



Clinical trial results:

A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects With Polymyalgia Rheumatica (PMR) Dependent on Glucocorticoid Treatment

Summary

EudraCT number	2021-000648-23
Trial protocol	ES DE HU NL IT PL AT
Global end of trial date	24 July 2023

Results information

Result version number	v1
This version publication date	03 August 2024
First version publication date	03 August 2024

Trial information

Trial identification

Sponsor protocol code	M20-370
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04972968
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, Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 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	24 July 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 July 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Polymyalgia rheumatica (PMR) is an inflammatory disease causing shoulder, hip, and neck pain and stiffness, in adults aged 50 years or older. This study evaluates how safe and effective ABBV-154 is in participants with glucocorticoid-dependent PMR. AEs and change in disease activity will be assessed.

ABBV-154 is an investigational drug being evaluated for the treatment of PMR. Participants will be randomized into 1 of 4 treatment groups or arms, each arm receiving a different treatment. There is a 1 in 4 chance that a participant will be assigned to placebo. Around 160 participants, of at least 50 years of age, with PMR will be enrolled in the study at approximately 95 sites worldwide.

The study is comprised of a 52 week double-blind, placebo-controlled period and a follow-up visit 70 days after the last dose of the study drug. All participants will receive a glucocorticoid taper along with the assigned dose of ABBV-154 or placebo, subcutaneously (SC) every other week (EOW).

Protection of trial subjects:

The investigator or his/her representative will explain the nature of the study to the subject, the benefits and risks anticipated from participation in the study, and answer all questions regarding this study. Prior to any study-related screening procedures being performed on the subject or any medications being discontinued by the subject in order to participate in this study, the informed consent statement will be reviewed, signed, and dated by the subject, the person who administered the informed consent, and any other signatories according to local requirements. A copy of the signed informed consent will be given to the subject and the original will be placed in the subject's medical record. An entry must also be made in the subject's dated source documents to confirm that informed consent was obtained prior to any study-related procedures and that the subject received a signed copy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 September 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	Australia: 6
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Hungary: 27
Country: Number of subjects enrolled	Italy: 5

Country: Number of subjects enrolled	Japan: 22
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	New Zealand: 16
Country: Number of subjects enrolled	Poland: 12
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	United States: 35
Worldwide total number of subjects	181
EEA total number of subjects	87

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)	43
From 65 to 84 years	134
85 years and over	4

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

181 glucocorticoid dependent PMR subjects were randomized into 4 groups and dosed for 52 wks. Subjects were dosed SC: Placebo, ABBV-154 (40mg, 150mg, or 340mg) with a glucocorticoid taper EOW. Beginning at Wk 3, subjects were to taper prednisone/prednisolone per protocol-defined glucocorticoid taper schedule to 0mg prednisone equivalent by Wk 24.

Period 1

Period 1 title	Overall Study Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants will receive placebo SC EOW for 52 Weeks. In addition, participants will receive a glucocorticoid oral tablet taper.

Placebo: Subcutaneous Injection; Glucocorticoid: Oral Tablet

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants will receive placebo SC EOW for 52 Weeks. In addition, participants will receive a glucocorticoid oral tablet taper.

Placebo: Subcutaneous Injection; Glucocorticoid: Oral Tablet

Investigational medicinal product name	Glucocorticoid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet

Arm title	ABBV-154, 40mg SC
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Arm description:

Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet

Arm type	Experimental
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Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet

Investigational medicinal product name	Glucocorticoid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet

Arm title	ABBV-154, 150mg SC
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Arm description:

Participants in this group received 150mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 150mg SC; Glucocorticoid: Oral Tablet

Arm type	Experimental
Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants in this group received 150mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 150mg SC; Glucocorticoid: Oral Tablet

Investigational medicinal product name	Glucocorticoid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants in this group received 150mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 150mg SC; Glucocorticoid: Oral Tablet

Arm title	ABBV-154, 340mg SC
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Arm description:

Participants in this group received 340mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 340mg SC; Glucocorticoid: Oral Tablet

Arm type	Experimental
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Investigational medicinal product name	ABBV-154
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants in this group received 340mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 340mg SC; Glucocorticoid: Oral Tablet

Investigational medicinal product name	Glucocorticoid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants in this group received 340mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 340mg SC; Glucocorticoid: Oral Tablet

Number of subjects in period 1	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC
Started	50	42	45
Completed	12	8	8
Not completed	38	34	37
Consent withdrawn by subject	7	4	3
Adverse event, non-fatal	3	1	1
Not specified	1	-	1
Study terminated by sponsor	25	28	32
Lack of efficacy	2	1	-

Number of subjects in period 1	ABBV-154, 340mg SC
Started	44
Completed	7
Not completed	37
Consent withdrawn by subject	2
Adverse event, non-fatal	7
Not specified	1
Study terminated by sponsor	27
Lack of efficacy	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants will receive placebo SC EOW for 52 Weeks. In addition, participants will receive a glucocorticoid oral tablet taper.

Placebo: Subcutaneous Injection; Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154, 40mg SC
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Reporting group description:

Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154, 150mg SC
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Reporting group description:

Participants in this group received 150mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 150mg SC; Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154, 340mg SC
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Reporting group description:

Participants in this group received 340mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: 340mg SC; Glucocorticoid: Oral Tablet

Reporting group values	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC
Number of subjects	50	42	45
Age categorical Units: Subjects			
< 65 years	9	16	12
65 - < 75 years	24	17	20
≥ 75 years	17	9	13
Age continuous Units: years			
arithmetic mean	71.0	67.5	69.8
standard deviation	± 7.15	± 7.98	± 8.34
Gender categorical Units: Subjects			
Female	33	30	25
Male	17	12	20
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	2
Not Hispanic or Latino	49	42	43
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
White	42	37	41
Black or African American	0	0	0

Asian	8	5	4
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	0	0	0

Reporting group values	ABBV-154, 340mg SC	Total	
Number of subjects	44	181	
Age categorical Units: Subjects			
< 65 years	6	43	
65 - < 75 years	31	92	
≥ 75 years	7	46	
Age continuous Units: years			
arithmetic mean	69.1		
standard deviation	± 6.23	-	
Gender categorical Units: Subjects			
Female	29	117	
Male	15	64	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	5	
Not Hispanic or Latino	42	176	
Unknown or Not Reported	0	0	
Race (NIH/OMB) Units: Subjects			
White	39	159	
Black or African American	0	0	
Asian	5	22	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Multiple	0	0	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants will receive placebo SC EOW for 52 Weeks. In addition, participants will receive a glucocorticoid oral tablet taper. Placebo: Subcutaneous Injection; Glucocorticoid: Oral Tablet	
Reporting group title	ABBV-154, 40mg SC
Reporting group description: Participants in this group received 40mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper. ABBV-154: 40mg SC; Glucocorticoid: Oral Tablet	
Reporting group title	ABBV-154, 150mg SC
Reporting group description: Participants in this group received 150mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper. ABBV-154: 150mg SC; Glucocorticoid: Oral Tablet	
Reporting group title	ABBV-154, 340mg SC
Reporting group description: Participants in this group received 340mg dose of ABBV-154 SC EOW for 52 Weeks. In addition, participants received a glucocorticoid oral tablet taper. ABBV-154: 340mg SC; Glucocorticoid: Oral Tablet	

Primary: Time to Flare

End point title	Time to Flare
End point description: Flare is defined as, presence of clinical signs and symptoms of PMR and requirement to increase the glucocorticoid dose per investigator. Analysis Population Description: ITT Population	
End point type	Primary
End point timeframe: Week 24	

End point values	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC	ABBV-154, 340mg SC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	42	45	44
Units: Count of Participants				
number (not applicable)	33	18	18	9

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v ABBV-154, 40mg SC
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 ^[1]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.273
upper limit	0.878

Notes:

[1] - P-value ≤ 0.05

Stratified by baseline randomization stratification factors [Glucocorticoid use at Baseline (≥ 10 mg/day; < 10 mg/day prednisone equivalent)]

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v ABBV-154, 150mg SC
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 ^[2]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.443
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.248
upper limit	0.794

Notes:

[2] - P-value ≤ 0.01

Stratified by baseline randomization stratification factors [Glucocorticoid use at Baseline(≥ 10 mg/day; < 10 mg/day prednisone equivalent)]

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v ABBV-154, 340mg SC
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[3]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.198

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.094
upper limit	0.419

Notes:

[3] - P-value ≤ 0.001

Stratified by baseline randomization stratification factors [Glucocorticoid use at Baseline(≥ 10 mg/day; < 10 mg/day prednisone equivalent)]

Secondary: Change from Baseline in Glucocorticoid Dose

End point title	Change from Baseline in Glucocorticoid Dose
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End point description:

Change from Baseline in glucocorticoid dose.

Analysis Population Description: ITT Population

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC	ABBV-154, 340mg SC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	28	29	30
Units: mg				
arithmetic mean (standard deviation)	-4.96 (\pm 3.943)	-6.29 (\pm 3.384)	-7.40 (\pm 3.554)	-7.88 (\pm 3.398)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v ABBV-154, 40mg SC
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039 ^[4]
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.08
upper limit	-0.08

Notes:

[4] - P-value ≤ 0.05 ; P-value based on ANCOVA adjusting for baseline randomization stratification factors (GC use at baseline)

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v ABBV-154, 150mg SC
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[5]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-2.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.15
upper limit	-1.16

Notes:

[5] - P-value ≤ 0.001 ; P-value based on an ANCOVA model adjusting for baseline randomization stratification factors (GC use at baseline)

95% CI based on an ANCOVA model adjusting for baseline randomization stratification factors (GC use at baseline)

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v ABBV-154, 340mg SC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[6]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.49
upper limit	-1.52

Notes:

[6] - P-value ≤ 0.001 ; P-value based on an ANCOVA model adjusting for baseline randomization stratification factors (GC use at baseline)

95% CI based on an ANCOVA model adjusting for baseline randomization stratification factors (GC use at baseline)

Secondary: Cumulative Glucocorticoid Dose

End point title	Cumulative Glucocorticoid Dose
End point description:	
Cumulative glucocorticoid dose.	
Analysis Population Description: ITT Population	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC	ABBV-154, 340mg SC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	28	29	30
Units: Glucocorticoid dose (mg)				
arithmetic mean (standard deviation)	984.576 (\pm 524.6579)	823.411 (\pm 397.9403)	734.310 (\pm 332.3137)	759.450 (\pm 381.1683)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v ABBV-154, 40mg SC
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.144 ^[7]
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-88.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-208.04
upper limit	30.71

Notes:

[7] - P-value and 95% CI based on an Analysis of covariance (ANCOVA) model adjusting for baseline randomization stratification factors [GC use at baseline (≥ 10 mg/day; < 10 mg/day prednisone equivalent)]

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v ABBV-154, 150mg SC
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 ^[8]
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-164.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-283.62
upper limit	-45.89

Notes:

[8] - P-value ≤ 0.01

P-value and 95% CI are based on an Analysis of covariance (ANCOVA) model adjusting for baseline

randomization stratification factors [Glucocorticoid use at baseline (≥ 10 mg/day; < 10 mg/day prednisone) equivalent)

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v ABBV-154, 340mg SC
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 ^[9]
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-182.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-300.52
upper limit	-64.58

Notes:

[9] - P-value ≤ 0.01

P-value and 95% CI based on an Analysis of covariance (ANCOVA) model adjusting for baseline randomization stratification factors [Glucocorticoid use at baseline (≥ 10 mg/day; <10 mg/day prednisone equivalent)]

Secondary: Percentage of Participants Achieving Flare-Free State

End point title	Percentage of Participants Achieving Flare-Free State
End point description:	Percentage of participants achieving flare-free state.
Analysis Population Description: ITT Population	
End point type	Secondary
End point timeframe:	Up to Week 24

End point values	Placebo	ABBV-154, 40mg SC	ABBV-154, 150mg SC	ABBV-154, 340mg SC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	28	32	34
Units: participants				
number (not applicable)	11	13	15	24

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	ABBV-154, 40mg SC v Placebo

Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.107 ^[10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Median difference (net)
Point estimate	18.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	41.4

Notes:

[10] - From Cochran-Mantel-Haenszel test adjusting for baseline randomization stratification factors [Glucocorticoid (GC) use at baseline (≥ 10 mg/day; < 10 mg/day prednisone equivalent); Length of prior GC treatment for PMR (≤ 1 year; > 1 year)].

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v ABBV-154, 150mg SC
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092 ^[11]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Median difference (net)
Point estimate	18.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	41

Notes:

[11] - P-value ≤ 0.1

Cochran-Mantel-Haenszel test adjusting for baseline randomization stratification factors [Glucocorticoid use at baseline (≥ 10 mg/day; < 10 mg/day prednisone equivalent); Length of prior GC treatment for PMR (≤ 1 year; > 1 year)].

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v ABBV-154, 340mg SC
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 ^[12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Median difference (net)
Point estimate	41.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.4
upper limit	62.3

Notes:

[12] - P-value ≤ 0.001

Cochran-Mantel-Haenszel test adjusting for baseline randomization stratification factors [Glucocorticoid use at baseline (≥ 10 mg/day; < 10 mg/day prednisone equivalent); Length of prior GC treatment for PMR (≤ 1 year; > 1 year)].

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality were reported from enrollment to the end of study, median time on follow up was 288.5, 292.0, 300.0, and 299.0 Days for Placebo and ABBV-154 (40mg/150mg/340mg), respectively.

Adverse event reporting additional description:

Treatment-emergent adverse events and serious adverse events were collected from first dose of study drug within 70 days after the last dose of study drug; mean duration on study drug was 235.2, 239.9, 234.6 and 230.3 days for Placebo and ABBV-154 (40mg/150mg/340mg), respectively.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects will receive placebo SC EOW for 52 weeks. In addition, subjects will receive a glucocorticoid oral tablet taper.

Placebo: Subcutaneous Injection

Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154_340mg_SC_EOW
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Reporting group description:

Subjects in this group received 340mg dose of ABBV-154 SC EOW for 52 weeks. In addition, subjects received a glucocorticoid oral tablet taper.

ABBV-154: Subcutaneous Injection Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154_150mg_SC_EOW
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Reporting group description:

Subjects in this group received 150mg dose of ABBV-154 SC EOW for 52 weeks. In addition, subjects received a glucocorticoid oral tablet taper.

ABBV-154: Subcutaneous Injection Glucocorticoid: Oral Tablet

Reporting group title	ABBV-154_40mg_SC_EOW
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Reporting group description:

Subjects in this group received 40mg dose of ABBV-154 SC EOW for 52 weeks. In addition, participants received a glucocorticoid oral tablet taper.

ABBV-154: Subcutaneous Injection Glucocorticoid: Oral Tablet

Serious adverse events	Placebo	ABBV-154_340mg_SC_EOW	ABBV-154_150mg_SC_EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 50 (16.00%)	9 / 44 (20.45%)	8 / 45 (17.78%)
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)			
ACUTE MYELOID LEUKAEMIA			

subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
PROSTATE CANCER			
subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
Congenital, familial and genetic disorders			
ATRIAL SEPTAL DEFECT			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
Cardiac disorders			
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
VENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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			
DIZZINESS			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
SCIATICA			
subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
THALAMIC INFARCTION			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
INGUINAL HERNIA			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
PANCREATIC PSEUDOCYST			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
PANCREATITIS			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			

subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
Respiratory, thoracic and mediastinal disorders			
DYSпноEA AT REST			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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			
OSTEOARTHRITIS			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
APPENDICITIS PERFORATED			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
CELLULITIS			
subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			

subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
PNEUMONIA			
subjects affected / exposed	0 / 50 (0.00%)	4 / 44 (9.09%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA PNEUMOCOCCAL			
subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 50 (0.00%)	1 / 44 (2.27%)	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
UROSEPSIS			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 50 (0.00%)	0 / 44 (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
DIABETES MELLITUS			

subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (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

Serious adverse events	ABBV-154_40mg_SC_EOW		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 42 (11.90%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PROSTATE CANCER			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
ATRIAL SEPTAL DEFECT			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SUPRAVENTRICULAR TACHYCARDIA			

subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
SCIATICA			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
THALAMIC INFARCTION			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
INGUINAL HERNIA			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PANCREATIC PSEUDOCYST			

subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
PANCREATITIS			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA AT REST			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
OSTEOARTHRITIS			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
APPENDICITIS PERFORATED			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
CELLULITIS			

subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
LOWER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PERITONITIS				
subjects affected / exposed	1 / 42 (2.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA PNEUMOCOCCAL				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SEPSIS				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
URINARY TRACT INFECTION				
subjects affected / exposed	0 / 42 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
UROSEPSIS				

subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
DIABETES MELLITUS			
subjects affected / exposed	0 / 42 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo	ABBV-154_340mg_SC_EOW	ABBV-154_150mg_SC_EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 50 (54.00%)	37 / 44 (84.09%)	30 / 45 (66.67%)
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 50 (0.00%)	3 / 44 (6.82%)	2 / 45 (4.44%)
occurrences (all)	0	7	2
SKIN LACERATION			
subjects affected / exposed	0 / 50 (0.00%)	2 / 44 (4.55%)	1 / 45 (2.22%)
occurrences (all)	0	2	1
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	5 / 50 (10.00%)	3 / 44 (6.82%)	4 / 45 (8.89%)
occurrences (all)	5	3	4
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	3 / 50 (6.00%)	2 / 44 (4.55%)	1 / 45 (2.22%)
occurrences (all)	3	2	1
HEADACHE			

subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	5 / 44 (11.36%) 10	4 / 45 (8.89%) 4
Blood and lymphatic system disorders NEUTROPENIA subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 44 (0.00%) 0	3 / 45 (6.67%) 4
General disorders and administration site conditions INJECTION SITE ERYTHEMA subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 44 (4.55%) 5	3 / 45 (6.67%) 4
INJECTION SITE PAIN subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	3 / 44 (6.82%) 3	0 / 45 (0.00%) 0
INJECTION SITE RASH subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 44 (2.27%) 1	3 / 45 (6.67%) 7
OEDEMA PERIPHERAL subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	3 / 44 (6.82%) 3	0 / 45 (0.00%) 0
PYREXIA subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 44 (0.00%) 0	1 / 45 (2.22%) 1
FATIGUE subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	2 / 44 (4.55%) 2	4 / 45 (8.89%) 5
Gastrointestinal disorders DIARRHOEA subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4	3 / 44 (6.82%) 4	2 / 45 (4.44%) 2
NAUSEA subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 3	3 / 44 (6.82%) 4	2 / 45 (4.44%) 2
Respiratory, thoracic and mediastinal disorders COUGH subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	4 / 44 (9.09%) 4	1 / 45 (2.22%) 1

Skin and subcutaneous tissue disorders	HYPERHIDROSIS			
	subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (0.00%)	1 / 45 (2.22%)
	occurrences (all)	1	0	1
	RASH			
	subjects affected / exposed	2 / 50 (4.00%)	3 / 44 (6.82%)	2 / 45 (4.44%)
	occurrences (all)	2	3	2
Musculoskeletal and connective tissue disorders	ARTHRALGIA			
	subjects affected / exposed	3 / 50 (6.00%)	3 / 44 (6.82%)	6 / 45 (13.33%)
	occurrences (all)	5	5	6
	OSTEOARTHRITIS			
	subjects affected / exposed	1 / 50 (2.00%)	0 / 44 (0.00%)	3 / 45 (6.67%)
	occurrences (all)	1	0	3
	ROTATOR CUFF SYNDROME			
	subjects affected / exposed	3 / 50 (6.00%)	1 / 44 (2.27%)	3 / 45 (6.67%)
	occurrences (all)	3	1	4
Infections and infestations	COVID-19			
	subjects affected / exposed	9 / 50 (18.00%)	7 / 44 (15.91%)	5 / 45 (11.11%)
	occurrences (all)	9	7	5
	NASOPHARYNGITIS			
	subjects affected / exposed	3 / 50 (6.00%)	7 / 44 (15.91%)	4 / 45 (8.89%)
	occurrences (all)	4	9	5
	UPPER RESPIRATORY TRACT INFECTION			
	subjects affected / exposed	2 / 50 (4.00%)	2 / 44 (4.55%)	3 / 45 (6.67%)
	occurrences (all)	2	2	3
	URINARY TRACT INFECTION			
	subjects affected / exposed	5 / 50 (10.00%)	6 / 44 (13.64%)	2 / 45 (4.44%)
	occurrences (all)	9	9	5

Non-serious adverse events	ABBV-154_40mg_SC_EOW		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 42 (59.52%)		
Injury, poisoning and procedural complications			

<p>CONTUSION</p> <p>subjects affected / exposed</p> <p>2 / 42 (4.76%)</p> <p>occurrences (all)</p> <p>2</p> <p>SKIN LACERATION</p> <p>subjects affected / exposed</p> <p>3 / 42 (7.14%)</p> <p>occurrences (all)</p> <p>5</p>			
<p>Vascular disorders</p> <p>HYPERTENSION</p> <p>subjects affected / exposed</p> <p>1 / 42 (2.38%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>Nervous system disorders</p> <p>DIZZINESS</p> <p>subjects affected / exposed</p> <p>0 / 42 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>HEADACHE</p> <p>subjects affected / exposed</p> <p>3 / 42 (7.14%)</p> <p>occurrences (all)</p> <p>3</p>			
<p>Blood and lymphatic system disorders</p> <p>NEUTROPENIA</p> <p>subjects affected / exposed</p> <p>0 / 42 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>General disorders and administration site conditions</p> <p>INJECTION SITE ERYTHEMA</p> <p>subjects affected / exposed</p> <p>2 / 42 (4.76%)</p> <p>occurrences (all)</p> <p>3</p> <p>INJECTION SITE PAIN</p> <p>subjects affected / exposed</p> <p>0 / 42 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>INJECTION SITE RASH</p> <p>subjects affected / exposed</p> <p>1 / 42 (2.38%)</p> <p>occurrences (all)</p> <p>2</p> <p>OEDEMA PERIPHERAL</p> <p>subjects affected / exposed</p> <p>0 / 42 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>PYREXIA</p>			

subjects affected / exposed	0 / 42 (0.00%)		
occurrences (all)	0		
FATIGUE			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences (all)	3		
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	2 / 42 (4.76%)		
occurrences (all)	3		
NAUSEA			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
HYPERHIDROSIS			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences (all)	4		
RASH			
subjects affected / exposed	2 / 42 (4.76%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	4 / 42 (9.52%)		
occurrences (all)	4		
OSTEOARTHRITIS			
subjects affected / exposed	1 / 42 (2.38%)		
occurrences (all)	1		
ROTATOR CUFF SYNDROME			
subjects affected / exposed	2 / 42 (4.76%)		
occurrences (all)	2		
Infections and infestations			
COVID-19			

subjects affected / exposed	9 / 42 (21.43%)		
occurrences (all)	9		
NASOPHARYNGITIS			
subjects affected / exposed	4 / 42 (9.52%)		
occurrences (all)	5		
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 42 (4.76%)		
occurrences (all)	3		
URINARY TRACT INFECTION			
subjects affected / exposed	3 / 42 (7.14%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 July 2021	Version 2.0: Global Amendment updated the synopsis, investigational plan, randomization/drug assignment, statistical analysis for efficacy, prohibited medications and therapy, disease activity and flare assessment language, study drug dosage clarification, toxicity management language, complaints and adverse events language, treatments administered language, selection and timing of dose for each subject.
21 February 2022	Version 3.0: Global Amendment updated the synopsis, investigational plan, overall study design and figure, randomization assignment, sample size, key eligibility criteria, prohibited medications and therapy, withdrawal of subjects and discontinuation language, toxicity management, and appendices language.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

AbbVie has decided to discontinue further subject enrollment in the M20-370 (ABBV-154) study. This decision is not based on a safety or an efficacy signal; rather this decision was made because of a change in AbbVie's development.

Notes: