127)	0.18 (± 0.682)	0.20 (± 0.537)	0.19 (± 0.620)	

Notes:

[154] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[155] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[156] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Specific Gravity (Urinalysis): Change From Baseline to End of Study

End point title	Specific Gravity (Urinalysis): Change From Baseline to End of Study[157]

End point description:

Samples for clinical laboratory tests were collected at study visits, and a certified central laboratory was used to process the samples and provide results.

End point type	Primary

End point timeframe:

Baseline, Weeks 6, 26, 39, and 52

Notes:

[157] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[158]	113[159]	244[160]	
Units: No units				
arithmetic mean (standard deviation)				
Week 6 (n=98, 88, 186)	0.00 (± 0.009)	0.00 (± 0.007)	0.00 (± 0.008)	
Week 26 (n=69, 61, 130)	0.00 (± 0.009)	0.00 (± 0.009)	0.00 (± 0.009)	
Week 39 (n=68, 54, 122)	0.00 (± 0.009)	0.00 (± 0.009)	0.00 (± 0.009)	
Week 52 (n=71, 56, 127)	0.00 (± 0.010)	0.00 (± 0.009)	0.00 (± 0.009)	

Notes:

[158] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[159] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[160] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Orthostatic Systolic Blood Pressure (Vital Signs): Change From Baseline to End of Study

End point title	Orthostatic Systolic Blood Pressure (Vital Signs): Change From Baseline to End of Study[161]

End point description:

Orthostatic blood pressure was measured after the participant had been supine (lying down with their face up) for at least 5 minutes and then, after the participant had been standing for 2 minutes. When vital sign measurements were scheduled at the same time as a blood collection, vital sign measurements were obtained prior to blood collection.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 6, 26, and 52 (orthostatic and standing); Baseline, Weeks 2, 4, 13, and 39 (supine)

Notes:

[161] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	128[162]	112[163]	240[164]	
Units: mmHg				
arithmetic mean (standard deviation)				
Week 1- orthostatic (n=119, 106, 225)	-1.5 (± 12.00)	3.5 (± 16.01)	0.9 (± 14.22)	
Week 6- orthostatic (n=97, 89, 186)	-1.5 (± 11.85)	2.6 (± 17.33)	0.5 (± 14.83)	
Week 26- orthostatic (n=69, 61, 130)	-2.4 (± 16.25)	-0.3 (± 14.38)	-1.4 (± 15.38)	
Week 52- orthostatic (n=70, 58, 128)	-1.3 (± 14.59)	0.7 (± 13.75)	-0.4 (± 14.19)	
Week 1- standing (n=122, 106, 228)	-2.3 (± 17.05)	-1.3 (± 25.50)	-1.9 (± 21.35)	
Week 6- standing (n=99, 90, 189)	-2.9 (± 18.32)	-3.1 (± 25.89)	-3.0 (± 22.19)	
Week 26- standing (n=71, 61, 132)	-4.7 (± 19.23)	-4.0 (± 21.01)	-4.4 (± 20.00)	

Week 52- standing (n=72, 58, 130)	-3.9 (± 19.81)	-1.5 (± 20.91)	-2.8 (± 20.26)	
Week 2- supine (n=121, 109, 230)	-1.0 (± 16.75)	-4.5 (± 21.94)	-2.7 (± 19.42)	
Week 4- supine (n=99, 89, 188)	-1.2 (± 16.67)	-6.7 (± 22.99)	-3.8 (± 20.05)	
Week 13- supine (n=29, 17, 46)	-4.0 (± 18.34)	-1.8 (± 24.89)	-3.2 (± 20.75)	
Week 39- supine (n=77, 66, 143)	-1.7 (± 19.12)	-1.8 (± 22.08)	-1.7 (± 20.47)	

Notes:

[162] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[163] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[164] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Orthostatic Diastolic Blood Pressure (Vital Signs): Change From Baseline to End of Study

End point title	Orthostatic Diastolic Blood Pressure (Vital Signs): Change From Baseline to End of Study[165]

End point description:

Orthostatic blood pressure was measured after the participant had been supine (lying down with their face up) for at least 5 minutes and then, after the participant had been standing for 2 minutes. When vital sign measurements were scheduled at the same time as a blood collection, vital sign measurements were obtained prior to blood collection.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 6, 26, and 52 (orthostatic and standing); Baseline, Weeks 2, 4, 13, and 39 (supine)

Notes:

[165] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	128[166]	112[167]	240[168]	
Units: mmHg				
arithmetic mean (standard deviation)				
Week 1- orthostatic (n=119, 106, 225)	-1.9 (± 10.61)	-0.7 (± 13.27)	-1.3 (± 11.92)	
Week 6- orthostatic (n=97, 89, 186)	0.0 (± 10.91)	-0.6 (± 10.00)	-0.3 (± 10.46)	
Week 26- orthostatic (n=69, 61, 130)	-1.7 (± 12.99)	0.3 (± 10.16)	-0.7 (± 11.75)	
Week 52- orthostatic (n=70, 58, 128)	-1.5 (± 10.44)	0.8 (± 11.42)	-0.4 (± 10.91)	
Week 1- standing (n=122, 106, 228)	-2.6 (± 12.00)	-2.1 (± 13.87)	-2.4 (± 12.88)	
Week 6- standing (n=99, 90, 189)	-0.8 (± 12.27)	-2.2 (± 14.76)	-1.5 (± 13.50)	
Week 26- standing (n=71, 61, 132)	-4.0 (± 12.20)	-1.2 (± 14.67)	-2.7 (± 13.42)	
Week 52- standing (n=72, 58, 130)	-1.7 (± 12.55)	1.1 (± 12.01)	-0.4 (± 12.34)	
Week 2- supine (n=121, 109, 230)	-1.1 (± 12.46)	-1.3 (± 13.46)	-1.2 (± 12.91)	
Week 4- supine (n=99, 89, 188)	-1.4 (± 12.06)	-2.1 (± 12.80)	-1.7 (± 12.38)	
Week 13- supine (n=29, 17, 46)	-2.6 (± 12.52)	-0.5 (± 9.59)	-1.8 (± 11.46)	
Week 39- supine (n=77, 66, 143)	0.2 (± 12.16)	0.2 (± 12.77)	0.2 (± 12.40)	

Notes:

[166] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[167] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Orthostatic Pulse Rate (Vital Signs): Change From Baseline to End of Study

End point title	Orthostatic Pulse Rate (Vital Signs): Change From Baseline to End of Study[169]

End point description:

Orthostatic pulse rate was measured after the participant had been supine (lying down with their face up) for at least 5 minutes and then, after the participant had been standing for 2 minutes. When vital sign measurements were scheduled at the same time as a blood collection, vital sign measurements were obtained prior to blood collection.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 6, 26, and 52 (orthostatic and standing); Baseline, Weeks 2, 4, 13, and 39 (supine)

Notes:

[169] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	128[170]	112[171]	240[172]	
Units: beats/minute				
arithmetic mean (standard deviation)				
Week 1- orthostatic (n=119, 106, 225)	-1.5 (± 8.49)	-1.8 (± 10.49)	-1.6 (± 9.46)	
Week 6- orthostatic (n=97, 89, 186)	-0.5 (± 10.86)	0.2 (± 10.16)	-0.1 (± 10.51)	
Week 26- orthostatic (n=69, 61, 130)	-0.9 (± 8.90)	0.3 (± 9.32)	-0.4 (± 9.08)	
Week 52- orthostatic (n=70, 58, 128)	0.5 (± 9.72)	-0.5 (± 8.55)	0.0 (± 9.19)	
Week 1- standing (n=122, 106, 228)	-5.1 (± 11.43)	-2.6 (± 12.50)	-3.9 (± 11.98)	
Week 6- standing (n=99, 90, 189)	-3.1 (± 12.45)	-3.0 (± 12.23)	-3.1 (± 12.31)	
Week 26- standing (n=71, 61, 132)	-2.9 (± 12.29)	-2.4 (± 12.43)	-2.7 (± 12.31)	
Week 52- standing (n=72, 58, 130)	-3.8 (± 12.88)	-4.3 (± 11.56)	-4.0 (± 12.27)	
Week 2- supine (n=121, 109, 230)	-3.3 (± 10.05)	-0.6 (± 11.10)	-2.0 (± 10.62)	
Week 4- supine (n=99, 89, 188)	-2.6 (± 10.06)	-3.3 (± 12.60)	-3.0 (± 11.31)	
Week 13- supine (n=29, 17, 46)	1.1 (± 11.72)	-4.8 (± 7.60)	-1.1 (± 10.68)	
Week 39- supine (n=77, 66, 143)	-3.7 (± 11.76)	-3.2 (± 11.16)	-3.4 (± 11.45)	

Notes:

[170] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[171] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[172] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Main Heart Rate: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Main Heart Rate: Change From Baseline to End of Study[173]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[173] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[174]	113[175]	244[176]	
Units: beats/minute				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	2.1 (± 9.51)	2.2 (± 9.76)	2.1 (± 9.61)	
Week 6 (n=100, 88, 188)	-2.3 (± 8.60)	-2.2 (± 10.28)	-2.2 (± 9.40)	
Week 52 (n=73, 58, 131)	-3.7 (± 9.51)	-0.7 (± 11.36)	-2.3 (± 10.44)	

Notes:

[174] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[175] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[176] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate PR Interval: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate PR Interval: Change From Baseline to End of Study[177]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[177] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	130[178]	107[179]	237[180]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=125, 105, 230)	0.4 (± 14.08)	-0.1 (± 13.76)	0.2 (± 13.91)	
Week 6 (n=99, 84, 183)	0.5 (± 13.97)	1.1 (± 16.84)	0.8 (± 15.31)	
Week 52 (n=72, 54, 126)	1.5 (± 12.48)	-5.8 (± 20.54)	-1.6 (± 16.75)	

Notes:

[178] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[179] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[180] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate QRS Duration: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate QRS Duration: Change From Baseline to End of Study[181]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[181] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[182]	113[183]	244[184]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	-2.3 (± 7.32)	-0.8 (± 8.41)	-1.6 (± 7.87)	
Week 6 (n=100, 88, 188)	-0.5 (± 8.32)	1.6 (± 8.96)	0.5 (± 8.67)	
Week 52 (n=72, 58, 130)	-0.2 (± 6.85)	0.9 (± 7.29)	0.3 (± 7.04)	

Notes:

[182] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[183] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[184] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate QT Interval: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate QT Interval: Change From Baseline to End of Study[185]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[185] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[186]	113[187]	244[188]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	-5.3 (± 20.72)	-4.2 (± 23.99)	-4.8 (± 22.27)	
Week 6 (n=99, 88, 187)	6.4 (± 20.96)	6.4 (± 24.61)	6.4 (± 22.69)	
Week 52 (n=72, 58, 130)	9.8 (± 24.66)	4.3 (± 26.24)	7.3 (± 25.42)	

Notes:

[186] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[187] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[188] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate QTcB Interval: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate QTcB Interval: Change From Baseline to End of Study[189]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[189] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[190]	113[191]	244[192]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	1.2 (± 17.96)	2.0 (± 17.21)	1.6 (± 17.58)	
Week 6 (n=99, 88, 187)	1.0 (± 19.91)	0.6 (± 18.34)	0.8 (± 19.14)	
Week 52 (n=72, 58, 130)	-0.1 (± 20.84)	2.1 (± 18.33)	0.9 (± 19.72)	

Notes:

[190] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[191] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[192] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate QTcF Interval: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate QTcF Interval: Change From Baseline to End of Study[193]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[193] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[194]	113[195]	244[196]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	-1.0 (± 14.03)	-0.2 (± 15.75)	-0.6 (± 14.84)	
Week 6 (n=99, 88, 187)	3.1 (± 16.49)	2.6 (± 15.63)	2.9 (± 16.05)	
Week 52 (n=72, 58, 130)	3.4 (± 18.05)	2.9 (± 15.40)	3.2 (± 16.86)	

Notes:

[194] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[195] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[196] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Primary: Electrocardiogram (ECG) Aggregate RR Interval: Change From Baseline to End of Study

End point title	Electrocardiogram (ECG) Aggregate RR Interval: Change From Baseline to End of Study[197]

End point description:

12-lead electrocardiograms (ECGs) were recorded at study visits after the participant had been supine for at least 5 minutes. Participants were instructed to remain stationary (no talking, laughing, deep breathing, sleeping, or swallowing) for approximately 10 seconds during the ECG recording. When an ECG was recorded at a time near that of a blood collection, the ECG was obtained prior to the blood collection. ECGs on Day 1 were recorded after initiation of the continuous subcutaneous infusion (CSCI) of ABBV-951 prior to the end of the study visit.

End point type	Primary

End point timeframe:

Baseline, Day 1 (postdose), Weeks 6 and 52

Notes:

[197] - 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: The statistical analysis results are presented in the endpoint data table, per protocol

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[198]	113[199]	244[200]	
Units: milliseconds				
arithmetic mean (standard deviation)				
Day 1 (postdose) (n=126, 111, 237)	-30.7 (± 122.48)	-28.3 (± 113.02)	-29.6 (± 117.90)	
Week 6 (n=100, 88, 188)	22.6 (± 112.51)	26.1 (± 129.35)	24.2 (± 120.37)	
Week 52 (n=73, 58, 131)	41.8 (± 122.96)	9.4 (± 141.91)	27.5 (± 132.15)	

Notes:

[198] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[199] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

[200] - Safety Analysis Set: all participants who received any ABBV-951 infusion with available data

Statistical analyses

No statistical analyses for this end point

Secondary: Average Daily Normalized "Off" Time: Change From Baseline to End of Study

End point title	Average Daily Normalized "Off" Time: Change From Baseline to End of Study

End point description:

Upon awakening and every 30 minutes during their normal waking time, participants recorded their state in the Parkinson's Disease Diary (PD Diary) for 2 consecutive days prior to study visits.

"Off" time is defined as periods of poor mobility, tremor, slowness, and stiffness. The daily "On" and "Off" times were normalized to a typical waking day (16 hours) to account for different sleep patterns across participants. When "Off" was the first morning symptom upon awakening, this was considered morning akinesia in this study.

Baseline value is defined as the average of normalized "Off" time collected over the 2 PD Diary days before the Enrollment visit. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126[201]	110[202]	236[203]	
Units: hours				
arithmetic mean (standard deviation)				
Week 1 (n=120, 105, 225)	-2.04 (± 3.51)	-1.84 (± 3.88)	-1.95 (± 3.68)	
Week 6 (n=110, 95, 205)	-2.43 (± 3.66)	-2.36 (± 3.56)	-2.40 (± 3.61)	
Week 13 (n=63, 51, 114)	-2.50 (± 3.83)	-2.34 (± 3.57)	-2.43 (± 3.70)	
Week 26 (n=69, 62, 131)	-3.31 (± 3.36)	-3.38 (± 3.15)	-3.35 (± 3.25)	
Week 39 (n=68, 54, 122)	-3.25 (± 3.43)	-3.52 (± 2.92)	-3.37 (± 3.21)	
Week 52 (n=62, 54, 116)	-3.43 (± 3.16)	-3.59 (± 3.11)	-3.51 (± 3.12)	

Notes:

[201] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[202] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[203] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	Average Daily Normalized Off Time/Average Daily Normalized

Statistical analyses

No statistical analyses for this end point

Secondary: Average Daily Normalized "On" Time With Troublesome Dyskinesia: Change From Baseline to End of Study

End point title	Average Daily Normalized "On" Time With Troublesome Dyskinesia: Change From Baseline to End of Study

End point description:

Upon awakening and every 30 minutes during their normal waking time, participants recorded their state in the Parkinson's Disease Diary (PD Diary) for 2 consecutive days prior to study visits.

"On" time is defined as periods of good motor symptom control. The daily "On" and "Off" times were normalized to a typical waking day (16 hours) to account for different sleep patterns across participants.

Baseline value is defined as the average of normalized "On" time with troublesome dyskinesia collected over the 2 PD Diary days before the Enrollment visit. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126[204]	110[205]	236[206]	
Units: hours				
arithmetic mean (standard deviation)				
Week 1 (n=120, 105, 225)	-0.00 (± 2.10)	0.11 (± 1.64)	0.05 (± 1.89)	
Week 6 (n=110, 95, 205)	-0.56 (± 1.95)	-0.23 (± 1.05)	-0.41 (± 1.60)	
Week 13 (n=63, 51, 114)	-0.60 (± 1.72)	-0.38 (± 1.04)	-0.50 (± 1.45)	
Week 26 (n=69, 62, 131)	-0.61 (± 1.95)	-0.27 (± 1.73)	-0.45 (± 1.85)	
Week 39 (n=68, 54, 122)	-0.49 (± 1.07)	-0.17 (± 1.59)	-0.35 (± 1.33)	
Week 52 (n=62, 54, 116)	-0.64 (± 1.73)	0.17 (± 2.53)	-0.27 (± 2.16)	

Notes:

[204] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[205] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[206] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	Average Daily Normalized On Time With TD/Average Daily

Statistical analyses

No statistical analyses for this end point

Secondary: Average Daily Normalized "On" Time Without Troublesome Dyskinesia: Change From Baseline to End of Study

End point title	Average Daily Normalized "On" Time Without Troublesome Dyskinesia: Change From Baseline to End of Study

End point description:

Upon awakening and every 30 minutes during their normal waking time, participants recorded their state in the Parkinson's Disease Diary (PD Diary) for 2 consecutive days prior to study visits.

"On" time is defined as periods of good motor symptom control. The daily "On" and "Off" times were normalized to a typical waking day (16 hours) to account for different sleep patterns across participants.

Baseline value is defined as the average of normalized "On" time without troublesome dyskinesia collected over the 2 PD Diary days before the Enrollment visit. Positive changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 1, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126[207]	110[208]	236[209]	
Units: hours				
arithmetic mean (standard deviation)				
Week 1 (n=120, 105, 225)	2.04 (± 3.55)	1.74 (± 4.04)	1.90 (± 3.78)	
Week 6 (n=110, 95, 205)	2.99 (± 3.60)	2.60 (± 3.58)	2.81 (± 3.59)	
Week 13 (n=63, 51, 114)	3.10 (± 3.32)	2.72 (± 3.68)	2.93 (± 3.48)	

Week 26 (n=69, 62, 131)	3.92 (± 3.76)	3.65 (± 3.31)	3.79 (± 3.55)	
Week 39 (n=68, 54, 122)	3.74 (± 3.40)	3.69 (± 3.32)	3.71 (± 3.35)	
Week 52 (n=62, 54, 116)	4.08 (± 3.28)	3.43 (± 3.28)	3.77 (± 3.28)	

Notes:

[207] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[208] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[209] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	Average Daily Normalized On Time Without TD/Average Daily

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I Score: Change From Baseline to End of Study

End point title	Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I Score: Change From Baseline to End of Study

End point description:

The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is an investigator-used rating tool to follow the longitudinal course of Parkinson's Disease (PD). Part I assesses the participant's non-motor aspects of experiences of daily living (nM-EDL) with 13 questions. (The numeric score for each question is between 0-4; 0=Normal,1=Slight,2=Mild,3=Moderate,4=Severe). Part I scores range from 0 to 52, with higher scores indicating more severe symptoms of PD. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 3, 4, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[210]	113[211]	244[212]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Day 2 (n=120, 102, 222)	-2.6 (± 4.28)	-1.8 (± 3.61)	-2.3 (± 4.00)	
Week 1 (n=120, 106, 226)	-2.6 (± 5.84)	-3.3 (± 5.50)	-2.9 (± 5.68)	
Week 2 (n=117, 95, 212)	-2.5 (± 5.29)	-2.1 (± 5.10)	-2.3 (± 5.20)	
Week 3 (n=107, 96, 203)	-2.3 (± 5.65)	-2.9 (± 5.91)	-2.6 (± 5.77)	
Week 4 (n=109, 94, 203)	-1.7 (± 6.22)	-3.0 (± 5.42)	-2.3 (± 5.88)	
Week 6 (n=104, 89, 193)	-1.1 (± 7.00)	-1.7 (± 5.15)	-1.4 (± 6.21)	
Week 13 (n=93, 77, 170)	-1.8 (± 5.80)	-1.7 (± 5.59)	-1.7 (± 5.69)	
Week 26 (n=79, 69, 148)	-1.1 (± 5.01)	-0.7 (± 5.88)	-0.9 (± 5.42)	
Week 39 (n=75, 60, 135)	-0.7 (± 5.64)	0.1 (± 6.00)	-0.4 (± 5.80)	
Week 52 (n=75, 58, 133)	-0.5 (± 5.30)	-1.3 (± 6.22)	-0.9 (± 5.71)	

Notes:

[210] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	MDS-UPDRS Part I Score/MDS-UPDRS Part I Score.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II Score: Change From Baseline to End of Study

End point title	Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II Score: Change From Baseline to End of Study

End point description:

The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is an investigator-used rating tool to follow the longitudinal course of Parkinson's Disease (PD). Part II assesses the participant's motor experiences of daily living (M-EDL) with 13 questions. (The numeric score for each question is between 0-4; 0=Normal,1=Slight,2=Mild,3=Moderate,4=Severe). Part II scores range from 0 to 52, with higher scores indicating more severe symptoms of PD. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 3, 4, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[213]	113[214]	244[215]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Day 2 (n=120, 102, 222)	-2.8 (± 4.55)	-1.2 (± 4.25)	-2.1 (± 4.47)	
Week 1 (n=120, 106, 226)	-3.6 (± 4.98)	-3.9 (± 5.85)	-3.7 (± 5.40)	
Week 2 (n=117, 95, 212)	-3.3 (± 6.06)	-3.4 (± 6.53)	-3.3 (± 6.26)	
Week 3 (n=107, 96, 203)	-3.5 (± 5.83)	-3.9 (± 6.63)	-3.7 (± 6.21)	
Week 4 (n=109, 84, 203)	-2.6 (± 5.50)	-4.9 (± 6.32)	-3.7 (± 5.98)	
Week 6 (n=104, 89, 193)	-2.5 (± 6.60)	-4.2 (± 6.09)	-3.3 (± 6.41)	
Week 13 (n=93, 77, 170)	-3.2 (± 6.44)	-4.3 (± 6.57)	-3.7 (± 6.50)	
Week 26 (n=79, 69, 148)	-2.6 (± 6.27)	-3.9 (± 7.05)	-3.2 (± 6.65)	
Week 39 (n=75, 60, 135)	-2.6 (± 6.32)	-4.0 (± 6.93)	-3.2 (± 6.61)	
Week 52 (n=75, 58, 133)	-2.1 (± 6.94)	-4.5 (± 7.07)	-3.2 (± 7.07)	

Notes:

Attachments (see zip file)	MDS-UPDRS Part II Score/MDS-UPDRS Part II Score.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III Score: Change From Baseline to End of Study

End point title	Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III Score: Change From Baseline to End of Study

End point description:

The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is an investigator-used rating tool to follow the longitudinal course of Parkinson's Disease (PD). Part III assesses the participant's motor examination (including Hoehn and Yahr stage) with 33 questions. (The numeric score for each question is between 0-4; 0=Normal,1=Slight,2=Mild,3=Moderate,4=Severe). Part III scores range from 0 to 132, with higher scores indicating more severe symptoms of PD. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 3, 4, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[216]	113[217]	244[218]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Day 2 (n=120, 102, 222)	-0.6 (± 8.45)	-0.8 (± 9.20)	-0.7 (± 8.78)	
Week 1 (n=119, 106, 225)	2.0 (± 11.55)	3.8 (± 11.00)	2.8 (± 11.31)	
Week 2 (n=117, 94, 211)	4.1 (± 13.02)	1.4 (± 10.93)	2.9 (± 12.18)	
Week 3 (n=107, 96, 203)	3.9 (± 11.98)	2.2 (± 12.07)	3.1 (± 12.02)	
Week 4 (n=107, 93, 200)	2.7 (± 12.84)	0.0 (± 10.97)	1.5 (± 12.05)	
Week 6 (n=104, 89, 193)	2.4 (± 13.74)	-0.7 (± 9.58)	0.9 (± 12.07)	
Week 13 (n=89, 70, 159)	1.4 (± 13.79)	-1.6 (± 11.82)	0.1 (± 13.01)	
Week 26 (n=75, 64, 139)	1.4 (± 12.71)	0.1 (± 11.61)	0.8 (± 12.19)	
Week 39 (n=75, 55, 130)	1.9 (± 12.70)	2.3 (± 13.26)	2.1 (± 12.89)	
Week 52 (n=75, 58, 133)	1.8 (± 12.53)	1.7 (± 13.02)	1.7 (± 12.69)	

Notes:

[216] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[217] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[218] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	MDS-UPDRS Part III Score/MDS-UPDRS Part III Score.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part IV Score: Change From Baseline to End of Study

End point title	Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part IV Score: Change From Baseline to End of Study

End point description:

The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is an investigator-used rating tool to follow the longitudinal course of Parkinson's Disease (PD). Part IV assesses the participant's motor complications with 6 questions. (The numeric score for each question is between 0-4; 0=Normal,1=Slight,2=Mild,3=Moderate,4=Severe). Part IV scores range from 0 to 24, with higher scores indicating more severe symptoms of PD. Negative changes from Baseline indicate improvement.

End point type	Secondary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 3, 4, 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[219]	113[220]	244[221]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Day 2 (n=117, 101, 218)	-1.8 (± 3.57)	-1.1 (± 3.45)	-1.5 (± 3.52)	
Week 1 (n=117, 105, 222)	-1.7 (± 3.86)	-1.7 (± 4.10)	-1.7 (± 3.96)	
Week 2 (n=115, 93, 208)	-2.5 (± 3.58)	-2.3 (± 3.56)	-2.4 (± 3.57)	
Week 3 (n=102, 96, 198)	-2.1 (± 4.06)	-2.3 (± 3.74)	-2.2 (± 3.90)	
Week 4 (n=106, 94, 200)	-3.0 (± 3.69)	-2.6 (± 3.78)	-2.8 (± 3.73)	
Week 6 (n=101, 89, 190)	-2.6 (± 3.34)	-2.8 (± 3.90)	-2.7 (± 3.61)	
Week 13 (n=89, 77, 166)	-3.7 (± 3.47)	-3.3 (± 4.04)	-3.5 (± 3.74)	
Week 26 (n=77, 69, 146)	-3.5 (± 3.43)	-3.5 (± 4.12)	-3.5 (± 3.76)	
Week 39 (n=73, 59, 132)	-3.5 (± 4.06)	-3.5 (± 4.11)	-3.5 (± 4.07)	
Week 52 (n=72, 58, 130)	-4.1 (± 3.75)	-3.8 (± 4.71)	-3.9 (± 4.19)	

Notes:

[219] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[220] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[221] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	MDS-UPDRS Part IV Score/MDS-UPDRS Part IV Score.pdf

Statistical analyses

No statistical analyses for this end point

Secondary: Sleep Symptoms as Assessed by the Parkinson's Disease Sleep Scale-2 (PDSS-2) Total Score: Change From Baseline to End of Study

End point title	Sleep Symptoms as Assessed by the Parkinson's Disease Sleep Scale-2 (PDSS-2) Total Score: Change From Baseline to End of Study

End point description:

The PDSS-2 consists of 15 questions that evaluate motor and non-motor symptoms at night and upon

wakening, as well as disturbed sleep grouped into 3 domains: motor symptoms at night (5 items), Parkinson's Disease (PD) symptoms at night (5 items), and disturbed sleep (5 items). The frequency is assessed for the 15 sleep problems based on a 5-point Likert-type scale (ranging from 0 [never] to 4 [very often] with the exception of Question 1 score ranging from 0 [very often] to 4 [never]). Scores are calculated for each of the 3 domains as well as a total score. The PDSS-2 domain scores range from 0 to 20 and the total score is a sum of the 3 domains and ranges from 0 to 60. Higher scores indicate higher frequency and more severe impact of PD on sleep. Negative changes indicate improvement from Baseline.

End point type	Secondary

End point timeframe:

Baseline, Weeks 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[222]	112[223]	243[224]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 6 (n=105, 91, 196)	-5.0 (± 11.39)	-7.3 (± 8.81)	-6.1 (± 10.31)	
Week 13 (n=93, 77, 170)	-6.9 (± 10.76)	-8.2 (± 8.89)	-7.5 (± 9.94)	
Week 26 (n=80, 69, 149)	-5.0 (± 13.06)	-8.4 (± 8.07)	-6.6 (± 11.12)	
Week 39 (n=76, 61, 137)	-7.0 (± 11.19)	-7.2 (± 9.21)	-7.1 (± 10.32)	
Week 52 (n=74, 57, 131)	-6.5 (± 12.34)	-8.7 (± 8.19)	-7.5 (± 10.75)	

Notes:

[222] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[223] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[224] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	Sleep Symptoms as Assessed by PDSS-2 Total Score/Sleep

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life Assessed by the Parkinson's Disease Questionnaire-39 Items (PDQ-39) Summary Index Score: Change From Baseline to End of Study

End point title	Quality of Life Assessed by the Parkinson's Disease Questionnaire-39 Items (PDQ-39) Summary Index Score: Change From Baseline to End of Study

End point description:

The Parkinson's Disease Questionnaire (PDQ-39) is a disease-specific instrument designed to measure aspects of health that are relevant to participants with Parkinson's Disease (PD), and which may not be included in general health status questionnaires. Each item is scored on the following 5-point scale: 0 = never, 1 = occasionally, 2 = sometimes, 3 = often, 4 = always (or cannot do at all, if applicable). Higher scores are consistently associated with more severe symptoms of the disease such as tremors and stiffness. The results can be presented in either domain scores or as a summary index score. The full range of the PDQ-39 summary index score is from 0 (no patient-related symptoms/quality of life unaffected) to 100 (highest patient-related symptoms/low quality of life). Negative changes indicate improvement from Baseline.

End point type	Secondary

End point timeframe:

Baseline, Weeks 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131[225]	112[226]	243[227]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 6 (n=105, 91, 196)	-7.0 (± 14.53)	-8.4 (± 10.53)	-7.6 (± 12.81)	
Week 13 (n=93, 77, 170)	-8.3 (± 15.33)	-8.2 (± 11.18)	-8.3 (± 13.57)	
Week 26 (n=79, 69, 148)	-7.4 (± 13.00)	-7.1 (± 12.27)	-7.3 (± 12.62)	
Week 39 (n=76, 61, 137)	-7.8 (± 13.81)	-7.5 (± 13.58)	-7.7 (± 13.66)	
Week 52 (n=75, 57, 132)	-7.2 (± 14.65)	-7.2 (± 12.35)	-7.2 (± 13.65)	

Notes:

[225] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[226] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[227] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	QoL Assessed by PDQ-39 Summary Index Score/Quality of Life

Statistical analyses

No statistical analyses for this end point

Secondary: The EuroQol 5-Dimension Questionnaire (EQ-5D-5L) Quality of Life Summary Index: Change From Baseline to End of Study

End point title	The EuroQol 5-Dimension Questionnaire (EQ-5D-5L) Quality of Life Summary Index: Change From Baseline to End of Study

End point description:

The EuroQol 5-dimension questionnaire (EQ-5D-5L) is a standardized non-disease specific instrument for describing and valuing health-related quality of life. The EQ-5D-5L descriptive system comprises 5 dimensions of health (mobility, self -care, usual activities, pain/discomfort, and anxiety/depression) to describe the participant's current health state. Each dimension comprises 5 levels with corresponding numeric scores, where 1 indicates no problems, and 5 indicates extreme problems. The health status is converted to an index value using the country-specific weighted scoring algorithm for the United States (US). The summary index value for the US ranges from a worst score of -0.109 to a best score of 1. An increase in the EQ-5D-5L total score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 6, 13, 26, 39, and 52

End point values	ABBV-951 Low Dose Subgroup	ABBV-951 High Dose Subgroup	ABBV-951 All Participants	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	125[228]	104[229]	229[230]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 6 (n=93, 82, 175)	0.060 (± 0.1921)	0.113 (± 0.1780)	0.085 (± 0.1870)	

Week 13 (n=80, 66, 146)	0.064 (± 0.2153)	0.122 (± 0.1984)	0.090 (± 0.2092)
Week 26 (n=70, 58, 128)	0.074 (± 0.1771)	0.122 (± 0.1803)	0.096 (± 0.1795)
Week 39 (n=72, 49, 121)	0.075 (± 0.1842)	0.129 (± 0.1995)	0.097 (± 0.1916)
Week 52 (n=70, 52, 122)	0.076 (± 0.2062)	0.126 (± 0.2213)	0.097 (± 0.2134)

Notes:

[228] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[229] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

[230] - FAS: participants receiving any infusion and had a BL and tx observation for at least 1 efficacy OM

Attachments (see zip file)	EQ-5D-5L Quality of Life Summary Index/EQ-5D-5L Quality of

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality is reported from enrollment to end of study; median time on follow-up was 367.0 days for the ABBV-951 Low Dose Subgroup, the ABBV-951 High Dose Subgroup, and the ABBV-951 All Participants group.

Adverse event reporting additional description:

TEAEs and SAEs were collected from first dose of study drug until 30 days after the last infusion; mean time on treatment was 244.9 days for the ABBV-951 Low Dose Subgroup, 240.6 days for the ABBV-951 High Dose Subgroup, and 242.9 days for the ABBV-951 All Participants group.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	ABBV-951 Low Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was < 2530 mg of Foslevodopa/day were analyzed as the Low Dose Subgroup.

Reporting group title	ABBV-951 All Participants

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period.

Reporting group title	ABBV-951 High Dose Subgroup

Reporting group description:

After a 4-week Optimization Period, participants continued receiving ABBV-951 by continuous subcutaneous infusion (CSCI) during the 48-week Maintenance Period. Participants whose modal total daily dose (most frequent dose) over the entire study was ≥ 2530 mg of Foslevodopa/day were analyzed as the High Dose Subgroup.

Serious adverse events	ABBV-951 Low Dose Subgroup	ABBV-951 All Participants	ABBV-951 High Dose Subgroup
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 131 (24.43%)	63 / 244 (25.82%)	31 / 113 (27.43%)
number of deaths (all causes)	0	5	5
number of deaths resulting from adverse events	0	3	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
RECTAL ADENOCARCINOMA			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
ORTHOSTATIC HYPOTENSION			

subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTHERMIA			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION SITE HAEMATOMA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION SITE INJURY			

subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIECTASIS			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
DOPAMINE DYSREGULATION SYNDROME			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DELUSIONAL DISORDER, UNSPECIFIED TYPE			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DELUSION			

subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DELIRIUM			
subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANXIETY			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HALLUCINATION			
subjects affected / exposed	6 / 131 (4.58%)	7 / 244 (2.87%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	5 / 6	6 / 7	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSYCHOTIC DISORDER			
subjects affected / exposed	4 / 131 (3.05%)	6 / 244 (2.46%)	2 / 113 (1.77%)
occurrences causally related to treatment / all	5 / 5	7 / 7	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BLOOD SODIUM DECREASED			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

FACE INJURY			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBDURAL HAEMATOMA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac disorders			
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
CARDIAC ARREST			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

CEREBRAL MASS EFFECT			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
COGNITIVE DISORDER			
subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSTONIA			
subjects affected / exposed	0 / 131 (0.00%)	2 / 244 (0.82%)	2 / 113 (1.77%)
occurrences causally related to treatment / all	0 / 0	2 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARKINSON'S DISEASE			
subjects affected / exposed	5 / 131 (3.82%)	6 / 244 (2.46%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	2 / 6	2 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARAESTHESIA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARKINSONISM			

subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSYCHOGENIC SEIZURE			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED TONIC-CLONIC SEIZURE			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANAESTHESIA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIPARESIS			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	1 / 131 (0.76%)	2 / 244 (0.82%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBOSACRAL RADICULOPATHY			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ON AND OFF PHENOMENON			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
PERIORBITAL PAIN			

subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS ISCHAEMIC			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRITIS REACTIVE			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOARTHRITIS			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHABDOMYOLYSIS			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SACROILIAC JOINT DYSFUNCTION			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
INFUSION SITE CELLULITIS			
subjects affected / exposed	4 / 131 (3.05%)	10 / 244 (4.10%)	6 / 113 (5.31%)
occurrences causally related to treatment / all	4 / 4	9 / 10	5 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION SITE INFECTION			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	2 / 131 (1.53%)	3 / 244 (1.23%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	3 / 131 (2.29%)	3 / 244 (1.23%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	2 / 3	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 131 (1.53%)	4 / 244 (1.64%)	2 / 113 (1.77%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION SITE ABSCESS			
subjects affected / exposed	5 / 131 (3.82%)	8 / 244 (3.28%)	3 / 113 (2.65%)
occurrences causally related to treatment / all	5 / 5	9 / 10	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			

subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS LIMB			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROTID ABSCESS			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 131 (0.00%)	1 / 244 (0.41%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	1 / 131 (0.76%)	1 / 244 (0.41%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	ABBV-951 Low Dose Subgroup	ABBV-951 All Participants	ABBV-951 High Dose Subgroup
Total subjects affected by non-serious adverse events			
subjects affected / exposed	111 / 131 (84.73%)	218 / 244 (89.34%)	107 / 113 (94.69%)
Investigations			
WEIGHT DECREASED			
subjects affected / exposed	10 / 131 (7.63%)	24 / 244 (9.84%)	14 / 113 (12.39%)
occurrences (all)	10	24	14

VITAMIN B6 DECREASED			
subjects affected / exposed	5 / 131 (3.82%)	11 / 244 (4.51%)	6 / 113 (5.31%)
occurrences (all)	5	11	6
Injury, poisoning and procedural complications			
SKIN LACERATION			
subjects affected / exposed	1 / 131 (0.76%)	7 / 244 (2.87%)	6 / 113 (5.31%)
occurrences (all)	1	7	6
FALL			
subjects affected / exposed	16 / 131 (12.21%)	39 / 244 (15.98%)	23 / 113 (20.35%)
occurrences (all)	42	77	35
CONTUSION			
subjects affected / exposed	2 / 131 (1.53%)	8 / 244 (3.28%)	6 / 113 (5.31%)
occurrences (all)	3	12	9
Vascular disorders			
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	6 / 131 (4.58%)	12 / 244 (4.92%)	6 / 113 (5.31%)
occurrences (all)	6	13	7
Nervous system disorders			
SOMNOLENCE			
subjects affected / exposed	9 / 131 (6.87%)	12 / 244 (4.92%)	3 / 113 (2.65%)
occurrences (all)	11	14	3
PARKINSON'S DISEASE			
subjects affected / exposed	7 / 131 (5.34%)	11 / 244 (4.51%)	4 / 113 (3.54%)
occurrences (all)	8	12	4
HEADACHE			
subjects affected / exposed	7 / 131 (5.34%)	14 / 244 (5.74%)	7 / 113 (6.19%)
occurrences (all)	7	17	10
DIZZINESS			
subjects affected / exposed	14 / 131 (10.69%)	24 / 244 (9.84%)	10 / 113 (8.85%)
occurrences (all)	18	28	10
DYSKINESIA			
subjects affected / exposed	12 / 131 (9.16%)	18 / 244 (7.38%)	6 / 113 (5.31%)
occurrences (all)	20	27	7
General disorders and administration site conditions			
INFUSION SITE PAIN			

subjects affected / exposed	18 / 131 (13.74%)	38 / 244 (15.57%)	20 / 113 (17.70%)
occurrences (all)	41	68	27

INFUSION SITE OEDEMA

subjects affected / exposed	19 / 131 (14.50%)	47 / 244 (19.26%)	28 / 113 (24.78%)
occurrences (all)	78	123	45

INFUSION SITE NODULE

subjects affected / exposed	36 / 131 (27.48%)	70 / 244 (28.69%)	34 / 113 (30.09%)
occurrences (all)	65	123	58

INFUSION SITE INFLAMMATION

subjects affected / exposed	3 / 131 (2.29%)	9 / 244 (3.69%)	6 / 113 (5.31%)
occurrences (all)	3	12	9

INFUSION SITE HAEMATOMA

subjects affected / exposed	10 / 131 (7.63%)	17 / 244 (6.97%)	7 / 113 (6.19%)
occurrences (all)	10	22	12

INFUSION SITE ERYTHEMA

subjects affected / exposed	64 / 131 (48.85%)	127 / 244 (52.05%)	63 / 113 (55.75%)
occurrences (all)	175	343	168

INFUSION SITE BRUISING

subjects affected / exposed	10 / 131 (7.63%)	18 / 244 (7.38%)	8 / 113 (7.08%)
occurrences (all)	15	30	15

INFUSION SITE PAPULE

subjects affected / exposed	7 / 131 (5.34%)	18 / 244 (7.38%)	11 / 113 (9.73%)
occurrences (all)	8	26	18

INFUSION SITE EXTRAVASATION

subjects affected / exposed	8 / 131 (6.11%)	20 / 244 (8.20%)	12 / 113 (10.62%)
occurrences (all)	10	25	15

INFUSION SITE REACTION

subjects affected / exposed	13 / 131 (9.92%)	30 / 244 (12.30%)	17 / 113 (15.04%)
occurrences (all)	26	62	36

INJECTION SITE ERYTHEMA

subjects affected / exposed	6 / 131 (4.58%)	14 / 244 (5.74%)	8 / 113 (7.08%)
occurrences (all)	22	36	14

INJECTION SITE NODULE

subjects affected / exposed	3 / 131 (2.29%)	9 / 244 (3.69%)	6 / 113 (5.31%)
occurrences (all)	15	23	8

INJECTION SITE PAIN

subjects affected / exposed	2 / 131 (1.53%)	8 / 244 (3.28%)	6 / 113 (5.31%)
occurrences (all)	2	8	6

Gastrointestinal disorders

NAUSEA

subjects affected / exposed	8 / 131 (6.11%)	19 / 244 (7.79%)	11 / 113 (9.73%)
occurrences (all)	11	24	13

CONSTIPATION

subjects affected / exposed	8 / 131 (6.11%)	20 / 244 (8.20%)	12 / 113 (10.62%)
occurrences (all)	8	20	12

Psychiatric disorders

ANXIETY

subjects affected / exposed	10 / 131 (7.63%)	28 / 244 (11.48%)	18 / 113 (15.93%)
occurrences (all)	12	34	22

HALLUCINATION, VISUAL

subjects affected / exposed	10 / 131 (7.63%)	15 / 244 (6.15%)	5 / 113 (4.42%)
occurrences (all)	14	20	6

HALLUCINATION

subjects affected / exposed	14 / 131 (10.69%)	35 / 244 (14.34%)	21 / 113 (18.58%)
occurrences (all)	22	49	27

DELUSION

subjects affected / exposed	7 / 131 (5.34%)	8 / 244 (3.28%)	1 / 113 (0.88%)
occurrences (all)	8	9	1

INSOMNIA

subjects affected / exposed	9 / 131 (6.87%)	18 / 244 (7.38%)	9 / 113 (7.96%)
occurrences (all)	9	18	9

Musculoskeletal and connective tissue disorders

BACK PAIN

subjects affected / exposed	8 / 131 (6.11%)	13 / 244 (5.33%)	5 / 113 (4.42%)
occurrences (all)	8	14	6

Infections and infestations

URINARY TRACT INFECTION

subjects affected / exposed	6 / 131 (4.58%)	15 / 244 (6.15%)	9 / 113 (7.96%)
occurrences (all)	7	21	14

INFUSION SITE INFECTION

subjects affected / exposed	7 / 131 (5.34%)	17 / 244 (6.97%)	10 / 113 (8.85%)
occurrences (all)	8	24	16

INFUSION SITE CELLULITIS			
subjects affected / exposed	25 / 131 (19.08%)	46 / 244 (18.85%)	21 / 113 (18.58%)
occurrences (all)	33	64	31
INFUSION SITE ABSCESS			
subjects affected / exposed	9 / 131 (6.87%)	19 / 244 (7.79%)	10 / 113 (8.85%)
occurrences (all)	9	21	12

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 November 2018	Version 2.0 -Allowed subjects from Study M15-738 and M15-739 to continue receiving ABBV-951 -Added minimum programmable lockout time of 60 minutes -Changed maximum infusion rate from 1.18 to 1.04 mL/hr -Added "Health-related quality of life as assessed by the EuroQOL 5-dimensions questionnaire (EQ-5D-5L)" as a secondary endpoint -Added A 9-mm Cleo 90 infusion set to Table 8
11 February 2019	Version 3.0 -Added Hallucinations/psychosis and somnolence as AESIs -Replace the Minnesota Impulse Disorder Interview (MIDI) with the QUIP-RS -Changed the neurological examination from "symptom-directed" to mandatory and added this to the Week 13 and 39 Visits -Removed assessment of orthostatic vital signs from Visits 6, 7, and 8 (V6, V7, and V8) based on safety data from the Phase 1b study (Study M15-739) -Clarified that during the Monitoring Period (i.e., 6 days before Visit 3 [V3]), subjects should be active (engaged in usual activities of daily living and not sitting or resting on a couch or chair or lying in bed) for at least 30 minutes before taking their first oral dose
28 August 2019	Version 4.0 -Removed the allowance of a legally authorized person to provided informed consent for a subject to participate in the study to ensure that appropriate subjects are enrolled -Added eligibility criterion 17 to clarify and exclude medical conditions for which levodopa is contraindicated -Modified eligibility criterion 22 to add that a female subject cannot donate eggs during the study or within 30 days after the end of study drug infusion and to clarify that a female subject does not intend to become pregnant within 30 days after the end of study drug infusion -Modified eligibility criterion 23 to clarify that a male subject does not intend to donate sperm or father a child within 30 days after the end of study drug infusion -Added language to clarify that MAO-A inhibitors are prohibited from 2 weeks prior to the start of levodopa therapy to the end of the Treatment Period -Added zosinamide to the list of allowable concomitant medications during the Treatment Period -Added device causality definitions were added -Incorporated procedures for reporting of events related to the study device -Reduced the duration of the Monitoring Period between Visits 2 and 3 was reduced from 6 to 2 days in situations where the PKG watch is not allowed, per country regulations. A minimum of a 2-day Monitoring Period is required prior to Visit 3 (Day 1) so that PD Diary data are collected. -Increased the frequency of pregnancy testing for women of childbearing potential to every month during the Treatment Period -Modified the instructions on priming of the infusion set -Added language to state that subjects will be instructed on how to return all devices and ancillaries and that study personnel must document compliance -Modified language to indicate that a loading dose is required if drug is suspended for 3 or more hours -Added language to reflect that 2 interim analyses will be performed during the course of the study.

09 April 2020	Version 6.0 -Added Neria Guard to the list of study devices -Added a post-treatment follow-up call after Week 52 (V13) to the activity schedule -Removed Unscheduled Visits from the Activity Schedule; added text to protocol to describe unscheduled visits -Removed text related to B12 re-testing outside of the 42-day screening period and clarified the B12 levels that are considered eligible at re-test -Removed text about sites submitting digital images; added that sites will request medical records from the dermatologic visit. Upon receipt of records or reports generated from the dermatologic visit, sites will promptly submit them to AbbVie or designee consistent with typical study data reporting requirements
12 February 2021	Version 7.0 -Updated sample size to approximately 240 subjects -Clarified that F3 infusion rate may be reduced beyond the 20% limit from the prescribed base infusion rate (F1) if medically necessary and only with approval from the AbbVie TA MD -Included information on the re-evaluation of the benefit and risk to subjects participating in the study to reflect that there is no additional risk to subjects due to COVID-19 -Modified/added eligibility criteria to minimize additional risk to study subjects or exclude subjects positive for COVID-19 -Clarified that protocol deviations may include modifications due to COVID-19 -Added instructions for COVID-19 pandemic-related acceptable protocol modifications and to refer to the Operations Manual for details on how to handle necessary changes to activities or procedures -Noted that AbbVie will modify the study protocol as necessary due to the COVID-19 pandemic. Investigators must also notify AbbVie if any urgent safety measures are taken -Noted that remote monitoring during the COVID-19 pandemic may be employed as needed -Updated Operations Manual to include details on how to perform specific activities/procedures that may be impacted by changes in global/local regulations due to the COVID-19 pandemic -Added additional details regarding ABBV-951 and infusion site reactions -Added hallucinations/psychosis as a common symptom in patients with PD and included general guidance -Added text to clarify that the appropriate cannula length will be selected by the investigator based on individual subject characteristics (thickness of the abdominal subcutaneous fat tissue) and noted that the investigator should consider instructing the subject to rotate the infusion site more frequently -Added alternative infusion site locations and considerations guidance -Removed references to "caregivers" throughout protocol and Operations Manual -Changed the reporting timeframe for product complaints to 24 hours

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported