



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects With Moderately to Severely Active Crohn's Disease (CD): AIM-CD

Summary

| | |
|--------------------------|-------------------------------|
| EudraCT number | 2021-002869-18 |
| Trial protocol | ES DE BE IT GR NL CZ BG SK HU |
| Global end of trial date | 20 July 2023 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 |
| This version publication date | 02 August 2024 |
| First version publication date | 02 August 2024 |

Trial information

Trial identification

| | |
|-----------------------|---------|
| Sponsor protocol code | M20-371 |
|-----------------------|---------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05068284 |
| 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 | 20 July 2023 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 20 July 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

ABBV-154 is an investigational drug being evaluated for the treatment of Crohn's disease (CD). In the induction period, there is a 1 in 5 chance that participants will be assigned to placebo. Depending on the dose received in the induction period, there is a 1 in 2 or 1 in 3 chance that participants will be assigned to placebo in the maintenance period. Around 265 participants 18-75 yrs of age with moderately to severely active CD will be enrolled in the study at approximately 200 sites worldwide. The study is comprised of a 12-week double-blind, placebo-controlled induction period, followed by either a 12-week double-blind re-induction period for non-responders or a 40-week double-blind placebo-controlled maintenance period for responders. In the maintenance period, responders will be randomized to receive subcutaneous placebo or ABBV-154 in 2 different doses every other week. Participants in the placebo group who are initial responders will receive ABBV-154 in the maintenance period.

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 | 31 January 2022 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Australia: 7 |
| Country: Number of subjects enrolled | Austria: 3 |
| Country: Number of subjects enrolled | Belgium: 4 |
| Country: Number of subjects enrolled | Bulgaria: 1 |
| Country: Number of subjects enrolled | Canada: 3 |
| Country: Number of subjects enrolled | France: 5 |
| Country: Number of subjects enrolled | Germany: 5 |
| Country: Number of subjects enrolled | Greece: 3 |

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Israel: 3 |
| Country: Number of subjects enrolled | Italy: 5 |
| Country: Number of subjects enrolled | Japan: 20 |
| Country: Number of subjects enrolled | Netherlands: 4 |
| Country: Number of subjects enrolled | New Zealand: 2 |
| Country: Number of subjects enrolled | Poland: 2 |
| Country: Number of subjects enrolled | Slovakia: 6 |
| Country: Number of subjects enrolled | Spain: 1 |
| Country: Number of subjects enrolled | Taiwan: 1 |
| Country: Number of subjects enrolled | United Kingdom: 1 |
| Country: Number of subjects enrolled | United States: 30 |
| Worldwide total number of subjects | 106 |
| EEA total number of subjects | 39 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 100 |
| From 65 to 84 years | 6 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Randomized into 5 Grps for 12 Wks (Induction Period [IP]). At Wk 12, subjects were categorized as responders or non-responders. Responders were re-randomized into a 40-Wk Maintenance Period (MP). Non-responders were re-randomized into the 12-Wk Re-IP. At Wk 12 of the Re-IP, those achieving clinical/endoscopic response were re-randomized into MP.

Pre-assignment

Screening details:

The N=24 non-responders were re-randomized into the 12-Wk Re-Induction Period as follows: ABBV-154 300mg IV, 230mg SC EOW N=12 started of which N=9 completed, N=1 study terminated by sponsor, N=2 lack of efficacy; ABBV-154 600mg IV, 530mg SC EOW N=12 started of which N=6 completed, N=2 adverse event, non-fatal, N=4 study terminated by sponsor.

Period 1

| | |
|------------------------------|-----------------------------------|
| Period 1 title | Double-Blind Induction (12 weeks) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Participants received Placebo Intravenous (IV) during Week (Wk) 0, followed by Placebo Subcutaneous (SC) Every Other Week (EOW) until Week 12.

| | |
|--|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for solution for infusion, Solution for solution for injection |
| Routes of administration | Intravenous use, Subcutaneous use |

Dosage and administration details:

Participants received Placebo Intravenous (IV) during Week (Wk) 0, followed by Placebo Subcutaneous (SC) Every Other Week (EOW) until Week 12.

| | |
|------------------|--------------------------------|
| Arm title | ABBV-154 150mg IV, 80mg SC EOW |
|------------------|--------------------------------|

Arm description:

Participants received a loading dose of 150mg IV of ABBV-154 during Wk 0, followed by ABBV-154 80mg SC during Wk 2 and EOW until Week 12.

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

Dosage and administration details:

Participants received a loading dose of 150mg IV of ABBV-154 during Wk 0, followed by ABBV-154 80mg SC during Wk 2 and EOW until Week 12.

| | |
|------------------|---------------------------------|
| Arm title | ABBV-154 300mg IV, 230mg SC EOW |
|------------------|---------------------------------|

Arm description:

Participants received 300mg IV of ABBV-154 during Wk 0, followed by ABBV-154 230mg SC during Wk 2 and EOW until Week 12.

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

Dosage and administration details:

Participants received 300mg IV of ABBV-154 during Wk 0, followed by ABBV-154 230mg SC during Wk 2 and EOW until Week 12.

| | |
|------------------|---------------------------------|
| Arm title | ABBV-154 600mg IV, 530mg SC EOW |
|------------------|---------------------------------|

Arm description:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 2 and EOW until Week 12.

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

Dosage and administration details:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 2 and EOW until Week 12.

| | |
|------------------|---------------------------------|
| Arm title | ABBV-154 600mg IV, 530mg SC E4W |
|------------------|---------------------------------|

Arm description:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 4; every 4 weeks (E4W).

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

Dosage and administration details:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 4; every 4 weeks (E4W).

| Number of subjects in period 1 | Placebo | ABBV-154 150mg IV, 80mg SC EOW | ABBV-154 300mg IV, 230mg SC EOW |
|---------------------------------------|---------|--------------------------------|---------------------------------|
| Started | 21 | 20 | 22 |
| Completed | 12 | 15 | 12 |
| Not completed | 9 | 5 | 10 |
| Consent withdrawn by subject | 2 | 3 | - |
| Adverse event, non-fatal | - | - | 3 |
| Study terminated by sponsor | 7 | 2 | 6 |

| | | | |
|------------------|---|---|---|
| Lack of efficacy | - | - | 1 |
|------------------|---|---|---|

| Number of subjects in period 1 | ABBV-154 600mg IV, 530mg SC EOW | ABBV-154 600mg IV, 530mg SC E4W |
|--------------------------------|---------------------------------|---------------------------------|
| Started | 20 | 23 |
| Completed | 15 | 12 |
| Not completed | 5 | 11 |
| Consent withdrawn by subject | - | - |
| Adverse event, non-fatal | - | - |
| Study terminated by sponsor | 5 | 10 |
| Lack of efficacy | - | 1 |

Period 2

| | |
|------------------------------|-------------------------------------|
| Period 2 title | Double-Blind Maintenance (40 Weeks) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

During the Maintenance Period, participants received Placebo SC, EOW for 40 weeks. No IV was administered during the Maintenance Period.

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

Dosage and administration details:

During the Maintenance Period, participants received Placebo SC, EOW for 40 weeks.

| | |
|------------------|----------------------|
| Arm title | ABBV-154 80mg SC EOW |
|------------------|----------------------|

Arm description:

During the Maintenance Period, participants received ABBV-154 80mg SC only. No IV was administered during the Maintenance Period.

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

Dosage and administration details:

During the Maintenance Period, participants received ABBV-154 80mg SC only.

| | |
|------------------|-----------------------|
| Arm title | ABBV-154 230mg SC EOW |
|------------------|-----------------------|

Arm description:

During the Maintenance Period, participants received ABBV-154 230mg SC only. No IV was administered during the Maintenance Period.

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

Dosage and administration details:

During the Maintenance Period, participants received ABBV-154 230mg SC only.

| | |
|------------------|--------------------------------------|
| Arm title | ABBV-154 80mg SC EOW, Non-Randomized |
|------------------|--------------------------------------|

Arm description:

During the Maintenance Period, placebo responders received ABBV-154 80mg SC only. No IV was administered during the Maintenance Period.

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

Dosage and administration details:

During the Maintenance Period, placebo responders received ABBV-154 80mg SC only.

| Number of subjects in period 2^[1] | Placebo | ABBV-154 80mg SC EOW | ABBV-154 230mg SC EOW |
|---|---------|----------------------|-----------------------|
| Started | 18 | 14 | 13 |
| Completed | 0 | 1 | 0 |
| Not completed | 18 | 13 | 13 |
| Lack of efficacy w/o receiving ABBV-154 rescue | 1 | - | - |
| Study terminated by sponsor after ABBV-154 rescue | 8 | 3 | 1 |
| AE w/o receiving ABBV-154 rescue | 1 | - | 1 |
| WD by subject w/o receiving ABBV-154 rescue | 1 | - | - |
| Not specified | - | - | - |
| Lack of efficacy after receiving ABBV-154 rescue | 1 | - | - |
| Study terminated by sponsor w/o ABBV-154 rescue | 6 | 10 | 11 |

| Number of subjects in period 2^[1] | ABBV-154 80mg SC EOW, Non-Randomized |
|---|--------------------------------------|
| Started | 4 |
| Completed | 0 |
| Not completed | 4 |
| Lack of efficacy w/o receiving ABBV-154 rescue | - |

| | |
|---|---|
| Study terminated by sponsor after ABBV-154 rescue | - |
| AE w/o receiving ABBV-154 rescue | - |
| WD by subject w/o receiving ABBV-154 rescue | - |
| Not specified | 1 |
| Lack of efficacy after receiving ABBV-154 rescue | - |
| Study terminated by sponsor w/o ABBV-154 rescue | 3 |

Notes:

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

Justification: Randomized into 5 Grps for 12 Wks (Induction Period [IP]). At Wk 12, subjects were categorized as responders or non-responders. Responders were re-randomized into a 40-Wk Maintenance Period (MP). Non-responders were re-randomized into the 12-Wk Re-IP. At Wk 12 of the Re-IP, those achieving clinical/endoscopic response were re-randomized into MP.

Baseline characteristics

Reporting groups

| | |
|--|---------------------------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants received Placebo Intravenous (IV) during Week (Wk) 0, followed by Placebo Subcutaneous (SC) Every Other Week (EOW) until Week 12. | |
| Reporting group title | ABBV-154 150mg IV, 80mg SC EOW |
| Reporting group description: | |
| Participants received a loading dose of 150mg IV of ABBV-154 during Wk 0, followed by ABBV-154 80mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 300mg IV, 230mg SC EOW |
| Reporting group description: | |
| Participants received 300mg IV of ABBV-154 during Wk 0, followed by ABBV-154 230mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 600mg IV, 530mg SC EOW |
| Reporting group description: | |
| Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 600mg IV, 530mg SC E4W |
| Reporting group description: | |
| Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 4; every 4 weeks (E4W). | |

| Reporting group values | Placebo | ABBV-154 150mg IV, 80mg SC EOW | ABBV-154 300mg IV, 230mg SC EOW |
|------------------------------|---------|--------------------------------|---------------------------------|
| Number of subjects | 21 | 20 | 22 |
| Age categorical | | | |
| Units: Subjects | | | |
| ≥ 18 - < 40 years | 14 | 11 | 10 |
| ≥ 40 - < 65 years | 6 | 8 | 11 |
| ≥ 65 years | 1 | 1 | 1 |
| Age continuous | | | |
| Double-Blind Induction Phase | | | |
| Units: years | | | |
| arithmetic mean | 38.8 | 41.7 | 39.6 |
| standard deviation | ± 13.23 | ± 14.27 | ± 12.23 |
| Gender categorical | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |
| Female | 8 | 8 | 8 |
| Male | 13 | 12 | 14 |
| Ethnicity (NIH/OMB) | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 1 |
| Not Hispanic or Latino | 21 | 20 | 21 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |

| | | | |
|---|---------|---------|----------|
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 4 | 5 | 4 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 17 | 15 | 17 |
| More than one race | 0 | 0 | 1 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Baseline Simple Endoscopic Score for Crohn's Disease (SES-CD) for ITT1 (all enrolled) | | | |
| Double-Blind Induction Phase. | | | |
| Measure Description: ITT1 population; all enrolled. Note: Percentages calculated on non-missing values. | | | |
| Units: Simplified Endoscopic Score for CD | | | |
| arithmetic mean | 14.86 | 13.53 | 16.73 |
| standard deviation | ± 8.928 | ± 6.816 | ± 10.533 |

| Reporting group values | ABBV-154 600mg IV, 530mg SC EOW | ABBV-154 600mg IV, 530mg SC E4W | Total |
|---|---------------------------------|---------------------------------|-------|
| Number of subjects | 20 | 23 | 106 |
| Age categorical | | | |
| Units: Subjects | | | |
| ≥ 18 - < 40 years | 8 | 12 | 55 |
| ≥ 40 - < 65 years | 11 | 9 | 45 |
| ≥ 65 years | 1 | 2 | 6 |
| Age continuous | | | |
| Double-Blind Induction Phase | | | |
| Units: years | | | |
| arithmetic mean | 43.1 | 42.0 | |
| standard deviation | ± 14.37 | ± 14.20 | - |
| Gender categorical | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |
| Female | 9 | 10 | 43 |
| Male | 11 | 13 | 63 |
| Ethnicity (NIH/OMB) | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 1 |
| Not Hispanic or Latino | 20 | 23 | 105 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) | | | |
| Double-Blind Induction Phase | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 5 | 4 | 22 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 1 | 2 | 3 |
| White | 14 | 17 | 80 |
| More than one race | 0 | 0 | 1 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|---|---------|---------|---|
| Baseline Simple Endoscopic Score for Crohn's Disease (SES-CD) for ITT1 (all enrolled) | | | |
| Double-Blind Induction Phase. | | | |
| Measure Description: ITT1 population; all enrolled. Note: Percentages calculated on non-missing values. | | | |
| Units: Simplified Endoscopic Score for CD | | | |
| arithmetic mean | 16.13 | 14.65 | |
| standard deviation | ± 6.472 | ± 6.748 | - |

End points

End points reporting groups

| | |
|--|--------------------------------------|
| Reporting group title | Placebo |
| Reporting group description: Participants received Placebo Intravenous (IV) during Week (Wk) 0, followed by Placebo Subcutaneous (SC) Every Other Week (EOW) until Week 12. | |
| Reporting group title | ABBV-154 150mg IV, 80mg SC EOW |
| Reporting group description: Participants received a loading dose of 150mg IV of ABBV-154 during Wk 0, followed by ABBV-154 80mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 300mg IV, 230mg SC EOW |
| Reporting group description: Participants received 300mg IV of ABBV-154 during Wk 0, followed by ABBV-154 230mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 600mg IV, 530mg SC EOW |
| Reporting group description: Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 2 and EOW until Week 12. | |
| Reporting group title | ABBV-154 600mg IV, 530mg SC E4W |
| Reporting group description: Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 4; every 4 weeks (E4W). | |
| Reporting group title | Placebo |
| Reporting group description: During the Maintenance Period, participants received Placebo SC, EOW for 40 weeks. No IV was administered during the Maintenance Period. | |
| Reporting group title | ABBV-154 80mg SC EOW |
| Reporting group description: During the Maintenance Period, participants received ABBV-154 80mg SC only. No IV was administered during the Maintenance Period. | |
| Reporting group title | ABBV-154 230mg SC EOW |
| Reporting group description: During the Maintenance Period, participants received ABBV-154 230mg SC only. No IV was administered during the Maintenance Period. | |
| Reporting group title | ABBV-154 80mg SC EOW, Non-Randomized |
| Reporting group description: During the Maintenance Period, placebo responders received ABBV-154 80mg SC only. No IV was administered during the Maintenance Period. | |

Primary: Percentage of Participants Achieving Endoscopic Response per Simple Endoscopic Score for Crohn's Disease (SES-CD)

| | |
|---|---|
| End point title | Percentage of Participants Achieving Endoscopic Response per Simple Endoscopic Score for Crohn's Disease (SES-CD) |
| End point description: The SES-CD assesses endoscopic disease severity by evidence of active intestinal mucosal inflammation. Endoscopic response is defined as a decrease in SES-CD > 50% from Baseline (or for participants with isolated ileal disease and a Baseline SES-CD of 4, at least a 2-point reduction from Baseline). | |
| Analysis Population Description: ITT1 Population - All enrolled. | |
| End point type | Primary |
| End point timeframe: Induction Period Week 12 | |

| End point values | Placebo | ABBV-154 150mg IV, 80mg SC EOW | ABBV-154 300mg IV, 230mg SC EOW | ABBV-154 600mg IV, 530mg SC EOW |
|-----------------------------------|-----------------|--------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 14 | 12 | 14 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 7.1 | 33.3 | 28.6 |

| End point values | ABBV-154 600mg IV, 530mg SC E4W | | | |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 27.3 | | | |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|--|
| Statistical analysis description: Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 150mg IV, 80mg SC EOW |
| Number of subjects included in analysis | 25 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.3 |
| upper limit | 20.6 |

| Statistical analysis title | Statistical Analysis 2 |
|---|---|
| Statistical analysis description: Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 300mg IV, 230mg SC EOW |

| | |
|---|----------------------|
| Number of subjects included in analysis | 23 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 33.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.7 |
| upper limit | 60 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 3 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC EOW |
| Number of subjects included in analysis | 25 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 28.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.9 |
| upper limit | 52.2 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 4 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC E4W |
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 27.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 53.6 |

| | |
|---|---|
| Secondary: Percentage of Participants Achieving Clinical Remission per SF/AP | |
| End point title | Percentage of Participants Achieving Clinical Remission per SF/AP |

End point description:

Clinical remission is defined as average daily liquid or very soft SF ≤ 2.8 and not worse than Baseline and average daily AP score ≤ 1 and not worse than Baseline.

Data were not collected for this outcome due to early termination of the study.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 40 in the Maintenance Period

| End point values | Placebo | ABBV-154 80mg SC EOW | ABBV-154 230mg SC EOW | |
|--|------------------|-------------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[1] | 0 ^[2] | 0 ^[3] | |
| Units: Overall Number of Participants Analyzed | | | | |

Notes:

[1] - Data were not collected for this Outcome Measure due to early termination of the study.

[2] - Data were not collected for this Outcome Measure due to early termination of the study.

[3] - Data were not collected for this Outcome Measure due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Endoscopic Response per SES-CD

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving Endoscopic Response per SES-CD |
|-----------------|---|

End point description:

The SES-CD assesses endoscopic disease severity by evidence of active intestinal mucosal inflammation. Endoscopic response is defined as a decrease in SES-CD $> 50\%$ from Baseline (or for participants with isolated ileal disease and a Baseline SES-CD of 4, at least a 2-point reduction from Baseline).

Data were not collected for this outcome due to early termination of the study.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 40 in the Maintenance Period

| End point values | Placebo | ABBV-154 80mg SC EOW | ABBV-154 230mg SC EOW | |
|--|------------------|-------------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[4] | 0 ^[5] | 0 ^[6] | |
| Units: Overall Number of Participants Analyzed | | | | |

Notes:

[4] - No data displayed because Outcome Measure has zero total participants analyzed.

[5] - No data displayed because Outcome Measure has zero total participants analyzed.

[6] - No data displayed because Outcome Measure has zero total participants analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Clinical Remission per CDAI

| | |
|-----------------|--|
| End point title | Percentage of Participants Achieving Clinical Remission per CDAI |
|-----------------|--|

End point description:

The CDAI consists of 8 components; 6 are based on participant diary entries, participant interviews, and physical examinations, and 2 are based on laboratory analysis, and measurement of body weight and height. Clinical remission is defined as CDAI < 150.

Data were not collected for this outcome due to early termination of the study.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 40 in the Maintenance Period

| End point values | Placebo | ABBV-154 80mg SC EOW | ABBV-154 230mg SC EOW | |
|--|------------------|-------------------------|-----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[7] | 0 ^[8] | 0 ^[9] | |
| Units: Overall Number of Participants Analyzed | | | | |

Notes:

[7] - Data were not collected for this Outcome Measure due to early termination of the study.

[8] - Data were not collected for this Outcome Measure due to early termination of the study.

[9] - Data were not collected for this Outcome Measure due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Clinical Remission per Crohn's Disease Activity Index (CDAI)

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving Clinical Remission per Crohn's Disease Activity Index (CDAI) |
|-----------------|---|

End point description:

The CDAI consists of 8 components; 6 are based on participant diary entries, participant interviews, and physical examinations, and 2 are based on laboratory analysis, and measurement of body weight and height. Clinical remission is defined as CDAI < 150.

Analysis Population Description: ITT1 Population - All enrolled.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Induction Period Week 12

| End point values | Placebo | ABBV-154 150mg IV, 80mg SC EOW | ABBV-154 300mg IV, 230mg SC EOW | ABBV-154 600mg IV, 530mg SC EOW |
|-----------------------------------|-----------------|--------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 14 | 13 | 14 |
| Units: percentage of participants | | | | |
| number (not applicable) | 16.7 | 28.6 | 46.2 | 35.7 |

| End point values | ABBV-154 600mg IV, 530mg SC E4W | | | |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 10 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 40 | | | |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|--|
| Comparison groups | Placebo v ABBV-154 150mg IV, 80mg SC EOW |
| Number of subjects included in analysis | 26 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[10] |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.8 |
| upper limit | 43.6 |

Notes:

[10] - Risk difference = (ABBV-154 - placebo)

| Statistical analysis title | Statistical Analysis 2 |
|---|---|
| Comparison groups | Placebo v ABBV-154 300mg IV, 230mg SC EOW |
| Number of subjects included in analysis | 25 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[11] |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.8 |
| upper limit | 63.8 |

Notes:

[11] - Risk difference = (ABBV-154 - placebo)

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 3 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC EOW |
| Number of subjects included in analysis | 26 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.7 |
| upper limit | 51.8 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 4 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC E4W |
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 23.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.6 |
| upper limit | 60.3 |

Secondary: Percentage of Participants Achieving Clinical Remission per Average Daily Liquid or Very Soft Stool Frequency (SF) and Average Daily Abdominal Pain (AP) Score (SF/AP)

| | |
|---|--|
| End point title | Percentage of Participants Achieving Clinical Remission per Average Daily Liquid or Very Soft Stool Frequency (SF) and Average Daily Abdominal Pain (AP) Score (SF/AP) |
| End point description: | |
| Clinical remission is defined as average daily liquid or very soft SF ≤ 2.8 and not worse than Baseline and average daily AP score ≤ 1 and not worse than Baseline. | |
| Analysis Population Description: ITT1 - All enrolled. | |
| End point type | Secondary |
| End point timeframe: | |
| Induction Period Week 12 | |

| End point values | Placebo | ABBV-154 150mg IV, 80mg SC EOW | ABBV-154 300mg IV, 230mg SC EOW | ABBV-154 600mg IV, 530mg SC EOW |
|-----------------------------------|-----------------|--------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 13 | 15 | 13 | 15 |
| Units: percentage of participants | | | | |
| number (not applicable) | 15.4 | 26.7 | 53.8 | 40 |

| End point values | ABBV-154 600mg IV, 530mg SC E4W | | | |
|-----------------------------------|---------------------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 54.5 | | | |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|--|
| Comparison groups | Placebo v ABBV-154 150mg IV, 80mg SC EOW |
| Number of subjects included in analysis | 28 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[12] |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 11.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -18.5 |
| upper limit | 41 |

Notes:

[12] - Risk difference = (ABBV-154 - placebo)

| Statistical analysis title | Statistical Analysis 2 |
|--|---|
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 300mg IV, 230mg SC EOW |

| | |
|---|----------------------|
| Number of subjects included in analysis | 26 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 38.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5 |
| upper limit | 71.9 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 3 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC EOW |
| Number of subjects included in analysis | 28 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 24.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7 |
| upper limit | 56.2 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 4 |
| Statistical analysis description: | |
| Risk difference = (ABBV-154 - placebo) | |
| Comparison groups | Placebo v ABBV-154 600mg IV, 530mg SC E4W |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 39.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.8 |
| upper limit | 74.5 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality were reported from enrollment to study termination, median time on follow up was 85 days(d) for Placebo and ABBV-154 150 IV/80 SC; 87.5d for ABBV-154 300 IV/230 SC; 86d for ABBV-154 600IV/530 SC; and 84d for ABBV-154 600 IV/530 SC E4W.

Adverse event reporting additional description:

Treatment-emergent and serious AE were collected from first dose until 70d after last dose; mean duration on study drug was 12 weeks for each group.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|--------|
| Reporting group title | IP_Pbo |
|-----------------------|--------|

Reporting group description:

Participants received Placebo Intravenous (IV) during Week (Wk) 0, followed by Placebo Subcutaneous (SC) Every Other Week (EOW) until Week 12

| | |
|-----------------------|---------------------------------|
| Reporting group title | P_ABBV-154_150mg_IV_80mg_SC_EOW |
|-----------------------|---------------------------------|

Reporting group description:

Participants received 150mg IV of ABBV-154 during Wk 0, followed by ABBV-154 80mg SC during Wk 2 and EOW until Week 12

| | |
|-----------------------|-----------------------------------|
| Reporting group title | IP_ABBV-154_600mg_IV_530mg_SC_E4W |
|-----------------------|-----------------------------------|

Reporting group description:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 4 and Wk 8; every 4 weeks (E4W)

| | |
|-----------------------|--|
| Reporting group title | IP_Pbo_ReIP_ABBV-154_300mg_IV_230mg_SC_EOW |
|-----------------------|--|

Reporting group description:

Following Induction Period (IP): Non-responding, Placebo-dosed Participants were re-induced (ReIP) with ABBV-154 300mg IV (Wk 12), followed by 230mg SC (Wk 14) and EOW until Wk 24

| | |
|-----------------------|--|
| Reporting group title | Rescue_ABBV-154_600mg_IV_230_mg_SC_EOW |
|-----------------------|--|

Reporting group description:

During MP: Inadequate-Responding, Placebo or ABBV-154-dosed Participants received ABBV-154 600mg IV followed by 230mg SC Rescue Therapy

| | |
|-----------------------|---|
| Reporting group title | IP_ABBV-154_ReIP_ABBV-154_300mg_IV_230mg_SC_EOW |
|-----------------------|---|

Reporting group description:

Participants received 300mg IV of ABBV-154 during Wk 0, followed by ABBV-154 230mg SC during Wk 2 and EOW until Week 12

| | |
|-----------------------|---|
| Reporting group title | IP_ABBV-154_ReIP_ABBV-154_600mg_IV_530mg_SC_EOW |
|-----------------------|---|

Reporting group description:

Participants received 600mg IV of ABBV-154 during Wk 0, followed by ABBV-154 530mg SC during Wk 2 and EOW until Week 12

| | |
|-----------------------|-------------|
| Reporting group title | MP_Rand_Pbo |
|-----------------------|-------------|

Reporting group description:

Following IP: Responding, ABBV-154-dosed Participants received Placebo SC EOW during the maintenance period (MP) of 40 weeks

| | |
|-----------------------|------------------------------|
| Reporting group title | MP_Rand_ABBV-154_80mg_SC_EOW |
|-----------------------|------------------------------|

Reporting group description:

Following IP: Responding, ABBV-154-dosed Participants received ABBV-154 80mg SC EOW during the maintenance period (MP) of 40 weeks

| | |
|-----------------------|-------------------------------|
| Reporting group title | MP_Rand_ABBV-154_230mg_SC_EOW |
|-----------------------|-------------------------------|

Reporting group description:

Following IP: Responding, ABBV-154-dosed Participants received ABBV-154 230mg SC EOW during the

maintenance period (MP) of 40 weeks

| | |
|--|--|
| Reporting group title | MP_Non-Rand_ABBV-154_80mg_SC_EOW |
| Reporting group description: | |
| Following IP: Responding, Placebo-dosed Participants received ABBV-154 80mg SC EOW during the maintenance period (MP) of 40 weeks | |
| Reporting group title | IP_ABBV-154_600mg_IV_530mg_SC_EOW |
| Reporting group description: | |
| Following IP: Non-responding, Placebo-dosed Participants were ReIP with ABBV-154 600mg IV (Wk 12), followed by 530mg SC (Wk 14) and EOW until Wk 24 | |
| Reporting group title | IP_ABBV-154_300mg_IV_230mg_SC_EOW |
| Reporting group description: | |
| Following IP: Non-responding, ABBV-154-dosed Participants were ReIP with ABBV-154 300mg IV (Wk 12), followed by 230mg SC (Wk 14) and EOW until Wk 24 | |
| Reporting group title | IP_Pbo_ReIP_ABBV-154_600mg_IV_530mg_SC_EOW |
| Reporting group description: | |
| Following IP: Non-responding, ABBV-154-dosed Participants were ReIP with ABBV-154 600mg IV (Wk 12), followed by 530mg SC (Wk 14) and EOW until Wk 24 | |

| Serious adverse events | IP_Pbo | P_ABBV-154_150mg_IV_80mg_SC_EOW | IP_ABBV-154_600mg_IV_530mg_SC_E4W |
|--|-----------------|---------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | 3 / 20 (15.00%) | 2 / 23 (8.70%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (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 |
| Immune system disorders | | | |
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (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 |
| SERUM SICKNESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| CROHN'S DISEASE | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 0 / 23 (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 |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (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 |
| Infections and infestations | | | |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (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 |
| ABDOMINAL ABSCESS | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (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 |
| COLONIC ABSCESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (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 |
| FOCAL PERITONITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (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 |

| | | | |
|---|----------------|----------------|----------------|
| INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTIOUS PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | IP_Pbo_ReIP_ABBV-154_300mg_IV_230 mg_SC_EOW | Rescue_ABBV-154_600mg_IV_230 mg_SC_EOW | IP_ABBV-154_ReIP_ABBV-154_300mg_IV_230 mg_SC_EOW |
|--|---|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 1 / 8 (12.50%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |

| | | | |
|--|---------------|----------------|---------------|
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| SERUM SICKNESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| ABDOMINAL ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| APPENDICITIS | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| COLONIC ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (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 |
| FOCAL PERITONITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (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 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTIOUS PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|-------------------------------|----------|-------------|---------------|
| Serious adverse events | IP_ABBV- | MP_Rand_Pbo | MP_Rand_ABBV- |
|-------------------------------|----------|-------------|---------------|

| | 154_ReIP_ABBV- 154_600mg_IV_530 mg_SC_EOW | | 154_80mg_SC_EOW |
|--|---|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 3 / 18 (16.67%) | 1 / 14 (7.14%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 18 (0.00%) | 0 / 14 (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 |
| SERUM SICKNESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 18 (5.56%) | 0 / 14 (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 |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (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 | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |

| | | | |
|---|---------------|----------------|----------------|
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (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 |
| ABDOMINAL ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (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 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (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 |
| COLONIC ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (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 |
| FOCAL PERITONITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (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 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTIOUS PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (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 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (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 |
| URINARY TRACT INFECTION | | | |

| | | | |
|---|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | MP_Rand_ABBV-154_230mg_SC_EOW | MP_Non-Rand_ABBV-154_80mg_SC_EOW | IP_ABBV-154_600mg_IV_530mg_SC_EOW |
|--|-------------------------------|----------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| SERUM SICKNESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| SMALL INTESTINAL OBSTRUCTION | | | |

| | | | |
|---|----------------|---------------|----------------|
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| ABDOMINAL ABSCESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| COLONIC ABSCESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| FOCAL PERITONITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (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 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|---------------|----------------|
| INFECTIOUS PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | IP_ABBV-154_300mg_IV_230mg_SC_EOW | IP_Pbo_ReIP_ABBV-154_600mg_IV_530mg_SC_EOW | |
|--|-----------------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 4 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| General disorders and administration site conditions | | | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SERUM SICKNESS | | | |

| | | | |
|---|----------------|---------------|--|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| FEMALE GENITAL TRACT FISTULA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL ABSCESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| APPENDICITIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COLONIC ABSCESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|----------------|---------------|--|
| FOCAL PERITONITIS | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFECTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFECTIOUS PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | IP_Pbo | P_ABBV- 154_150mg_IV_80m g_SC_EOW | IP_ABBV- 154_600mg_IV_530 mg_SC_E4W |
|---|-----------------|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 21 (33.33%) | 12 / 20 (60.00%) | 13 / 23 (56.52%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| SKIN PAPILLOMA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Vascular disorders | | | |
| DEEP VEIN THROMBOSIS subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| HOT FLUSH subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| CHEST PAIN subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| INJECTION SITE ERYTHEMA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| INJECTION SITE DRYNESS subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 2 / 20 (10.00%) 2 | 0 / 23 (0.00%) 0 |
| INJECTION SITE BRUISING subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| INFLUENZA LIKE ILLNESS subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 2 |
| FEELING ABNORMAL subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| FATIGUE subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 2 |
| INJECTION SITE EXFOLIATION | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 2 / 23 (8.70%) |
| occurrences (all) | 0 | 0 | 2 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INJECTION SITE SWELLING | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE RASH | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE PRURITUS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE INDENTATION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| SEASONAL ALLERGY | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED | | | |
| HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|--|---------------------|---------------------|----------------------|
| PROSTATOMEGALY subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| CERVICAL DYSPLASIA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders DYSPHONIA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| COUGH subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 3 |
| NASAL CONGESTION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 2 |
| OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 2 |
| Psychiatric disorders INSOMNIA subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| DEPRESSED MOOD subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| AGITATION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Investigations ALANINE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| WEIGHT INCREASED subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 3 / 23 (13.04%) 3 |

| | | | |
|--|----------------|----------------|-----------------|
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FAECAL CALPROTECTIN INCREASED | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 | 1 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FALL | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| MIGRAINE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HEADACHE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 5 / 23 (21.74%) |
| occurrences (all) | 0 | 1 | 5 |

| | | | |
|--|---------------------|---------------------|---------------------|
| OPHTHALMIC MIGRAINE subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| SYNCOPE subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| LYMPHOPENIA subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| LYMPHADENOPATHY subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| LEUKOCYTOSIS subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| Eye disorders | | | |
| VISION BLURRED subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 1 / 23 (4.35%) 1 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISTENSION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| ABDOMINAL PAIN subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| CONSTIPATION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 2 |
| APHTHOUS ULCER subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| ABDOMINAL PAIN UPPER subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| CROHN'S DISEASE | | | |

| | | | |
|--|----------------|-----------------|----------------|
| subjects affected / exposed | 1 / 21 (4.76%) | 4 / 20 (20.00%) | 2 / 23 (8.70%) |
| occurrences (all) | 1 | 4 | 2 |
| HAEMATOOCHEZIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HAEMORRHOIDS THROMBOSED | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| LIVER DISORDER | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS CONTACT | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ALOPECIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ACNE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| DERMATITIS PSORIASIFORM | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ERYTHROSIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LICHENOID KERATOSIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PSORIASIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RASH | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| RASH VESICULAR subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| SKIN LESION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Renal and urinary disorders RENAL COLIC subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| URINARY RETENTION subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Endocrine disorders CUSHING'S SYNDROME subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 20 (5.00%) 1 | 2 / 23 (8.70%) 2 |
| TENDON PAIN subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| MUSCULOSKELETAL CHEST PAIN subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 2 / 23 (8.70%) 2 |
| MUSCLE SPASMS subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 20 (5.00%) 1 | 0 / 23 (0.00%) 0 |
| JOINT SWELLING subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 20 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| BACK PAIN | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 2 | 0 / 20 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| Infections and infestations | | | |
| BRONCHITIS VIRAL | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| CRYPTOSPORIDIOSIS INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CYSTITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| GINGIVITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PARONYCHIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PHARYNGITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH PUSTULAR | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SALMONELLOSIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|----------------|----------------|----------------|
| TINEA INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VIRAEMIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 | 1 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 0 | 1 |
| IRON DEFICIENCY | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INCREASED APPETITE | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 20 (5.00%) | 1 / 23 (4.35%) |
| occurrences (all) | 0 | 1 | 1 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 20 (0.00%) | 0 / 23 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------------|-----------------------------------|------------------------------|------------------------|
| Non-serious adverse events | IP_Pbo_ReIP_ABBV-154_300mg_IV_230 | Rescue_ABBV-154_600mg_IV_230 | IP_ABBV-154_ReIP_ABBV- |
|-----------------------------------|-----------------------------------|------------------------------|------------------------|

| | mg_SC_EOW | _mg_SC_EOW | 154_300mg_IV_230 mg_SC_EOW |
|---|-----------------|-----------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 8 / 14 (57.14%) | 5 / 8 (62.50%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SKIN PAPILLOMA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE ERYTHEMA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| INJECTION SITE DRYNESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE BRUISING | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 2 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---------------|----------------|----------------|
| FATIGUE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE EXFOLIATION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE SWELLING | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE RASH | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE PRURITUS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INJECTION SITE INDENTATION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| SEASONAL ALLERGY | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED HYPERSENSITIVITY REACTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERSENSITIVITY | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 1 / 8 (12.50%) 1 |
| Reproductive system and breast disorders PROSTATOMEGALY subjects affected / exposed occurrences (all) | 1 / 4 (25.00%) 1 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| CERVICAL DYSPLASIA subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders DYSPHONIA subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 1 / 8 (12.50%) 1 |
| COUGH subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| NASAL CONGESTION subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| Psychiatric disorders INSOMNIA subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| DEPRESSED MOOD subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| AGITATION subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| Investigations ALANINE AMINOTRANSFERASE INCREASED | | | |

| | | | |
|--|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FAECAL CALPROTECTIN INCREASED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| Injury, poisoning and procedural complications | | | |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| FALL | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MIGRAINE | | | |

| | | | |
|---|--------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| HEADACHE subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| OPHTHALMIC MIGRAINE subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| SYNCOPE subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| Blood and lymphatic system disorders LYMPHOPENIA subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| LYMPHADENOPATHY subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| LEUKOCYTOSIS subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| Eye disorders VISION BLURRED subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 1 / 8 (12.50%) 1 |
| Gastrointestinal disorders ABDOMINAL DISTENSION subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| ABDOMINAL PAIN subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 8 (0.00%) 0 |
| CONSTIPATION subjects affected / exposed occurrences (all) | 0 / 4 (0.00%) 0 | 0 / 14 (0.00%) 0 | 1 / 8 (12.50%) 1 |
| APHTHOUS ULCER | | | |

| | | | |
|-----------------------------|---------------|-----------------|---------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 2 / 14 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HAEMATOCHEZIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMORRHOIDS THROMBOSED | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatobiliary disorders | | | |
| LIVER DISORDER | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------|----------------|----------------|
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS CONTACT | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ALOPECIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ACNE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS PSORIASIFORM | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ERYTHROSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LICHENOID KERATOSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PSORIASIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| RASH VESICULAR | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN LESION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| RENAL COLIC | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY RETENTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Endocrine disorders | | | |
| CUSHING'S SYNDROME | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| TENDON PAIN | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCLE SPASMS | | | |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| JOINT SWELLING | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| BRONCHITIS VIRAL | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| CRYPTOSPORIDIOSIS INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CYSTITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| GINGIVITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 14 (7.14%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PARONYCHIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PHARYNGITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH PUSTULAR | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SALMONELLOSIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|---------------|----------------|----------------|
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| TINEA INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| VIRAEMIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| IRON DEFICIENCY | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INCREASED APPETITE | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |

| | | | |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 14 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | IP_ABBV- 154_ReIP_ABBV- 154_600mg_IV_530 mg_SC_EOW | MP_Rand_Pbo | MP_Rand_ABBV- 154_80mg_SC_EOW |
|--|---|-----------------|----------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 9 / 18 (50.00%) | 10 / 14 (71.43%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SKIN PAPILLOMA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular disorders | | | |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HOT FLUSH | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 2 / 18 (11.11%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE ERYTHEMA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INJECTION SITE DRYNESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE BRUISING | | | |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE EXFOLIATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INJECTION SITE SWELLING | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE RASH | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE PRURITUS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INJECTION SITE INDENTATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Immune system disorders | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| SEASONAL ALLERGY subjects affected / exposed occurrences (all) | 1 / 8 (12.50%) 1 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| INFUSION RELATED HYPERSENSITIVITY REACTION subjects affected / exposed occurrences (all) | 2 / 8 (25.00%) 2 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| HYPERSENSITIVITY subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Reproductive system and breast disorders PROSTATOMEGALY subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| CERVICAL DYSPLASIA subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Respiratory, thoracic and mediastinal disorders DYSPHONIA subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| COUGH subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| NASAL CONGESTION subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Psychiatric disorders INSOMNIA subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| DEPRESSED MOOD | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| AGITATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| FAECAL CALPROTECTIN INCREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|--------------------|---------------------|---------------------|
| FALL subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| MIGRAINE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| HEADACHE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| OPHTHALMIC MIGRAINE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| SYNCOPE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Blood and lymphatic system disorders LYMPHOPENIA subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| LYMPHADENOPATHY subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| LEUKOCYTOSIS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Eye disorders VISION BLURRED subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Gastrointestinal disorders ABDOMINAL DISTENSION subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 14 (0.00%) 0 |

| | | | |
|-----------------------------|---------------|----------------|-----------------|
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONSTIPATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| APHTHOUS ULCER | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 3 / 14 (21.43%) |
| occurrences (all) | 0 | 1 | 4 |
| HAEMATOCHEZIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 2 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMORRHOIDS THROMBOSED | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 1 | 1 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|--------------------|---------------------|---------------------|
| RECTAL HAEMORRHAGE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Hepatobiliary disorders LIVER DISORDER subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 14 (0.00%) 0 |
| Skin and subcutaneous tissue disorders DERMATITIS CONTACT subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| DERMATITIS ACNEIFORM subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| DERMATITIS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| ALOPECIA subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| ACNE subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| DERMATITIS PSORIASIFORM subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 1 / 18 (5.56%) 1 | 0 / 14 (0.00%) 0 |
| ECCHYMOSIS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| ERYTHROSIS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| HYPERHIDROSIS subjects affected / exposed occurrences (all) | 0 / 8 (0.00%) 0 | 0 / 18 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| LICHENOID KERATOSIS | | | |

| | | | |
|---|---------------|-----------------|----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 2 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 2 / 18 (11.11%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PSORIASIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH VESICULAR | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN LESION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| RENAL COLIC | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY RETENTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| CUSHING'S SYNDROME | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 1 | 1 |
| TENDON PAIN | | | |

| | | | |
|-----------------------------|---------------|----------------|-----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| JOINT SWELLING | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| BRONCHITIS VIRAL | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 2 / 14 (14.29%) |
| occurrences (all) | 0 | 1 | 2 |
| CRYPTOSPORIDIOSIS INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CYSTITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|---------------|----------------|----------------|
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GINGIVITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PARONYCHIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PHARYNGITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH PUSTULAR | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|---------------|----------------|----------------|
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SALMONELLOSIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TINEA INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VIRAEMIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| IRON DEFICIENCY | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INCREASED APPETITE | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 18 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 18 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 18 (5.56%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| Non-serious adverse events | MP_Rand_ABBV- 154_230mg_SC_EOW | MP_Non- Rand_ABBV- 154_80mg_SC_EOW | IP_ABBV- 154_600mg_IV_530 mg_SC_EOW |
|---|-----------------------------------|--|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 8 / 13 (61.54%) | 2 / 4 (50.00%) | 14 / 20 (70.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SKIN PAPILLOMA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE ERYTHEMA | | | |

| | | | |
|-----------------------------|----------------|---------------|-----------------|
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INJECTION SITE DRYNESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE BRUISING | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INJECTION SITE EXFOLIATION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| INJECTION SITE SWELLING | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE RASH | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 1 | 0 | 4 |
| INJECTION SITE PRURITUS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INJECTION SITE INDENTATION | | | |

| | | | |
|---|---------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| PYREXIA subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Immune system disorders SEASONAL ALLERGY subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| INFUSION RELATED HYPERSENSITIVITY REACTION subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| HYPERSENSITIVITY subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Reproductive system and breast disorders PROSTATOMEGALY subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| CERVICAL DYSPLASIA subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders DYSPHONIA subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| COUGH subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| NASAL CONGESTION subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 1 / 20 (5.00%) 1 |

| | | | |
|--|----------------|---------------|----------------|
| Psychiatric disorders | | | |
| INSOMNIA | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DEPRESSED MOOD | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| AGITATION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FAECAL CALPROTECTIN INCREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|--------------------------------------|----------------|---------------|-----------------|
| TOOTH FRACTURE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FALL | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| DIZZINESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MIGRAINE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| HEADACHE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| OPHTHALMIC MIGRAINE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| SYNCOPE | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| LYMPHOPENIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LYMPHADENOPATHY | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LEUKOCYTOSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| CONSTIPATION | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| APHTHOUS ULCER | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 2 / 4 (50.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HAEMATOCHEZIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 1 / 4 (25.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMORRHOIDS THROMBOSED | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NAUSEA | | | |

| | | | |
|--|----------------|---------------|-----------------|
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| LIVER DISORDER | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS CONTACT | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ALOPECIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| ACNE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| DERMATITIS PSORIASIFORM | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ECCHYMOSIS | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| ERYTHROSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 2 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| LICHENOID KERATOSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PSORIASIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 1 / 4 (25.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RASH VESICULAR | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN LESION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal and urinary disorders | | | |
| RENAL COLIC | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| URINARY RETENTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|--------------------|---------------------|
| Endocrine disorders CUSHING'S SYNDROME subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| TENDON PAIN subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| MUSCULOSKELETAL CHEST PAIN subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| MUSCLE SPASMS subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| JOINT SWELLING subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| BACK PAIN subjects affected / exposed occurrences (all) | 2 / 13 (15.38%) 2 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| Infections and infestations BRONCHITIS VIRAL subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 1 / 20 (5.00%) 1 |
| ANAL ABSCESS subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| CELLULITIS subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |
| CONJUNCTIVITIS subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 20 (0.00%) 0 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| COVID-19 | | | |
| subjects affected / exposed | 2 / 13 (15.38%) | 1 / 4 (25.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 2 | 1 | 2 |
| CRYPTOSPORIDIOSIS INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CYSTITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ESCHERICHIA INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GINGIVITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 3 / 20 (15.00%) |
| occurrences (all) | 0 | 0 | 4 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PARONYCHIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PHARYNGITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|----------------|---------------|-----------------|
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| RASH PUSTULAR | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SALMONELLOSIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TINEA INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 1 | 0 | 1 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 2 / 20 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| VIRAEMIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |

| | | | |
|-----------------------------|----------------|---------------|----------------|
| DECREASED APPETITE | | | |
| subjects affected / exposed | 1 / 13 (7.69%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| IRON DEFICIENCY | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 1 / 20 (5.00%) |
| occurrences (all) | 0 | 0 | 1 |
| INCREASED APPETITE | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | 0 / 4 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | IP_ABBV- 154_300mg_IV_230 mg_SC_EOW | IP_Pbo_ReIP_ABBV- 154_600mg_IV_530 mg_SC_EOW | |
|---|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 22 (45.45%) | 1 / 4 (25.00%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SKIN PAPILLOMA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vascular disorders | | | |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | | |
|--|----------------|---------------|--|
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INJECTION SITE ERYTHEMA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INJECTION SITE DRYNESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INJECTION SITE BRUISING | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INJECTION SITE EXFOLIATION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| PAIN | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| INJECTION SITE SWELLING | | | |

| | | | |
|--|---------------------|--------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| INJECTION SITE RASH subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| INJECTION SITE PRURITUS subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| INJECTION SITE INDENTATION subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| PYREXIA subjects affected / exposed occurrences (all) | 2 / 22 (9.09%) 2 | 0 / 4 (0.00%) 0 | |
| Immune system disorders SEASONAL ALLERGY subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| INFUSION RELATED HYPERSENSITIVITY REACTION subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| HYPERSENSITIVITY subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Reproductive system and breast disorders PROSTATOMEGALY subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| CERVICAL DYSPLASIA subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders DYSPHONIA subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |

| | | | |
|--|----------------|---------------|--|
| COUGH | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| INSOMNIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DEPRESSED MOOD | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| AGITATION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| LIVER FUNCTION TEST ABNORMAL | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| FAECAL CALPROTECTIN INCREASED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed occurrences (all) ASPARTATE AMINOTRANSFERASE INCREASED subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 | |
| Injury, poisoning and procedural complications TOOTH FRACTURE subjects affected / exposed occurrences (all) PROCEDURAL PAIN subjects affected / exposed occurrences (all) FALL subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 | |
| Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all) MIGRAINE subjects affected / exposed occurrences (all) HEADACHE subjects affected / exposed occurrences (all) OPHTHALMIC MIGRAINE subjects affected / exposed occurrences (all) SYNCOPE subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 1 / 22 (4.55%) 1 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 | |
| Blood and lymphatic system disorders LYMPHOPENIA subjects affected / exposed occurrences (all) LYMPHADENOPATHY | 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 | |

| | | | |
|-----------------------------|----------------|---------------|--|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| LEUKOCYTOSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Eye disorders | | | |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| CONSTIPATION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| APHTHOUS ULCER | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 2 / 22 (9.09%) | 0 / 4 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| HAEMATOCHEZIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DENTAL CARIES | | | |

| | | | |
|--|----------------|---------------|--|
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| HAEMORRHOIDS THROMBOSED | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| VOMITING | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatobiliary disorders | | | |
| LIVER DISORDER | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin and subcutaneous tissue disorders | | | |
| DERMATITIS CONTACT | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DERMATITIS ACNEIFORM | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DERMATITIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ALOPECIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ACNE | | | |

| | | | |
|-----------------------------|----------------|---------------|--|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DERMATITIS PSORIASIFORM | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| ERYTHROSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| LICHENOID KERATOSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| PSORIASIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RASH | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RASH VESICULAR | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| SKIN LESION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Renal and urinary disorders | | | |

| | | | |
|---|---------------------|---------------------|--|
| RENAL COLIC subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| URINARY RETENTION subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Endocrine disorders CUSHING'S SYNDROME subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 4 (0.00%) 0 | |
| TENDON PAIN subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| MUSCULOSKELETAL CHEST PAIN subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| MUSCLE SPASMS subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| JOINT SWELLING subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| BACK PAIN subjects affected / exposed occurrences (all) | 1 / 22 (4.55%) 1 | 0 / 4 (0.00%) 0 | |
| Infections and infestations BRONCHITIS VIRAL subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 0 / 4 (0.00%) 0 | |
| ANAL ABSCESS subjects affected / exposed occurrences (all) | 0 / 22 (0.00%) 0 | 1 / 4 (25.00%) 1 | |

| | | |
|-----------------------------|----------------|---------------|
| CELLULITIS | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| CONJUNCTIVITIS | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| COVID-19 | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| CRYPTOSPORIDIOSIS INFECTION | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| CYSTITIS | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| ESCHERICHIA INFECTION | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| GASTROENTERITIS | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| GINGIVITIS | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| INFLUENZA | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| NASOPHARYNGITIS | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 |
| ORAL CANDIDIASIS | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |
| ORAL HERPES | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | | |
|-----------------------------------|----------------|---------------|--|
| PARONYCHIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| PHARYNGITIS | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RASH PUSTULAR | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| SALMONELLOSIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| TINEA INFECTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| URINARY TRACT INFECTION | | | |

| | | | |
|------------------------------------|----------------|---------------|--|
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| VIRAEMIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| IRON DEFICIENCY | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| INCREASED APPETITE | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 1 / 22 (4.55%) | 0 / 4 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| HYPOALBUMINAEMIA | | | |
| subjects affected / exposed | 0 / 22 (0.00%) | 0 / 4 (0.00%) | |
| occurrences (all) | 0 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 11 October 2021 | Version 2.0, Global Amendment updated eligibility criterion and corrected typographical errors. |
| 18 May 2022 | Version 3.0, Global Amendment updated synopsis errors, specified terminology for ITT1 populations, clarified efficacy endpoints and planned assessments, clarified Rescue Therapy options, updated eligibility criterion, specified duration of contraception requirements and females of child-bearing potential, changed time period for prohibited medications, updated appendices language. |
| 20 December 2022 | Version 4.0, Global Amendment updated synopsis, investigational plan, key eligibility criteria, added to prohibited medications list, updated language to outline information security policies, updated protocol signatories. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

AbbVie has decided to discontinue further subject enrollment in the M20-371 (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: