



## 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          | v2 (current)                                                                                                                 |
| This version publication date  | 18 December 2024                                                                                                             |
| First version publication date | 03 August 2024                                                                                                               |
| Version creation reason        | <ul style="list-style-type: none"><li>• Correction of full data set</li><li>• Clarifying edit to primary endpoint.</li></ul> |

#### Trial information

##### Trial identification

|                       |         |
|-----------------------|---------|
| Sponsor protocol code | M20-370 |
|-----------------------|---------|

##### 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:

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### 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                | Investigator, Assessor, Subject       |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | 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

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | ABBV-154, 40mg SC |
|------------------|-------------------|

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 |
|----------|--------------|

|                                        |                        |
|----------------------------------------|------------------------|
| 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

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | ABBV-154, 150mg SC |
|------------------|--------------------|

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

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | ABBV-154, 340mg SC |
|------------------|--------------------|

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 |
|----------|--------------|

|                                        |                        |
|----------------------------------------|------------------------|
| 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

| <b>Number of subjects in period 1</b> | 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                 | -                  |

| <b>Number of subjects in period 1</b> | 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 |
|-----------------------|---------|

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

| Reporting group values                 | Placebo | ABBV-154, 40mg SC | ABBV-154, 150mg SC |
|----------------------------------------|---------|-------------------|--------------------|
| Number of subjects                     | 50      | 42                | 45                 |
| Age categorical<br>Units: Subjects     |         |                   |                    |
| < 65 years                             | 9       | 16                | 12                 |
| 65 - < 75 years                        | 24      | 17                | 20                 |
| ≥ 75 years                             | 17      | 9                 | 13                 |
| Age continuous<br>Units: years         |         |                   |                    |
| arithmetic mean                        | 71.0    | 67.5              | 69.8               |
| standard deviation                     | ± 7.15  | ± 7.98            | ± 8.34             |
| Gender categorical<br>Units: Subjects  |         |                   |                    |
| Female                                 | 33      | 30                | 25                 |
| Male                                   | 17      | 12                | 20                 |
| Ethnicity (NIH/OMB)<br>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)<br>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 |

| <b>Reporting group values</b>             | ABBV-154, 340mg SC | Total |  |
|-------------------------------------------|--------------------|-------|--|
| Number of subjects                        | 44                 | 181   |  |
| Age categorical<br>Units: Subjects        |                    |       |  |
| < 65 years                                | 6                  | 43    |  |
| 65 - < 75 years                           | 31                 | 92    |  |
| ≥ 75 years                                | 7                  | 46    |  |
| Age continuous<br>Units: years            |                    |       |  |
| arithmetic mean                           | 69.1               |       |  |
| standard deviation                        | ± 6.23             | -     |  |
| Gender categorical<br>Units: Subjects     |                    |       |  |
| Female                                    | 29                 | 117   |  |
| Male                                      | 15                 | 64    |  |
| Ethnicity (NIH/OMB)<br>Units: Subjects    |                    |       |  |
| Hispanic or Latino                        | 2                  | 5     |  |
| Not Hispanic or Latino                    | 42                 | 176   |  |
| Unknown or Not Reported                   | 0                  | 0     |  |
| Race (NIH/OMB)<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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

|                                         |                             |
|-----------------------------------------|-----------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[1]</sup>      |
| 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  $\leq 0.05$

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

|                                         |                              |
|-----------------------------------------|------------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[2]</sup>       |
| 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  $\leq 0.01$

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

|                                         |                              |
|-----------------------------------------|------------------------------|
| <b>Statistical analysis title</b>       | 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                                 | $< 0.001$ <sup>[3]</sup>     |
| 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  $\leq 0.001$

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

## Secondary: Change from Baseline in Glucocorticoid Dose

|                 |                                             |
|-----------------|---------------------------------------------|
| End point title | Change from Baseline in Glucocorticoid Dose |
|-----------------|---------------------------------------------|

End point description:

Change from Baseline in glucocorticoid dose.

Analysis Population Description: ITT Population with data available for analysis

|                |           |
|----------------|-----------|
| 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: 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 <sup>[4]</sup>      |
| 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  $\leq 0.05$ ; P-value based on ANCOVA adjusting for baseline randomization stratification factors (GC use at baseline)

|                                         |                                |
|-----------------------------------------|--------------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[5]</sup>         |
| 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  $\leq 0.001$ ; 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)

|                                         |                                |
|-----------------------------------------|--------------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[6]</sup>         |
| 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  $\leq 0.001$ ; 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                                         |                                |

| <b>End point values</b>              | Placebo                      | ABBV-154,<br>40mg SC         | ABBV-154,<br>150mg SC        | ABBV-154,<br>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 ( $\pm$<br>524.6579) | 823.411 ( $\pm$<br>397.9403) | 734.310 ( $\pm$<br>332.3137) | 759.450 ( $\pm$<br>381.1683) |

## Statistical analyses

| <b>Statistical analysis title</b>       | 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 <sup>[7]</sup>      |
| 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 ( $\geq 10$  mg/day;  $< 10$  mg/day prednisone equivalent)]

| <b>Statistical analysis title</b>       | 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 <sup>[8]</sup>       |
| 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  $\leq 0.01$

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

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

|                                         |                              |
|-----------------------------------------|------------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[9]</sup>       |
| 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  $\leq 0.01$

P-value and 95% CI based on an Analysis of covariance (ANCOVA) model adjusting for baseline randomization stratification factors [Glucocorticoid use at baseline ( $\geq 10$  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 with data available for analysis        |
| 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

|                                   |                             |
|-----------------------------------|-----------------------------|
| <b>Statistical analysis title</b> | 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 <sup>[10]</sup> |
| 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 ( $\geq 10$  mg/day;  $< 10$  mg/day prednisone equivalent); Length of prior GC treatment for PMR ( $\leq 1$  year;  $> 1$  year)].

|                                         |                              |
|-----------------------------------------|------------------------------|
| <b>Statistical analysis title</b>       | 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 <sup>[11]</sup>      |
| 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  $\leq 0.1$

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

|                                         |                              |
|-----------------------------------------|------------------------------|
| <b>Statistical analysis title</b>       | 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                                 | $< 0.001$ <sup>[12]</sup>    |
| 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  $\leq 0.001$

Cochran-Mantel-Haenszel test adjusting for baseline randomization stratification factors [Glucocorticoid use at baseline ( $\geq 10$  mg/day;  $< 10$  mg/day prednisone equivalent); Length of prior GC treatment for PMR ( $\leq 1$  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 |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

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_150mg_SC_EOW |
|-----------------------|-----------------------|

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_340mg_SC_EOW |
|-----------------------|-----------------------|

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_40mg_SC_EOW |
|-----------------------|----------------------|

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_150mg_SC_EOW | ABBV-154_340mg_SC_EOW |
|---------------------------------------------------------------------|-----------------|-----------------------|-----------------------|
| Total subjects affected by serious adverse events                   |                 |                       |                       |
| subjects affected / exposed                                         | 8 / 50 (16.00%) | 8 / 45 (17.78%)       | 9 / 44 (20.45%)       |
| 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%) | 0 / 45 (0.00%) | 1 / 44 (2.27%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| PROSTATE CANCER                                 |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 45 (0.00%) | 1 / 44 (2.27%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| 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 / 45 (0.00%) | 0 / 44 (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%) | 1 / 45 (2.22%) | 0 / 44 (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          |
| ATRIAL FIBRILLATION                             |                |                |                |
| subjects affected / exposed                     | 1 / 50 (2.00%) | 1 / 45 (2.22%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| SUPRAVENTRICULAR TACHYCARDIA                    |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 1 / 45 (2.22%) | 0 / 44 (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          |
| VENTRICULAR EXTRASYSTOLES                       |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 1 / 45 (2.22%) | 0 / 44 (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          |
| LEFT VENTRICULAR FAILURE                        |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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%) | 0 / 45 (0.00%) | 1 / 44 (2.27%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| THALAMIC INFARCTION                             |                |                |                |
| subjects affected / exposed                     | 1 / 50 (2.00%) | 0 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 / 45 (0.00%) | 0 / 44 (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 |                |                |                |
| DYSPNOEA AT REST                                |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (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%) | 1 / 45 (2.22%) | 0 / 44 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| APPENDICITIS PERFORATED                         |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 45 (0.00%) | 0 / 44 (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%) | 0 / 45 (0.00%) | 1 / 44 (2.27%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| LOWER RESPIRATORY TRACT INFECTION               |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 1 / 45 (2.22%) | 0 / 44 (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          |
| PERITONITIS                                     |                |                |                |

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

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 50 (2.00%) | 0 / 45 (0.00%) | 0 / 44 (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_150mg_SC_EOW | ABBV-154_340mg_SC_EOW |
|-------------------------------------------------------|------------------|-----------------------|-----------------------|
| Total subjects affected by non-serious adverse events |                  |                       |                       |
| subjects affected / exposed                           | 27 / 50 (54.00%) | 30 / 45 (66.67%)      | 37 / 44 (84.09%)      |
| Injury, poisoning and procedural complications        |                  |                       |                       |
| CONTUSION                                             |                  |                       |                       |
| subjects affected / exposed                           | 0 / 50 (0.00%)   | 2 / 45 (4.44%)        | 3 / 44 (6.82%)        |
| occurrences (all)                                     | 0                | 2                     | 7                     |
| SKIN LACERATION                                       |                  |                       |                       |
| subjects affected / exposed                           | 0 / 50 (0.00%)   | 1 / 45 (2.22%)        | 2 / 44 (4.55%)        |
| occurrences (all)                                     | 0                | 1                     | 2                     |
| Vascular disorders                                    |                  |                       |                       |
| HYPERTENSION                                          |                  |                       |                       |
| subjects affected / exposed                           | 5 / 50 (10.00%)  | 4 / 45 (8.89%)        | 3 / 44 (6.82%)        |
| occurrences (all)                                     | 5                | 4                     | 3                     |
| Nervous system disorders                              |                  |                       |                       |
| DIZZINESS                                             |                  |                       |                       |
| subjects affected / exposed                           | 3 / 50 (6.00%)   | 1 / 45 (2.22%)        | 2 / 44 (4.55%)        |
| occurrences (all)                                     | 3                | 1                     | 2                     |
| HEADACHE                                              |                  |                       |                       |

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

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

|                                                       |                      |  |  |
|-------------------------------------------------------|----------------------|--|--|
| <b>Non-serious adverse events</b>                     | 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:

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### 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: