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	v2 (current)
This version publication date	18 December 2024
First version publication date	02 August 2024
Version creation reason	• Correction of full data set Uploaded new AE Tables

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	New Zealand: 2
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 30
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	France: 5
Country: Number of subjects enrolled	Germany: 5

Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Netherlands: 4
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	Australia: 7
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Japan: 20
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	Investigator, Assessor, Subject

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). The SES-CD evaluates 4 endoscopic variables (ulcer size, ulcerated surface, affected surface, and narrowing, each on a scale from 0 (none) to 3 (worst) in 5 segments assessed during ileocolonoscopy (ileum, right colon, transverse colon, sigmoid and left colon, and	

rectum). The total
score is the sum of the 4 endoscopic variable scores and ranges from 0 to 56, where higher scores indicate more
severe disease.

Analysis Population Description: ITT1 Population for whom data was collected and available for analysis.

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 for whom data was collected and available for analysis.

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) andAverage 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) andAverage 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 Population for whom data was collected and available for analysis.

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 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_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_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_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	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

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	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	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_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	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	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

Serious adverse events	IP_Pbo	P_ABBV-154_150mg_IV_80mg_SC_EOW	IP_ABBV-154_300mg_IV_230mg_SC_EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 21 (14.29%)	3 / 20 (15.00%)	2 / 22 (9.09%)
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 / 22 (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 / 22 (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%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
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%)	0 / 22 (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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 22 (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 / 22 (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 / 22 (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 / 22 (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 / 22 (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 / 22 (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%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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 / 22 (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 / 22 (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 / 22 (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%)	0 / 22 (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 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (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_600mg_IV_530mg_SC_EOW	IP_ABBV-154_600mg_IV_530mg_SC_E4W	IP_Pbo_ReIP_ABBV-154_300mg_IV_230mg_SC_EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (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
Metabolism and nutrition disorders			
HYPOKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (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_600mg_IV_530 mg_SC_EOW	IP_ABBV-154_ReIP_ABBV-154_600mg_IV_530 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%)	2 / 8 (25.00%)	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 / 8 (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%)	1 / 8 (12.50%)	0 / 8 (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
SERUM SICKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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%)	1 / 8 (12.50%)	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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (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 / 8 (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 / 8 (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 / 8 (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%)	0 / 8 (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
FOCAL PERITONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (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 / 8 (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 / 8 (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 / 8 (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 / 8 (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	MP_Rand_Pbo	MP_Rand_ABBV-154_80mg_SC_EOW	MP_Non-Rand_ABBV-154_80mg_SC_EOW
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 18 (16.67%)	1 / 14 (7.14%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (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
SMALL INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (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
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (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
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (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 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MP_Rand_ABBV-154_230mg_SC_EOW	Rescue_ABBV-154_600mg_IV_230_mg_SC_EOW	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
CROHN'S DISEASE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

FOCAL PERITONITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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 / 13 (0.00%)	0 / 14 (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_80mg_SC_EOW	IP_ABBV-154_300mg_IV_230mg_SC_EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 21 (33.33%)	12 / 20 (60.00%)	10 / 22 (45.45%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

SKIN PAPILLOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE DRYNESS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FEELING ABNORMAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE EXFOLIATION			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
INJECTION SITE SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE RASH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PRURITUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE INDENTATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED HYPERSENSITIVITY REACTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

PROSTATOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CERVICAL DYSPLASIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
AGITATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

WEIGHT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FAECAL CALPROTECTIN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (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 / 22 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 22 (4.55%)
occurrences (all)	0	1	1

OPHTHALMIC MIGRAINE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
CONSTIPATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
CROHN'S DISEASE			

subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	2 / 22 (9.09%)
occurrences (all)	1	4	2
HAEMATOCHEZIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PROCTALGIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
LIVER DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (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 / 22 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ACNE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ERYTHROSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LICHENOID KERATOSIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
NIGHT SWEATS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PSORIASIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
RASH			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SKIN LESION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
RENAL COLIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
CUSHING'S SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
TENDON PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
JOINT SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			

subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Infections and infestations			
BRONCHITIS VIRAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANAL ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
CRYPTOSPORIDIOSIS INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
CYSTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
GINGIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

NASOPHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
ORAL HERPES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
PHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
PNEUMONIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
SALMONELLOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

TINEA INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VIRAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
DEHYDRATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INCREASED APPETITE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	IP_ABBV-154_600mg_IV_530	IP_ABBV-154_600mg_IV_530	IP_Pbo_ReIP_ABBV-154_300mg_IV_230

	mg_SC_EOW	mg_SC_E4W	mg_SC_EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 20 (70.00%)	13 / 23 (56.52%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
SKIN PAPILLOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
HOT FLUSH			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE DRYNESS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
FEELING ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

FATIGUE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
INJECTION SITE EXFOLIATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE RASH			
subjects affected / exposed	2 / 20 (10.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
INJECTION SITE PRURITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE INDENTATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED HYPERSENSITIVITY REACTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			

subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
PROSTATOMEGALY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CERVICAL DYSPLASIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
COUGH			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
NASAL CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
AGITATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	3 / 23 (13.04%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FAECAL CALPROTECTIN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
TOOTH FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MIGRAINE			

subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
HEADACHE			
subjects affected / exposed	2 / 20 (10.00%)	5 / 23 (21.74%)	0 / 4 (0.00%)
occurrences (all)	2	5	0
OPHTHALMIC MIGRAINE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
SYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
CONSTIPATION			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
APHTHOUS ULCER			

subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CROHN'S DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
LIVER DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
ACNE			
subjects affected / exposed	2 / 20 (10.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ECCHYMOSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ERYTHROSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
HYPERHIDROSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
LICHENOID KERATOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH VESICULAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
RENAL COLIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
CUSHING'S SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
TENDON PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 23 (8.70%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
MUSCLE SPASMS			

subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
BRONCHITIS VIRAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ANAL ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	2 / 20 (10.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
CRYPTOSPORIDIOSIS INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

GINGIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	3 / 20 (15.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
RASH PUSTULAR			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SALMONELLOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

SINUSITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TINEA INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 20 (10.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
VIRAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
IRON DEFICIENCY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INCREASED APPETITE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 23 (4.35%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 23 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	IP_Pbo_ReIP_ABBV-154_600mg_IV_530 mg_SC_EOW	IP_ABBV-154_ReIP_ABBV-154_600mg_IV_530 mg_SC_EOW	IP_ABBV-154_ReIP_ABBV-154_300mg_IV_230 mg_SC_EOW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	5 / 8 (62.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
SKIN PAPILLOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
INJECTION SITE DRYNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE BRUISING			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
FEELING ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
INJECTION SITE EXFOLIATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE INDENTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

SEASONAL ALLERGY			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
INFUSION RELATED HYPERSENSITIVITY REACTION			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
PROSTATOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CERVICAL DYSPLASIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DEPRESSED MOOD			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
AGITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
WEIGHT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
FAECAL CALPROTECTIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
OPHTHALMIC MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
APHTHOUS ULCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CROHN'S DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HAEMATOCHEZIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
LIVER DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
DERMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ACNE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ECCHYMOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ERYTHROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
LICHENOID KERATOSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
RASH VESICULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Endocrine disorders			
CUSHING'S SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
TENDON PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS VIRAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ANAL ABSCESS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
CRYPTOSPORIDIOSIS INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
INFLUENZA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SALMONELLOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
TINEA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
VIRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (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 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
INCREASED APPETITE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

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

subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE DRYNESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FEELING ABNORMAL			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE EXFOLIATION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE SWELLING			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE RASH			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PRURITUS			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
INJECTION SITE INDENTATION			

subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED HYPERSENSITIVITY REACTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERSENSITIVITY			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
PROSTATOMEGALY			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CERVICAL DYSPLASIA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DEPRESSED MOOD			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
AGITATION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FAECAL CALPROTECTIN INCREASED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

TOOTH FRACTURE			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
MIGRAINE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
OPHTHALMIC MIGRAINE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

VISION BLURRED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
APHTHOUS ULCER			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CROHN'S DISEASE			
subjects affected / exposed	1 / 18 (5.56%)	3 / 14 (21.43%)	2 / 4 (50.00%)
occurrences (all)	1	4	2
HAEMATOCHEZIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
DIARRHOEA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
DENTAL CARIES			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NAUSEA			

subjects affected / exposed	1 / 18 (5.56%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
PROCTALGIA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
VOMITING			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
LIVER DISORDER			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DERMATITIS			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
ALOPECIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ACNE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ECCHYMOSIS			

subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ERYTHROSIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LICHENOID KERATOSIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
PRURITUS			
subjects affected / exposed	2 / 18 (11.11%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
PSORIASIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RASH VESICULAR			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SKIN LESION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
RENAL COLIC			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY RETENTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
CUSHING'S SYNDROME			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 18 (5.56%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
TENDON PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
BACK PAIN			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BRONCHITIS VIRAL			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ANAL ABSCESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

COVID-19			
subjects affected / exposed	1 / 18 (5.56%)	2 / 14 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
CRYPTOSPORIDIOSIS INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CYSTITIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

PNEUMONIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RECTAL ABSCESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SALMONELLOSIS			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
SINUSITIS			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
TINEA INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VIRAEMIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

DECREASED APPETITE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DEHYDRATION			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INCREASED APPETITE			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 18 (0.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 18 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 18 (5.56%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	MP_Rand_ABBV-154_230mg_SC_EOW	Rescue_ABBV-154_600mg_IV_230_mg_SC_EOW	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 13 (61.54%)	8 / 14 (57.14%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
SKIN PAPILLOMA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HOT FLUSH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
CHEST PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE ERYTHEMA			
subjects affected / exposed	1 / 13 (7.69%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
INJECTION SITE DRYNESS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
FEELING ABNORMAL			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
FATIGUE			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
INJECTION SITE EXFOLIATION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE SWELLING			

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INJECTION SITE RASH			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
INJECTION SITE PRURITUS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
INJECTION SITE INDENTATION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
PYREXIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INFUSION RELATED HYPERSENSITIVITY REACTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HYPERSENSITIVITY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
PROSTATOMEGALY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
CERVICAL DYSPLASIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
DYSPHONIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

COUGH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
NASAL CONGESTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
DEPRESSED MOOD			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
AGITATION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
WEIGHT INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
WEIGHT DECREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
FAECAL CALPROTECTIN INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
BLOOD CREATINE PHOSPHOKINASE INCREASED			

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
TOOTH FRACTURE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
PROCEDURAL PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
FALL			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
MIGRAINE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HEADACHE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
OPHTHALMIC MIGRAINE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
SYNCOPE			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
LYMPHOPENIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
LYMPHADENOPATHY			

subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
LEUKOCYTOSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
VISION BLURRED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
CONSTIPATION			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
APHTHOUS ULCER			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
CROHN'S DISEASE			
subjects affected / exposed	0 / 13 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
HAEMATOCHEZIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
DIARRHOEA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
DENTAL CARIES			

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HAEMORRHOIDS THROMBOSED			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
NAUSEA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
PROCTALGIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
VOMITING			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
LIVER DISORDER			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
DERMATITIS CONTACT			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
DERMATITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ALOPECIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ACNE			

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ECCHYMOSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ERYTHROSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HYPERHIDROSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
LICHENOID KERATOSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
NIGHT SWEATS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
PRURITUS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
PSORIASIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
RASH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
RASH VESICULAR			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
SKIN LESION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			

RENAL COLIC			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
URINARY RETENTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
CUSHING'S SYNDROME			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
TENDON PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
MUSCLE SPASMS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
JOINT SWELLING			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
BACK PAIN			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
BRONCHITIS VIRAL			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ANAL ABSCESS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	

CELLULITIS			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
CONJUNCTIVITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	2 / 13 (15.38%)	1 / 14 (7.14%)	
occurrences (all)	2	1	
CRYPTOSPORIDIOSIS INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
CYSTITIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
GASTROENTERITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
GINGIVITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INFLUENZA			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
NASOPHARYNGITIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
ORAL HERPES			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	

PARONYCHIA				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
PHARYNGITIS				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
PNEUMONIA				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
RASH PUSTULAR				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
RECTAL ABSCESS				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
RESPIRATORY TRACT INFECTION				
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)		
occurrences (all)	1	0		
SALMONELLOSIS				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
SINUSITIS				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
SUBCUTANEOUS ABSCESS				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
TINEA INFECTION				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)		
occurrences (all)	1	0		
URINARY TRACT INFECTION				

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
VIRAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
DEHYDRATION			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
IRON DEFICIENCY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
INCREASED APPETITE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HYPOKALAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (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: