Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects With Moderately to Severely Active Rheumatoid Arthritis With Inadequate Response to Biologic and/or Targeted Synthetic Disease-Modifying Anti-Rheumatic Drugs (b/tsDMARDs)

Summary

EudraCT number	2020-005303-39
Trial protocol	ES DE SK NL CZ PL GR IT
Global end of trial date	04 August 2023

Results information

Result version number	v2 (current)
This version publication date	08 November 2024
First version publication date	11 August 2024
Version creation reason	• Correction of full data set Clarifying edits to unit of measure for outcome measure 10

Trial information

Trial identification

Sponsor protocol code	M20-466

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04888585
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	04 August 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 August 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Rheumatoid Arthritis (RA) is an inflammatory disease of the joints causing pain, stiffness, swelling and loss of joint function. This study aimed to evaluate how safe and effective ABBV-154 is in subjects treated for moderately to severely active RA. Adverse events and change in the disease activity were assessed.

ABBV-154 is an investigational drug being evaluated for the treatment of RA. Approximately 425 subjects 18-75 years of age with moderate to severe RA were enrolled in the study at approximately 270 sites worldwide. Subjects attended regular visits during the study at a hospital or clinic. The effect of the treatment was checked by medical assessments, blood tests, checking for side effects, and completing questionnaires.

Protection of trial subjects:

Subjects read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 June 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Hungary: 42
Country: Number of subjects enrolled	Israel: 12
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Japan: 66
Country: Number of subjects enrolled	Poland: 22
Country: Number of subjects enrolled	Puerto Rico: 8
Country: Number of subjects enrolled	Russian Federation: 6
Country: Number of subjects enrolled	Slovakia: 13
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	Taiwan: 1

Country: Number of subjects enrolled	United States: 232
Country: Number of subjects enrolled	Czechia: 25
Worldwide total number of subjects	473
EEA total number of subjects	144

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)	337
From 65 to 84 years	136
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 473 participants (All Randomized Population) were enrolled in the study. The ITT Population (N=472) included all participants who were randomized and received at least 1 dose of study drug. One randomized participant was not treated and thus not included in the ITT Population.

Pre-assignment

Screening details:

After a 12 week placebo-controlled period, subjects in the Placebo group were re-randomized to ABBV-154 at 2 different doses SC every other week, while others remained on their previous dose. There was a planned double-blind long term extension (LTE) of 66 weeks and a LTE 2 of 104 weeks. The study was terminated before any subjects entered LTE 2.

Period 1

Period 1 title	Placebo-Controlled Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Subjects were randomized to 5 treatment groups in a 1:1:1:1:1 ratio to receive blinded ABBV-154 at a dose of 40 mg, 150 mg, or 340 mg, subcutaneously (SC) every other week (EOW); 340 mg SC E4W; or placebo SC EOW for 12 weeks.

Arms

Are arms mutually exclusive?	Yes
Arm title	Period 1 (Placebo-Controlled Period) Placebo

Arm description:

Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized at 1:1 ratio to receive ABBV-154 150 mg or 340 mg SC EOW for 66 weeks in the long term extension (LTE) period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection

Arm title	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW

Arm description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW

Arm description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period. One randomized subject in this arm was ineligible and did not receive treatment. This subject was not included in the ITT population.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Arm description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W

Arm description:

Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Number of subjects in period 1[1]	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Started	96	98	94
Completed	92	93	86
Not completed	4	5	8
Consent withdrawn by subject	-	1	4

Other	4	4	3
Lost to follow-up	-	-	1

Number of subjects in period 1[1]	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Started	90	94
Completed	85	89
Not completed	5	5
Consent withdrawn by subject	3	3
Other	2	1
Lost to follow-up	-	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: One randomized subject was ineligible and did not receive treatment. This subject was was not included in the ITT population.

Period 2

Period 2 title	Long-Term Extension Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Period 2 (Extension Period) Placebo to ABBV-154 150 mg EOW

Arm description:

Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized in 1:1 ratio to receive ABBV-154 150 mg or 340 mg respectively SC EOW for 66 weeks in the long term extension (LTE) period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 2 (Extension Period) Placebo to ABBV-154 340 mg EOW

Arm description:

Subjects in this group received placebo SC EOW for 12 weeks in the placebo-controlled period and were re-randomized in 1:1 ratio to receive ABBV-154 150 mg or 340 mg respectively SC EOW for 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 2 (Extension Period) ABBV-154 40 mg EOW

Arm description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 2 (Extension Period) ABBV-154 150 mg EOW

Arm description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 2 (Extension Period) ABBV-154 340 mg EOW

Arm description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Arm title	Period 2 (Extension Period) ABBV-154 340 mg E4W

Arm description:

Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Arm type	Active comparator

Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous Injection

Number of subjects in period 2[2]	Period 2 (Extension Period) Placebo to ABBV-154 150 mg EOW	Period 2 (Extension Period) Placebo to ABBV-154 340 mg EOW	Period 2 (Extension Period) ABBV-154 40 mg EOW
Started	45	46	93
Completed	0	0	0
Not completed	45	46	93
Consent withdrawn by subject	5	5	8
Other	3	1	4
Death	-	-	1
Study terminated by sponsor	37	36	78
Lost to follow-up	-	4	2

Number of subjects in period 2[2]	Period 2 (Extension Period) ABBV-154 150 mg EOW	Period 2 (Extension Period) ABBV-154 340 mg EOW	Period 2 (Extension Period) ABBV-154 340 mg E4W
Started	86	85	89
Completed	0	0	0
Not completed	86	85	89
Consent withdrawn by subject	8	8	11
Other	5	5	3
Death	-	-	3
Study terminated by sponsor	71	71	72
Lost to follow-up	2	1	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: One subject from Period 1 Placebo group did not enter Period 2.

Baseline characteristics

Reporting groups	
Reporting group title	Period 1 (Placebo-Controlled Period) Placebo
Reporting group description:	
Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized at 1:1 ratio to receive ABBV-154 150 mg or 340 mg SC EOW for 66 weeks in the long term extension (LTE) period.	
Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Reporting group description:	
Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.	
Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Reporting group description:	
Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period. One randomized subject in this arm was ineligible and did not receive treatment. This subject was not included in the ITT population.	
Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Reporting group description:	
Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.	
Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Reporting group description:	
Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.	

Reporting group values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects	96	98	94
Age categorical Units: Subjects			
< 40	6	7	5
40–65	60	68	65
>=65	30	23	24
Age continuous Units: years			
arithmetic mean	57.8	56.2	56.8
standard deviation	± 11.28	± 10.17	± 9.91
Gender categorical Units: Subjects			
Female	80	76	73
Male	16	22	21

Reporting group values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W	Total
Number of subjects	90	94	472

Age categorical Units: Subjects			
< 40	6	9	33
40–65	55	55	303
>=65	29	30	136
Age continuous Units: years			
arithmetic mean	59.5	57.9	
standard deviation	± 10.72	± 10.70	-
Gender categorical Units: Subjects			
Female	70	74	373
Male	20	20	99

End points

End points reporting groups

Reporting group title	Period 1 (Placebo-Controlled Period) Placebo

Reporting group description:

Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized at 1:1 ratio to receive ABBV-154 150 mg or 340 mg SC EOW for 66 weeks in the long term extension (LTE) period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW

Reporting group description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW

Reporting group description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period. One randomized subject in this arm was ineligible and did not receive treatment. This subject was not included in the ITT population.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) Placebo to ABBV-154 150 mg EOW

Reporting group description:

Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized in 1:1 ratio to receive ABBV-154 150 mg or 340 mg respectively SC EOW for 66 weeks in the long term extension (LTE) period.

Reporting group title	Period 2 (Extension Period) Placebo to ABBV-154 340 mg EOW

Reporting group description:

Subjects in this group received placebo SC EOW for 12 weeks in the placebo-controlled period and were re-randomized in 1:1 ratio to receive ABBV-154 150 mg or 340 mg respectively SC EOW for 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 40 mg EOW

Reporting group description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 150 mg EOW

Reporting group description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 340 mg EOW

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 340 mg E4W

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Primary: Achievement of 50% Improvement as Measured by American College of Rheumatology Response Criteria (ACR50) at Week 12

End point title	Achievement of 50% Improvement as Measured by American College of Rheumatology Response Criteria (ACR50) at Week 12

End point description:

Subjects who met the following 3 conditions for improvement from baseline were classified as meeting the ACR50 response criteria:
≥ 50% improvement in 68-tender joint count;
≥ 50% improvement in 66-swollen joint count; and
≥ 50% improvement in at least 3 of the 5 following parameters:
- Physician's Global Assessment of Disease Activity (NRS)
- Patient's Global Assessment of Disease Activity (NRS)
- Patient's Assessment of Pain (NRS)
- Health Assessment Questionnaire - Disability Index (HAQ-DI)
- High-sensitivity C-reactive protein (hsCRP).

End point type	Primary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[1]	98[2]	94[3]	90[4]
Units: percentage of subjects				
number (confidence interval 95%)	6.3 (1.4 to 11.1)	25.5 (16.9 to 34.1)	33.3 (23.7 to 42.9)	44.4 (34.2 to 54.7)

Notes:

[1] - ITT analysis set subjects were included (N=472)

[2] - ITT analysis set subjects were included (N=472)

[3] - ITT analysis set subjects were included (N=472)

[4] - ITT analysis set subjects were included (N=472)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[5]			
Units: percentage of subjects				
number (confidence interval 95%)	30.9 (21.5 to 40.2)			

Notes:

[5] - ITT analysis set subjects were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1

	(Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	21.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.5
upper limit	31

Notes:

[6] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	26.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.5
upper limit	36.7

Notes:

[7] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	37.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.4
upper limit	48.1

Notes:

[8] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	23.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	32.6

Notes:

[9] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Change From Baseline in Disease Activity Score (DAS) 28 (CRP) at Week 12

End point title	Change From Baseline in Disease Activity Score (DAS) 28 (CRP) at Week 12

End point description:

The DAS28 is a composite index used to assess rheumatoid arthritis disease activity, calculated based on the tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS), and hsCRP (in mg/L). Scores on the DAS28 range from 0 to approximately 10, where higher scores indicate more disease activity. A negative change from Baseline in DAS28 (CRP) indicates improvement in disease activity.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93[10]	95[11]	90[12]	86[13]
Units: Units on a scale				
least squares mean (confidence interval 95%)	-1.08 (-1.35 to -0.82)	-1.59 (-1.85 to -1.33)	-2.09 (-2.37 to -1.82)	-2.51 (-2.78 to -2.23)

Notes:

[10] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

[11] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

[12] - ITT population subjects with non-missing baseline and at least one post-baseline value were included
[13] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[14]			
Units: Units on a scale				
least squares mean (confidence interval 95%)	-1.71 (-1.96 to -1.45)			

Notes:
[14] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [15]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	-0.14

Notes:
[15] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.38
upper limit	-0.64

Notes:

[16] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	-1.05

Notes:

[17] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [18]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	-0.26

Notes:

[18] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Secondary: Change in Clinical Disease Activity Index (CDAI) at Week 12

End point title	Change in Clinical Disease Activity Index (CDAI) at Week 12

End point description:

CDAI is a composite index for assessing disease activity based on the sum of the total tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS), and Physician's Global Assessment of Disease Activity (NRS). The total CDAI score ranges from 0 to 76 with higher scores indicating higher disease activity.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92[19]	91[20]	88[21]	86[22]
Units: Units on a scale				
least squares mean (confidence interval 95%)	-14.21 (-16.81 to -11.60)	-18.77 (-21.41 to -16.13)	-22.21 (-24.94 to -19.48)	-25.62 (-28.31 to -22.93)

Notes:

[19] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

[20] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

[21] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

[22] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	93[23]			
Units: Units on a scale				
least squares mean (confidence interval 95%)	-19.50 (-22.06 to -16.94)			

Notes:

[23] - ITT population subjects with non-missing baseline and at least one post-baseline value were included

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	183
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014 [24]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.21
upper limit	-0.92

Notes:

[24] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-8.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	-4.31

Notes:

[25] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [26]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.1
upper limit	-7.73

Notes:

[26] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [27]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-5.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.89
upper limit	-1.69

Notes:

[27] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Secondary: Percentage of Subjects Achieving American College of Rheumatology 20% (ACR20) Response at Week 12

End point title	Percentage of Subjects Achieving American College of Rheumatology 20% (ACR20) Response at Week 12

End point description:

Subjects who met the following 3 conditions for improvement from baseline were classified as meeting the ACR20 response criteria:
≥ 20% improvement in 68-tender joint count;
≥ 20% improvement in 66-swollen joint count; and
≥ 20% improvement in at least 3 of the 5 following parameters:
- Physician's Global Assessment of Disease Activity (NRS)
- Patient's Global Assessment of Disease Activity (NRS)
- Patient's Assessment of Pain (NRS)
- Health Assessment Questionnaire - Disability Index (HAQ-DI)
- High-sensitivity C-reactive protein (hsCRP).

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[28]	98[29]	94[30]	90[31]
Units: Percentage of subjects				
number (confidence interval 95%)	28.1 (19.1 to 37.1)	52.7 (42.7 to 62.7)	59.3 (49.3 to 69.2)	74.4 (65.4 to 83.5)

Notes:

[28] - ITT analysis set participants were included (N=472)

[29] - ITT analysis set participants were included (N=472)

[30] - ITT analysis set participants were included (N=472)

[31] - ITT analysis set participants were included (N=472)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[32]			
Units: Percentage of subjects				
number (confidence interval 95%)	54.3 (44.2 to 64.3)			

Notes:
[32] - ITT analysis set participants were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.1
upper limit	37.3

Notes:
[33] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [34]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	30.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.4
upper limit	42.9

Notes:
[34] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [35]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	45.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.5
upper limit	57.4

Notes:

[35] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.9
upper limit	37.3

Notes:

[36] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Response at Week 12

End point title	Percentage of Subjects Achieving American College of Rheumatology 70% (ACR70) Response at Week 12

End point description:

Subjects who met the following 3 conditions for improvement from baseline were classified as meeting the ACR70 response criteria:
≥ 70% improvement in 68-tender joint count;
≥ 70% improvement in 66-swollen joint count; and
≥ 70% improvement in at least 3 of the 5 following parameters:
- Physician's Global Assessment of Disease Activity (NRS)
- Patient's Global Assessment of Disease Activity (NRS)
- Patient's Assessment of Pain (NRS)
- Health Assessment Questionnaire - Disability Index (HAQ-DI)
- High-sensitivity C-reactive protein (hsCRP).

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[37]	98[38]	94[39]	90[40]
Units: Percentage of subjects				
number (confidence interval 95%)	3.1 (0.0 to 6.6)	9.2 (3.5 to 14.9)	12.8 (6.1 to 19.6)	13.3 (6.3 to 20.4)

Notes:

[37] - ITT analysis set subjects were included (N=472)

[38] - ITT analysis set subjects were included (N=472)

[39] - ITT analysis set subjects were included (N=472)

[40] - ITT analysis set subjects were included (N=472)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[41]			
Units: Percentage of subjects				
number (confidence interval 95%)	4.3 (0.2 to 8.3)			

Notes:

[41] - ITT analysis set subjects were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031 [42]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	12.4

Notes:

[42] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [43]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	9.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	17

Notes:

[43] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [44]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	10.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.6
upper limit	18.2

Notes:

[44] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.709 [45]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	5.9

Notes:

[45] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Percentage of Subjects Achieving Low Disease Activity (LDA) Defined by DAS28 (CRP) <= 3.2 at Week 12

End point title	Percentage of Subjects Achieving Low Disease Activity (LDA) Defined by DAS28 (CRP) <= 3.2 at Week 12

End point description:

Low disease activity (LDA) was defined as a DAS28 score less than or equal to 3.2. The DAS28 is a composite index used to assess rheumatoid arthritis disease activity, calculated based on the tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS) and Physician's Global Assessment of Disease Activity (NRS), and hsCRP (in mg/L). Scores on the DAS28 range from 0 to approximately 10, where higher scores indicate more disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[46]	98[47]	94[48]	90[49]
Units: Percentage of subjects				
number (confidence interval 95%)	20.8 (12.7 to 29.0)	38.9 (29.2 to 48.6)	48.2 (38.0 to 58.3)	53.3 (43.0 to 63.6)

Notes:

[46] - ITT analysis set participants were included (N=472)

[47] - ITT analysis set participants were included (N=472)

[48] - ITT analysis set participants were included (N=472)

[49] - ITT analysis set participants were included (N=472)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[50]			
Units: Percentage of subjects				
number (confidence interval 95%)	45.7 (35.7 to 55.8)			

Notes:

[50] - ITT analysis set participants were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW

Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [51]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	16.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.9
upper limit	28.9

Notes:

[51] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [52]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	25.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.5
upper limit	38.1

Notes:

[52] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [53]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	31.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.9
upper limit	44.2

Notes:

[53] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [54]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	23.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	11
upper limit	35.4

Notes:

[54] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Percentage of Subjects Achieving LDA Defined by CDAI <= 10 at Week 12

End point title	Percentage of Subjects Achieving LDA Defined by CDAI <= 10 at Week 12

End point description:

Low disease activity based on CDAI is defined as a CDAI score less than or equal to 10. CDAI is a composite index for assessing disease activity based on the sum of the total tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS), and Physician's Global Assessment of Disease Activity (NRS). The total CDAI score ranges from 0 to 76 with higher scores indicating higher disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[55]	98[56]	94[57]	90[58]
Units: Percentage of subjects				
number (confidence interval 95%)	21.9 (13.6 to 30.1)	36.8 (27.3 to 46.4)	46.1 (36.0 to 56.2)	46.7 (36.4 to 57.0)

Notes:

[55] - ITT analysis set subjects were included (N=472)

[56] - ITT analysis set subjects were included (N=472)

[57] - ITT analysis set subjects were included (N=472)

[58] - ITT analysis set subjects were included (N=472)

End point values	Period 1 (Placebo-Controlled			

	Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[59]			
Units: Percentage of subjects				
number (confidence interval 95%)	36.2 (26.5 to 45.9)			

Notes:

[59] - ITT analysis set subjects were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022 [60]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	26.2

Notes:

[60] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [61]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	22.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	10
upper limit	35.5

Notes:

[61] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [62]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.6
upper limit	37

Notes:

[62] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W v Period 1 (Placebo-Controlled Period) Placebo
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042 [63]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	24.7

Notes:

[63] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Percentage of Subjects Achieving Clinical Remission (CR) Defined by DAS28 (CRP) < 2.6 at Week 12

End point title	Percentage of Subjects Achieving Clinical Remission (CR) Defined by DAS28 (CRP) < 2.6 at Week 12

End point description:

Clinical remission was defined as a DAS28 (CRP) score less than 2.6. The DAS28 is a composite index used to assess rheumatoid arthritis disease activity, calculated based on the tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS), and hsCRP (in mg/L). Scores on the DAS28 range from 0 to approximately 10, where higher scores indicate more disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96[64]	98[65]	94[66]	90[67]
Units: Percentage of subjects				
number (confidence interval 95%)	12.5 (5.9 to 19.1)	18.4 (10.7 to 26.1)	33.0 (23.5 to 42.6)	37.8 (27.8 to 47.8)

Notes:

[64] - ITT analysis set subjects were included (N=472)

[65] - ITT analysis set subjects were included (N=472)

[66] - ITT analysis set subjects were included (N=472)

[67] - ITT analysis set subjects were included (N=472)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94[68]			
Units: Percentage of subjects				
number (confidence interval 95%)	27.7 (18.6 to 36.7)			

Notes:

[68] - ITT analysis set subjects were included (N=472)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.296 [69]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	14.6

Notes:

[69] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW

Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [70]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.7
upper limit	30.2

Notes:

[70] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [71]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	25.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.3
upper limit	36.7

Notes:

[71] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [72]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	24.5

Notes:

[72] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Percentage of Subjects Achieving CR Defined by CDAI <= 2.8 at Week 12

End point title	Percentage of Subjects Achieving CR Defined by CDAI <= 2.8 at Week 12

End point description:

Clinical Remission was defined by CDAI as a score less than or equal to 2.8. CDAI is a composite index for assessing disease activity based on the summation of the total tender joint count (out of 28 evaluated joints), swollen joint count (out of 28 evaluated joints), Patient's Global Assessment of Disease Activity (NRS), and Physician's Global Assessment of Disease Activity (NRS). The total CDAI score ranges from 0 to 76 with higher scores indicating higher disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	96	98	94	90
Units: Percentage of subjects				
number (confidence interval 95%)	2.1 (0.0 to 4.9)	9.2 (3.5 to 14.9)	4.3 (0.2 to 8.3)	4.4 (0.2 to 8.7)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94			
Units: Percentage of subjects				
number (confidence interval 95%)	3.2 (0.0 to 6.7)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	194
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017 [73]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	7.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	13

Notes:

[73] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.424 [74]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.8
upper limit	6.8

Notes:

[74] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.303 [75]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	7.5

Notes:

[75] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W

Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.551 [76]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	5.4

Notes:

[76] - Cochran-Mantel-Haenszel (CMH) test adjusted for the stratification factors.

Secondary: Change From Baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) to Week 12

End point title	Change From Baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) to Week 12

End point description:

The Health Assessment Questionnaire - Disability Index is a participant-reported questionnaire that measures the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Participants assessed their ability to do each task on a scale from 0 (without any difficulty) to 3 (unable to do). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 represents no disability and 3 represents very severe, high-dependency disability. A negative change from Baseline in the overall score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline to Week 12

End point values	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	95	90	86
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.08 (-0.19 to 0.03)	-0.26 (-0.36 to -0.15)	-0.33 (-0.45 to -0.22)	-0.41 (-0.52 to -0.29)

End point values	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W			
Subject group type	Reporting group			
Number of subjects analysed	94			

Units: units on a scale				
least squares mean (confidence interval 95%)	-0.29 (-0.39 to -0.18)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW
Number of subjects included in analysis	189
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022 [77]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	-0.03

Notes:

[77] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Number of subjects included in analysis	184
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [78]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.41
upper limit	-0.1

Notes:

[78] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 3
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [79]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	-0.17

Notes:

[79] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Statistical analysis title	Statistical Analysis 4
Comparison groups	Period 1 (Placebo-Controlled Period) Placebo v Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [80]
Method	Mixed Model for Repeated Measures
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	-0.06

Notes:

[80] - MMRM model includes treatment, visit, treatment-by-visit interaction, stratification factors, and the baseline measurement as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality and adverse event tables include events reported from enrollment to end of study.

Adverse event reporting additional description:

Median time subjects were followed was 85 days for all groups in Period 1. For each LTE group, the median time subjects were followed was 412 days (Placebo-ABBV-154 150mg); 389 days (Placebo-ABBV-154 340mg); 390 days (ABBV-154 40mg EOW); 402.5 days (ABBV-154 150mg EOW), 404 days (ABBV-154 340mg EOW), and 380 days (ABBV-154 340mg E4W), respectively.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Period 1 (Placebo-Controlled Period) Placebo

Reporting group description:

Subjects in this group received placebo subcutaneously (SC) every other week (EOW) for 12 weeks in the placebo-controlled period and were re-randomized at 1:1 ratio to receive ABBV-154 150 mg or 340 mg SC EOW for 66 weeks in the long term extension (LTE) period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW

Reporting group description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

One subject experienced an AE in Period 1 that was ongoing and resulted in death in Period 2.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW

Reporting group description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC every 4 weeks (E4W) for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) Placebo to ABBV-154 150mg EOW

Reporting group description:

Subjects in this group received placebo SC EOW for 12 weeks in the placebo-controlled period and then received ABBV-154 150mg SC EOW for 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) Placebo to ABBV-154 340mg EOW

Reporting group description:

Subjects in this group received placebo SC EOW for 12 weeks in the placebo-controlled period and then received ABBV-154 340mg SC EOW for 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 40 mg EOW

Reporting group description:

Subjects in this group received 40 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 150 mg EOW

Reporting group description:

Subjects in this group received 150 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 340 mg EOW

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC EOW for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Reporting group title	Period 2 (Extension Period) ABBV-154 340 mg E4W

Reporting group description:

Subjects in this group received 340 mg of ABBV-154 SC E4W for 12 weeks in the placebo-controlled period and 66 weeks in the LTE period.

Serious adverse events	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 96 (2.08%)	4 / 98 (4.08%)	6 / 95 (6.32%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC STENOSIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
ANKLE FRACTURE			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIMB FRACTURE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LACERATION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL RUPTURE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON INJURY			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRADYCARDIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STROKE IN EVOLUTION			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOCHEZIA			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCARCERATED INGUINAL HERNIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINE POLYP			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
EXOSTOSIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHEUMATOID ARTHRITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL CYST			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TENOSYNOVITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIOUS MONONUCLEOSIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROLOGICAL INFECTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPPORTUNISTIC INFECTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			

subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Q FEVER			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W	Period 2 (Extension Period) Placebo to ABBV-154 150mg EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 90 (5.56%)	3 / 94 (3.19%)	3 / 45 (6.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC STENOSIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

ANAPHYLACTIC REACTION			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ANKLE FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIMB FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LACERATION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL RUPTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON INJURY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRADYCARDIA			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STROKE IN EVOLUTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 90 (0.00%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCARCERATED INGUINAL HERNIA			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINE POLYP			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
EXOSTOSIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHEUMATOID ARTHRITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL CYST			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENOSYNOVITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 90 (0.00%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIOUS MONONUCLEOSIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROLOGICAL INFECTION			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPPORTUNISTIC INFECTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 90 (0.00%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Q FEVER			

subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 2 (Extension Period) Placebo to ABBV-154 340mg EOW	Period 2 (Extension Period) ABBV-154 40 mg EOW	Period 2 (Extension Period) ABBV-154 150 mg EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 46 (13.04%)	7 / 91 (7.69%)	8 / 86 (9.30%)
number of deaths (all causes)	0	1	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC STENOSIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ANKLE FRACTURE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIMB FRACTURE			

subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LACERATION			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL RUPTURE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON INJURY			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRADYCARDIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			

subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STROKE IN EVOLUTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			

subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCARCERATED INGUINAL HERNIA			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINE POLYP			

subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
EXOSTOSIS			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHEUMATOID ARTHRITIS			
subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVIAL CYST			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNOVITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	2 / 86 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENOSYNOVITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACTERAEMIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIOUS MONONUCLEOSIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			
subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROLOGICAL INFECTION			

subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPPORTUNISTIC INFECTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 46 (2.17%)	0 / 91 (0.00%)	1 / 86 (1.16%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Q FEVER			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			

subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	0 / 46 (0.00%)	1 / 91 (1.10%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	0 / 86 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 2 (Extension Period) ABBV-154 340 mg EOW	Period 2 (Extension Period) ABBV-154 340 mg E4W	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 84 (11.90%)	9 / 89 (10.11%)	
number of deaths (all causes)	0	3	
number of deaths resulting from adverse events	0	3	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF COLON			

subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST CANCER			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GLIOBLASTOMA			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
AORTIC STENOSIS			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
UTERINE POLYP			

subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PNEUMONITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEPRESSION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ANKLE FRACTURE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PATELLA FRACTURE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIMB FRACTURE			

subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN LACERATION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNOVIAL RUPTURE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TENDON INJURY			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRADYCARDIA			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			

subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 84 (1.19%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
METABOLIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STROKE IN EVOLUTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			

subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
RETINAL DETACHMENT			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOD POISONING			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOCHEZIA			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCARCERATED INGUINAL HERNIA			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE POLYP			

subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
EXOSTOSIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHEUMATOID ARTHRITIS			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNOVIAL CYST			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNOVITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TENOSYNOVITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

BACTERAEMIA			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTIOUS MONONUCLEOSIS			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARYNGITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUROLOGICAL INFECTION			

subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OPPORTUNISTIC INFECTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOMYELITIS			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	1 / 84 (1.19%)	2 / 89 (2.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS			
subjects affected / exposed	0 / 84 (0.00%)	1 / 89 (1.12%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Q FEVER			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			

subjects affected / exposed	0 / 84 (0.00%)	2 / 89 (2.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUSITIS			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 84 (1.19%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Period 1 (Placebo-Controlled Period) Placebo	Period 1 (Placebo-Controlled Period) ABBV-154 40 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 150 mg EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 96 (26.04%)	43 / 98 (43.88%)	26 / 95 (27.37%)
Injury, poisoning and procedural complications			

CONTUSION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	3 / 95 (3.16%)
occurrences (all)	0	0	3
FALL			
subjects affected / exposed	1 / 96 (1.04%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences (all)	1	1	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	2 / 95 (2.11%)
occurrences (all)	0	0	2
Nervous system disorders			
HEADACHE			
subjects affected / exposed	3 / 96 (3.13%)	4 / 98 (4.08%)	3 / 95 (3.16%)
occurrences (all)	3	4	3
General disorders and administration site conditions			
INJECTION SITE DISCOLOURATION			
subjects affected / exposed	0 / 96 (0.00%)	3 / 98 (3.06%)	1 / 95 (1.05%)
occurrences (all)	0	4	2
INJECTION SITE BRUISING			
subjects affected / exposed	2 / 96 (2.08%)	3 / 98 (3.06%)	0 / 95 (0.00%)
occurrences (all)	2	4	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	1 / 96 (1.04%)	3 / 98 (3.06%)	1 / 95 (1.05%)
occurrences (all)	3	7	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	1 / 95 (1.05%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	1 / 96 (1.04%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences (all)	1	0	0
DIARRHOEA			

subjects affected / exposed	1 / 96 (1.04%)	2 / 98 (2.04%)	3 / 95 (3.16%)
occurrences (all)	1	2	5
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	3 / 95 (3.16%)
occurrences (all)	0	2	5
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 96 (0.00%)	2 / 98 (2.04%)	1 / 95 (1.05%)
occurrences (all)	0	2	1
BACK PAIN			
subjects affected / exposed	2 / 96 (2.08%)	3 / 98 (3.06%)	0 / 95 (0.00%)
occurrences (all)	2	4	0
RHEUMATOID ARTHRITIS			
subjects affected / exposed	7 / 96 (7.29%)	5 / 98 (5.10%)	2 / 95 (2.11%)
occurrences (all)	8	6	2
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 96 (2.08%)	2 / 98 (2.04%)	1 / 95 (1.05%)
occurrences (all)	2	2	1
COVID-19			
subjects affected / exposed	1 / 96 (1.04%)	13 / 98 (13.27%)	5 / 95 (5.26%)
occurrences (all)	1	13	5
INFLUENZA			
subjects affected / exposed	0 / 96 (0.00%)	1 / 98 (1.02%)	0 / 95 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	2 / 96 (2.08%)	2 / 98 (2.04%)	4 / 95 (4.21%)
occurrences (all)	2	2	5
PHARYNGITIS			
subjects affected / exposed	0 / 96 (0.00%)	0 / 98 (0.00%)	0 / 95 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 96 (1.04%)	3 / 98 (3.06%)	0 / 95 (0.00%)
occurrences (all)	1	3	0
URINARY TRACT INFECTION			

subjects affected / exposed	3 / 96 (3.13%)	5 / 98 (5.10%)	1 / 95 (1.05%)
occurrences (all)	3	5	1

Non-serious adverse events	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg EOW	Period 1 (Placebo-Controlled Period) ABBV-154 340 mg E4W	Period 2 (Extension Period) Placebo to ABBV-154 150mg EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 90 (28.89%)	27 / 94 (28.72%)	31 / 45 (68.89%)
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	2 / 90 (2.22%)	1 / 94 (1.06%)	1 / 45 (2.22%)
occurrences (all)	2	1	1
Nervous system disorders			
HEADACHE			
subjects affected / exposed	4 / 90 (4.44%)	2 / 94 (2.13%)	2 / 45 (4.44%)
occurrences (all)	4	2	2
General disorders and administration site conditions			
INJECTION SITE DISCOLOURATION			
subjects affected / exposed	4 / 90 (4.44%)	1 / 94 (1.06%)	4 / 45 (8.89%)
occurrences (all)	4	1	5
INJECTION SITE BRUISING			
subjects affected / exposed	1 / 90 (1.11%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	1	1	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	3 / 90 (3.33%)	6 / 94 (6.38%)	2 / 45 (4.44%)
occurrences (all)	6	7	3
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
PYREXIA			

subjects affected / exposed	2 / 90 (2.22%)	0 / 94 (0.00%)	2 / 45 (4.44%)
occurrences (all)	2	0	2
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	1 / 90 (1.11%)	3 / 94 (3.19%)	0 / 45 (0.00%)
occurrences (all)	1	3	0
DIARRHOEA			
subjects affected / exposed	2 / 90 (2.22%)	0 / 94 (0.00%)	2 / 45 (4.44%)
occurrences (all)	2	0	2
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	2 / 90 (2.22%)	2 / 94 (2.13%)	0 / 45 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	1	0	1
BACK PAIN			
subjects affected / exposed	2 / 90 (2.22%)	1 / 94 (1.06%)	1 / 45 (2.22%)
occurrences (all)	2	1	1
RHEUMATOID ARTHRITIS			
subjects affected / exposed	1 / 90 (1.11%)	2 / 94 (2.13%)	5 / 45 (11.11%)
occurrences (all)	1	2	6
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 90 (1.11%)	0 / 94 (0.00%)	2 / 45 (4.44%)
occurrences (all)	1	0	2
COVID-19			
subjects affected / exposed	2 / 90 (2.22%)	7 / 94 (7.45%)	12 / 45 (26.67%)
occurrences (all)	2	7	12
INFLUENZA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	5 / 45 (11.11%)
occurrences (all)	0	0	6
NASOPHARYNGITIS			
subjects affected / exposed	1 / 90 (1.11%)	3 / 94 (3.19%)	4 / 45 (8.89%)
occurrences (all)	1	3	4

PHARYNGITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	4 / 90 (4.44%)	4 / 94 (4.26%)	9 / 45 (20.00%)
occurrences (all)	5	4	11
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 90 (2.22%)	0 / 94 (0.00%)	8 / 45 (17.78%)
occurrences (all)	2	0	10

Non-serious adverse events	Period 2 (Extension Period) Placebo to ABBV-154 340mg EOW	Period 2 (Extension Period) ABBV-154 40 mg EOW	Period 2 (Extension Period) ABBV-154 150 mg EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 46 (54.35%)	54 / 91 (59.34%)	56 / 86 (65.12%)
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	1 / 46 (2.17%)	2 / 91 (2.20%)	5 / 86 (5.81%)
occurrences (all)	1	2	5
FALL			
subjects affected / exposed	0 / 46 (0.00%)	6 / 91 (6.59%)	2 / 86 (2.33%)
occurrences (all)	0	6	2
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 46 (2.17%)	4 / 91 (4.40%)	3 / 86 (3.49%)
occurrences (all)	1	4	3
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 46 (2.17%)	3 / 91 (3.30%)	5 / 86 (5.81%)
occurrences (all)	1	3	5
General disorders and administration site conditions			
INJECTION SITE DISCOLOURATION			
subjects affected / exposed	3 / 46 (6.52%)	2 / 91 (2.20%)	5 / 86 (5.81%)
occurrences (all)	5	2	5
INJECTION SITE BRUISING			
subjects affected / exposed	5 / 46 (10.87%)	2 / 91 (2.20%)	2 / 86 (2.33%)
occurrences (all)	13	3	4

INJECTION SITE ERYTHEMA			
subjects affected / exposed	3 / 46 (6.52%)	7 / 91 (7.69%)	3 / 86 (3.49%)
occurrences (all)	9	35	14
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 46 (0.00%)	0 / 91 (0.00%)	3 / 86 (3.49%)
occurrences (all)	0	0	3
PYREXIA			
subjects affected / exposed	1 / 46 (2.17%)	6 / 91 (6.59%)	3 / 86 (3.49%)
occurrences (all)	1	6	3
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	2 / 46 (4.35%)	2 / 91 (2.20%)	5 / 86 (5.81%)
occurrences (all)	2	2	7
DIARRHOEA			
subjects affected / exposed	0 / 46 (0.00%)	3 / 91 (3.30%)	5 / 86 (5.81%)
occurrences (all)	0	4	6
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	3 / 46 (6.52%)	4 / 91 (4.40%)	4 / 86 (4.65%)
occurrences (all)	3	4	9
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 46 (2.17%)	6 / 91 (6.59%)	3 / 86 (3.49%)
occurrences (all)	1	8	3
BACK PAIN			
subjects affected / exposed	0 / 46 (0.00%)	3 / 91 (3.30%)	8 / 86 (9.30%)
occurrences (all)	0	3	8
RHEUMATOID ARTHRITIS			
subjects affected / exposed	4 / 46 (8.70%)	10 / 91 (10.99%)	11 / 86 (12.79%)
occurrences (all)	6	12	14
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 46 (0.00%)	6 / 91 (6.59%)	2 / 86 (2.33%)
occurrences (all)	0	6	2
COVID-19			

subjects affected / exposed	8 / 46 (17.39%)	15 / 91 (16.48%)	15 / 86 (17.44%)
occurrences (all)	8	17	16
INFLUENZA			
subjects affected / exposed	1 / 46 (2.17%)	1 / 91 (1.10%)	3 / 86 (3.49%)
occurrences (all)	1	1	3
NASOPHARYNGITIS			
subjects affected / exposed	4 / 46 (8.70%)	9 / 91 (9.89%)	11 / 86 (12.79%)
occurrences (all)	4	11	13
PHARYNGITIS			
subjects affected / exposed	0 / 46 (0.00%)	5 / 91 (5.49%)	3 / 86 (3.49%)
occurrences (all)	0	6	3
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	5 / 46 (10.87%)	6 / 91 (6.59%)	8 / 86 (9.30%)
occurrences (all)	5	6	10
URINARY TRACT INFECTION			
subjects affected / exposed	5 / 46 (10.87%)	3 / 91 (3.30%)	6 / 86 (6.98%)
occurrences (all)	10	3	8

Non-serious adverse events	Period 2 (Extension Period) ABBV-154 340 mg EOW	Period 2 (Extension Period) ABBV-154 340 mg E4W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 84 (61.90%)	47 / 89 (52.81%)	
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	3 / 84 (3.57%)	1 / 89 (1.12%)	
occurrences (all)	3	1	
FALL			
subjects affected / exposed	0 / 84 (0.00%)	0 / 89 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	4 / 84 (4.76%)	5 / 89 (5.62%)	
occurrences (all)	4	5	
Nervous system disorders			
HEADACHE			

subjects affected / exposed	3 / 84 (3.57%)	1 / 89 (1.12%)	
occurrences (all)	5	1	
General disorders and administration site conditions			
INJECTION SITE DISCOLOURATION			
subjects affected / exposed	3 / 84 (3.57%)	3 / 89 (3.37%)	
occurrences (all)	3	3	
INJECTION SITE BRUISING			
subjects affected / exposed	2 / 84 (2.38%)	6 / 89 (6.74%)	
occurrences (all)	2	6	
INJECTION SITE ERYTHEMA			
subjects affected / exposed	5 / 84 (5.95%)	5 / 89 (5.62%)	
occurrences (all)	8	8	
OEDEMA PERIPHERAL			
subjects affected / exposed	7 / 84 (8.33%)	0 / 89 (0.00%)	
occurrences (all)	7	0	
PYREXIA			
subjects affected / exposed	3 / 84 (3.57%)	0 / 89 (0.00%)	
occurrences (all)	3	0	
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	1 / 84 (1.19%)	2 / 89 (2.25%)	
occurrences (all)	1	2	
DIARRHOEA			
subjects affected / exposed	2 / 84 (2.38%)	2 / 89 (2.25%)	
occurrences (all)	2	2	
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	3 / 84 (3.57%)	0 / 89 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 84 (1.19%)	1 / 89 (1.12%)	
occurrences (all)	1	1	
BACK PAIN			
subjects affected / exposed	3 / 84 (3.57%)	2 / 89 (2.25%)	
occurrences (all)	3	2	

RHEUMATOID ARTHRITIS			
subjects affected / exposed	5 / 84 (5.95%)	8 / 89 (8.99%)	
occurrences (all)	5	10	
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	2 / 84 (2.38%)	6 / 89 (6.74%)	
occurrences (all)	2	6	
COVID-19			
subjects affected / exposed	17 / 84 (20.24%)	16 / 89 (17.98%)	
occurrences (all)	18	17	
INFLUENZA			
subjects affected / exposed	3 / 84 (3.57%)	4 / 89 (4.49%)	
occurrences (all)	3	6	
NASOPHARYNGITIS			
subjects affected / exposed	6 / 84 (7.14%)	11 / 89 (12.36%)	
occurrences (all)	6	15	
PHARYNGITIS			
subjects affected / exposed	3 / 84 (3.57%)	1 / 89 (1.12%)	
occurrences (all)	3	1	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	12 / 84 (14.29%)	7 / 89 (7.87%)	
occurrences (all)	13	7	
URINARY TRACT INFECTION			
subjects affected / exposed	8 / 84 (9.52%)	5 / 89 (5.62%)	
occurrences (all)	10	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 April 2022	Protocol Version 2.0 Typographical corrections or edits were made for consistency. In addition, updates and clarifications were made to study procedures, including but not limited to the following: • Added a 104-week LTE Period 2 and renamed the originally planned double-blind LTE period "Double-Blind, Long-term Extension Period 1" • Updated wording to clarify when unblinding would occur • Updated/clarified eligibility criteria related to b/tsDMARDs • Changed the definition of ITT population from all randomized subjects to all subjects who were randomized and received at least 1 dose of study drug • Updates/clarifications to Objectives, Hypotheses, and Estimands • The Optional Synovial Biopsy Substudy was removed as it was determined it will not be possible to enroll enough subjects into the Substudy to achieve scientific goals • Added 70-Day Follow-up Period to the description of the overall study design • Clarified primary and final analysis timing • Clarified that subjects previously on placebo will be re-randomized • Updates/clarifications made to the section on requirements for contraception, breastfeeding, and pregnancy

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported