Clinical trial results:
A Randomized, Placebo-Controlled, Double-blind, Multicenter Study to Assess the Efficacy and Safety of Multiple Doses of BMS-986165 in Subjects with Active Psoriatic Arthritis (PsA)

Summary

EudraCT number	2018-004293-10
Trial protocol	CZ DE HU BE ES IT
Global end of trial date	27 January 2021

Results information

Result version number	v1 (current)
This version publication date	10 February 2022
First version publication date	10 February 2022

Trial information

Trial identification

Sponsor protocol code	IM011-084

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	27 May 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the dose-response relationship of BMS-986165 (6 or 12 mg once daily [QD]) at Week 16 in the treatment of subjects with active PsA

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czechia: 21
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	Poland: 58
Country: Number of subjects enrolled	Russian Federation: 48
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	United States: 39
Worldwide total number of subjects	203
EEA total number of subjects	116

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)	170
From 65 to 84 years	33
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

203 participants were randomized and treated.

Period 1

Period 1 title	Treatment Period - Part A
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.

Arm type	Placebo
Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Arm title	BMS-986165 6 mg

Arm description:

In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 6 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)

Arm type	Experimental
Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6 mg - 1 tablet daily

Arm title	BMS-986165 12 mg

Arm description:

In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 12 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)

Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

12 mg - 1 tablet daily

Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Number of subjects in period 1	Placebo	BMS-986165 6 mg	BMS-986165 12 mg
Started	66	70	67
Completed	58	63	59
Not completed	8	7	8
Consent withdrawn by subject	5	2	3
Adverse event, non-fatal	1	3	4
Other	2	1	-
Randomized by mistake with study treatment	-	1	1

Period 2

Period 2 title	Treatment Period - Part B
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Data analyst, Assessor, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo in Part A, Ustekinumab in Part B

Arm description:

In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.

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

Dosage and administration details:

45-90 mg Q4W

Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Arm title	BMS-986165 6 mg in Part A and Part B

Arm description:

In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, BMS-986165 at 6 mg

Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6 mg - 1 tablet daily

Investigational medicinal product name	Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Q4W

Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details: 1 tablet daily	

Arm title	BMS-986165 6 mg in Part A, Ustekinumab in Part B
Arm description: In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ	
Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 45-90 mg Q4W	
Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 1 tablet daily	
Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 1 tablet daily	
Arm title	BMS-986165 12 mg in Part A and Part B
Arm description: In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, BMS-986165 at 12 mg	
Arm type	Experimental
Investigational medicinal product name	BMS-986165
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 12 mg - 1 tablet daily	
Investigational medicinal product name	Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Q4W	
Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Arm title	BMS-986165 12 mg in Part A, Ustekinumab in Part B

Arm description:

In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ

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

Dosage and administration details:

45-90 mg Q4W

Investigational medicinal product name	Placebo matching BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Investigational medicinal product name	Placebo matching BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet daily

Number of subjects in period 2[1]	Placebo in Part A, Ustekinumab in Part B	BMS-986165 6 mg in Part A and Part B	BMS-986165 6 mg in Part A, Ustekinumab in Part B
Started	55	13	47
Completed	47	12	42
Not completed	8	1	5
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	-	-	-
Site terminated by sponsor	1	-	-
Other reasons	4	1	2
Lost to follow-up	1	-	1
Lack of efficacy	1	-	1

Number of subjects in period 2[1]	BMS-986165 12 mg in Part A and Part B	BMS-986165 12 mg in Part A, Ustekinumab in Part B
Started	16	42
Completed	13	34
Not completed	3	8
Adverse event, serious fatal	-	1
Consent withdrawn by subject	-	1
Adverse event, non-fatal	1	2
Site terminated by sponsor	1	2
Other reasons	1	2
Lost to follow-up	-	-
Lack of efficacy	-	-

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: Participation in Part B was voluntary. Some of the participants who completed Part A decided not to start Part B.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.	
Reporting group title	BMS-986165 6 mg
Reporting group description:	
In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 6 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)	
Reporting group title	BMS-986165 12 mg
Reporting group description:	
In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 12 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)	

Reporting group values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg
Number of subjects	66	70	67
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	59	57	54
From 65-84 years	7	13	13
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	48.5	50.5	50.5
standard deviation	± 13.17	± 13.69	± 13.75
Sex: Female, Male Units: Participants			
Female	40	30	34
Male	26	40	33
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	3	0
White	65	67	67
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	7	4	5
Not Hispanic or Latino	59	65	62
Unknown or Not Reported	0	1	0

Reporting group values	Total		
Number of subjects	203		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	170		
From 65-84 years	33		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	104		
Male	99		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	0		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	4		
White	199		
More than one race	0		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	16		
Not Hispanic or Latino	186		
Unknown or Not Reported	1		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.	
Reporting group title	BMS-986165 6 mg
Reporting group description:	
In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 6 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)	
Reporting group title	BMS-986165 12 mg
Reporting group description:	
In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, participants received either BMS-986165 at 12 mg (if they achieved minimal disease activity (MDA) in Part A) or Ustekinumab SQ (if they did not achieve MDA in Part A)	
Reporting group title	Placebo in Part A, Ustekinumab in Part B
Reporting group description:	
In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.	
Reporting group title	BMS-986165 6 mg in Part A and Part B
Reporting group description:	
In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, BMS-986165 at 6 mg	
Reporting group title	BMS-986165 6 mg in Part A, Ustekinumab in Part B
Reporting group description:	
In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ	
Reporting group title	BMS-986165 12 mg in Part A and Part B
Reporting group description:	
In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, BMS-986165 at 12 mg	
Reporting group title	BMS-986165 12 mg in Part A, Ustekinumab in Part B
Reporting group description:	
In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ	

Primary: Percentage of Participants Achieving the American College of Rheumatology (ACR) 20 Response at Week 16

End point title	Percentage of Participants Achieving the American College of Rheumatology (ACR) 20 Response at Week 16
End point description:	
A participant is considered an ACR 20 responder if the following three conditions are met: 1) ≥ 20% improvement from baseline in the number of tender joints (68 joint count). 2) ≥ 20% improvement from baseline in the number of swollen joints (66 joint count). 3) ≥ 20% improvement from baseline in at least 3 of the following 5 domains: o Subject Global Assessment of disease activity o Physician Global Assessment of psoriatic arthritis o Subject Global Assessment of pain o Health Assessment Questionnaire-Disability Index (HAQ-DI) o High-sensitivity C-reactive protein (hsCRP)	
End point type	Primary
End point timeframe:	
16 weeks after first dose	

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	31.8 (20.6 to 43.1)	52.9 (41.2 to 64.6)	62.7 (51.1 to 74.3)	

Statistical analyses

Statistical analysis title	ACR20-Week 16
Comparison groups	BMS-986165 6 mg v Placebo v BMS-986165 12 mg
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Slope Coefficient of Dose
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	0.17

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

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

End point description:

The HAQ-DI is measured by the use of a patient-reported outcome measure questionnaire, assessing the degree of difficulty a person has experienced during the past week in 8 domains of daily living activities. Each activity category consists of 2 to 3 questions (total of 20 questions). For reach question the level of activity is scored from 0 to 3, with 0 representing "no difficulty" and 3 as "unable to do". Any activity that requires assistance from another individual or an assistive device adjusts to a minimum score of 2. For each activity category, the highest score reported in the 2 or 3 questions pertinent to that category represents the category score. Scores from the 8 categories are then summed and divided by 8 to generate the final score. The final score can range from 0 (most desirable outcome) to 3 (least desirable outcome).
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	-0.11 (± 0.066)	-0.37 (± 0.065)	-0.39 (± 0.067)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving the Psoriasis Area and Severity Index (PASI) 75 Response

End point title	Percentage of Participants Achieving the Psoriasis Area and Severity Index (PASI) 75 Response

End point description:

The PASI is a measure of the average erythema, induration thickness and scaling of psoriatic skin lesions (each graded on a 0 to 4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. The PASI 75 response rate represents the percentage of participants who experienced at least a 75% improvement in PASI score as compared with the baseline value. PASI assessment was performed by trained professionals.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	59	52	
Units: Percent of Participants				
number (confidence interval 95%)	20.4 (9.6 to 31.1)	42.4 (29.8 to 55.0)	59.6 (46.3 to 73.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change From Baseline in the Physical Component Summary (PCS) Score of the Short Form Health Survey-36 (SF-36) Questionnaire

End point title	Adjusted Change From Baseline in the Physical Component Summary (PCS) Score of the Short Form Health Survey-36 (SF-36) Questionnaire

End point description:

The SF-36 is a patient-reported outcome measure, which includes 36 items in a Likert-type format to measure the following 8 health dimensions over the past week: 1) limitations in physical activities, such as bathing or dressing 2) limitations in social activities because of physical or emotional problems 3) limitations in usual role activities because of physical health problems 4) bodily pain 5) general mental

health (psychological distress and well-being) 6) limitations in usual role activities because of emotional problems 7) vitality (energy and fatigue) and 8) general health perceptions.
The 8 health dimensions assessed are grouped into 2 main components, physical and mental. Each of the 8 dimensions contribute to both the Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score.
PCS and MCS scores range from 0 to 100, with high scores indicating a better health status.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	2.3 (± 0.97)	5.6 (± 0.94)	5.8 (± 0.97)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving the American College of Rheumatology (ACR) 50 Response at Week 16

End point title	Percentage of Participants Achieving the American College of Rheumatology (ACR) 50 Response at Week 16

End point description:

A participant is considered an ACR 50 responder if the following three conditions are met:
1) ≥ 50% improvement from baseline in the number of tender joints (68 joint count).
2) ≥ 50% improvement from baseline in the number of swollen joints (66 joint count).
3) ≥ 50% improvement from baseline in at least 3 of the following 5 domains:
o Subject Global Assessment of disease activity
o Physician Global Assessment of psoriatic arthritis
o Subject Global Assessment of pain
o Health Assessment Questionnaire-Disability Index (HAQ-DI)
o High-sensitivity C-reactive protein (hsCRP)

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	10.6 (3.2 to 18.0)	24.3 (14.2 to 34.3)	32.8 (21.6 to 44.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving the American College of Rheumatology (ACR) 70 Response at Week 16

End point title	Percentage of Participants Achieving the American College of Rheumatology (ACR) 70 Response at Week 16

End point description:

A participant is considered an ACR 70 responder if the following three conditions are met:
1) ≥ 70% improvement from baseline in the number of tender joints (68 joint count).
2) ≥ 70% improvement from baseline in the number of swollen joints (66 joint count).
3) ≥ 70% improvement from baseline in at least 3 of the following 5 domains:
o Subject Global Assessment of disease activity
o Physician Global Assessment of psoriatic arthritis
o Subject Global Assessment of pain
o Health Assessment Questionnaire-Disability Index (HAQ-DI)
o High-sensitivity C-reactive protein (hsCRP)

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	1.5 (0.0 to 4.5)	14.3 (6.1 to 22.5)	19.4 (9.9 to 28.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Low Disease Activity According to the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP)

End point title	Percentage of Participants Achieving Low Disease Activity According to the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP)

End point description:

A Disease Activity Score (DAS) is a scoring system used to assess disease activity.
DAS 28 CRP is a composite outcome measure that assesses:
• How many joints in the hands (including metacarpophalangeal and proximal interphalangeal joints, but excluding distal interphalangeal joints), wrists, elbows, shoulders, and knees are swollen and/or tender over a total of 28.

• C Reactive Protein (CRP) levels in the blood (as a measure of the degree of inflammation)
• Subject Global Assessment of disease activity
The results are combined to produce the DAS 28 CRP score, which correlates with the extent of disease activity as follows:
• < 2.6: Disease remission
• 2.6 – 3.2: Low disease activity
• 3.2 – 5.1: Moderate disease activity
• > 5.1: High disease activity.
Only participants with a score < 3.2 are considered to have achieved low disease activity.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	22.7 (12.6 to 32.8)	37.1 (25.8 to 48.5)	43.3 (31.4 to 55.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Remission According to the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP)

End point title	Percentage of Participants Achieving Remission According to the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP)

End point description:

A Disease Activity Score (DAS) is a scoring system used to assess disease activity.
DAS 28 CRP is a composite outcome measure that assesses:
• How many joints in the hands (including metacarpophalangeal and proximal interphalangeal joints, but excluding distal interphalangeal joints), wrists, elbows, shoulders, and knees are swollen and/or tender over a total of 28.
• C Reactive Protein (CRP) levels in the blood (as a measure of the degree of inflammation)
• Subject Global Assessment of disease activity
The results are combined to produce the DAS 28 CRP score, which correlates with the extent of disease activity as follows:
• < 2.6: Disease remission
• 2.6 – 3.2: Low disease activity
• 3.2 – 5.1: Moderate disease activity
• > 5.1: High disease activity.
Only participants with a score < 2.6 are considered to have achieved remission.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	6.1 (0.3 to 11.8)	24.3 (14.2 to 34.3)	25.4 (15.0 to 35.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP) Score

End point title	Adjusted Change from Baseline in the Disease Activity Score-28 Using C Reactive Protein (DAS 28 CRP) Score

End point description:

A Disease Activity Score (DAS) is a scoring system used to assess disease activity.
DAS 28 CRP is a composite outcome measure that assesses:
• How many joints in the hands (including metacarpophalangeal and proximal interphalangeal joints, but excluding distal interphalangeal joints), wrists, elbows, shoulders, and knees are swollen and/or tender over a total of 28.
• C Reactive Protein (CRP) levels in the blood (as a measure of the degree of inflammation)
• Subject Global Assessment of disease activity
The results are combined to produce the DAS 28 CRP score, which correlates with the extent of disease activity as follows:
• < 2.6: Disease remission
• 2.6 – 3.2: Low disease activity
• 3.2 – 5.1: Moderate disease activity
• > 5.1: High disease activity.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	-0.9 (± 0.15)	-1.7 (± 0.15)	-1.7 (± 0.15)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in Dactylitis Count

End point title	Adjusted Change from Baseline in Dactylitis Count

End point description:

The number of digits in hands and feet with dactylitis (Tender + Non-Tender) was counted and change from baseline at week 16 was assessed.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	33	27	
Units: Digits with dactylitis				
arithmetic mean (standard error)	-1.8 (± 0.40)	-2.0 (± 0.38)	-2.5 (± 0.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in the Leeds Dactylitis Index (LDI) Basic Score

End point title	Adjusted Change from Baseline in the Leeds Dactylitis Index (LDI) Basic Score

End point description:

The Leeds Dactylitis Index (LDI) Basic is a quantitative measurement of dactylitis in the 20 digits using a dactylometer. The circumference of the affected and contralateral digits, and tenderness of the affected digits are measured to generate a total score. For each dactylitic digit, the final score is defined as: [{(A/B) – 1}*100]*C, where A is circumference of involved digit, B is circumference of the opposite, unaffected, digit or reference, and C is tenderness (0 or 1). The total score is determined by summing the relative score of all digits. A higher score indicates worse dactylitis.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	30	23	
Units: Score on a scale				
arithmetic mean (standard error)	-28.3 (± 8.87)	-41.8 (± 8.35)	-44.5 (± 8.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Dactylitis Resolution

End point title	Percentage of Participants Achieving Dactylitis Resolution

End point description:

Dactylitis resolution (tender digits only) is defined as a dactylitis count of 0 in participants with dactylitis count ≥ 1 at baseline

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	30	24	
Units: Percent of Participants				
number (confidence interval 95%)	60.0 (40.8 to 79.2)	76.7 (61.5 to 91.8)	79.2 (62.9 to 95.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in Enthesitis by the Leeds Enthesitis Index (LEI)

End point title	Adjusted Change from Baseline in Enthesitis by the Leeds Enthesitis Index (LEI)

End point description:

The LEI was developed specifically for psoriatic arthritis. An overall score of 0 to 6 is derived from the presence or absence of tenderness at 6 entheseal sites (right and left: lateral epicondyle, medial femoral condyle, and Achilles tendon insertion) at the time of evaluation. A higher count indicates a greater enthesitis burden.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	39	26	
Units: Score on a scale				
arithmetic mean (standard error)	-1.2 (± 0.27)	-1.5 (± 0.25)	-1.7 (± 0.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in Enthesitis by the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index

End point title	Adjusted Change from Baseline in Enthesitis by the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index

End point description:

The SPARCC Enthesitis Index has a 0 to 16 score that is derived from the evaluation of 8 locations: the greater trochanter (R/L), quadriceps tendon insertion into the patella (R/L), patellar ligament insertion into the patella and tibial tuberosity (R/L), Achilles tendon insertion (R/L), plantar fascia insertion (R/L), medial and lateral epicondyles (R/L), and the supraspinatus insertion (R/L). A higher count indicates a higher enthesitis burden based on the current evaluation.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	43	34	
Units: Score on a scale				
arithmetic mean (standard error)	-1.2 (± 0.54)	-2.9 (± 0.48)	-3.1 (± 0.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Enthesitis Resolution by the Leeds Enthesitis Index (LEI)

End point title	Percentage of Participants Achieving Enthesitis Resolution by the Leeds Enthesitis Index (LEI)

End point description:

The LEI was developed specifically for psoriatic arthritis. An overall score of 0 to 6 is derived from the presence or absence of tenderness at 6 entheseal sites (right and left: lateral epicondyle, medial femoral condyle, and Achilles tendon insertion) at the time of evaluation. A higher count indicates a greater enthesitis burden.
Enthesitis resolution is defined as s LEI score of 0, in subjects with LEI ≥ 1 at baseline

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	39	26	
Units: Percent of Participants				
number (confidence interval 95%)	22.6 (7.9 to 37.3)	51.3 (35.6 to 67.0)	50.0 (30.8 to 69.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Enthesitis Resolution by the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index

End point title	Percentage of Participants Achieving Enthesitis Resolution by the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index

End point description:

The SPARCC Enthesitis Index has a 0 to 16 score that is derived from the evaluation of 8 locations: the greater trochanter (R/L), quadriceps tendon insertion into the patella (R/L), patellar ligament insertion into the patella and tibial tuberosity (R/L), Achilles tendon insertion (R/L), plantar fascia insertion (R/L), medial and lateral epicondyles (R/L), and the supraspinatus insertion (R/L). A higher count indicates a higher enthesitis burden based on the current evaluation.
Enthesitis resolution defined as a SPARCC enthesitis index score of 0, in subjects with SPARCC ≥ 1 at baseline.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	43	34	
Units: Percent of Participants				
number (confidence interval 95%)	17.6 (4.8 to 30.5)	51.2 (36.2 to 66.1)	41.2 (24.6 to 57.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Physicians Global Assessment-Fingernails (PGA-F) Score of 0 or 1

End point title	Percentage of Participants Achieving a Physicians Global

	Assessment-Fingernails (PGA-F) Score of 0 or 1

End point description:

In participants with psoriasis fingernail involvement, the PGA-F score is used to evaluate the overall condition of the fingernails in terms of disease severity.
The assessment is performed by the investigator, who rates the fingernail condition on a 5-point scale based on the higher of the nail bed/nail matrix score.
Scores are 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe).

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	14	20	
Units: Percent of Participants				
number (confidence interval 95%)	0 (0.0 to 0.0)	21.4 (0.0 to 42.9)	50.0 (28.1 to 71.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Minimal Disease Activity (MDA) Response

End point title	Percentage of Participants Achieving Minimal Disease Activity (MDA) Response

End point description:

A Minimal Disease Activity (MDA) responder is defined as a participant fulfilling 5 of the following 7 outcomes:
• Tender joint count ≤ 1
• Swollen joint count ≤ 1
• Psoriasis Area and Severity Index (PASI) ≤ 1 or body surface area (BSA) ≤ 3%
• Subject Global Assessment of pain ≤ 15
• Subject Global Assessment of disease activity ≤ 20
• Health Assessment Questionnaire-Disability Index (HAQ-DI) ≤ 0.5
• Tender entheseal points ≤ 1

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	7.6 (1.2 to 14.0)	22.9 (13.0 to 32.7)	23.9 (13.7 to 34.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in the Psoriatic Arthritis Disease Activity Score (PASDAS)

End point title	Adjusted Change from Baseline in the Psoriatic Arthritis Disease Activity Score (PASDAS)

End point description:

PASDAS is a composite measure calculated from the Physician Global Assessment of psoriatic arthritis, the Subject Global Assessment of disease activity, the Short Form Health Survey-36 Item (SF-36) Physical Component Summary (PCS), the swollen joint count, the tender joint count, the Leeds Enthesitis Index (LEI), the Leeds Dactylitis Index (LDI) (Basic), and the the levels of high-sensitivity C-reactive Protein (hsCRP).
Each item contributes differently to the final score, which ranges from 0 to 10 (higher scores represent a higher level of disease activity).
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	70	66	
Units: Score on a scale				
arithmetic mean (standard error)	-1.1 (± 0.21)	-2.0 (± 0.20)	-2.1 (± 0.20)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in the Disease Activity Index for Psoriatic Arthritis Score (DAPSA)

End point title	Adjusted Change from Baseline in the Disease Activity Index for Psoriatic Arthritis Score (DAPSA)

End point description:

DAPSA is a composite measure to assess peripheral joint involvement that is based upon numerical summation of 5 variables of disease activity: tender/painful joint count 68, swollen joint count 66, Subject Global Assessment of disease activity, Subject Global Assessment of pain, and the levels of C-reactive Protein (CRP).
Final scores are interpreted as follows:
- ≤4 = Remission (REM)
- > 4 and ≤ 28 = moderate disease activity (MDA)
- >28 = high disease activity (HDA).

Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	-13.3 (± 2.20)	-23.2 (± 2.16)	-25.6 (± 2.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Psoriatic Arthritis Response Criteria (PsARC)

End point title	Percentage of Participants Achieving Psoriatic Arthritis Response Criteria (PsARC)

End point description:

PsARC consists of 4 measurements:
tender/painful joint count, swollen joint count, Physician Global Assessment of psoriatic arthritis, and Subject Global Assessment of pain ≤ 15.
In order to be classified as a PsARC responder, participants must achieve improvement in 2 of 4 measures, one of which must be joint pain or swelling, without worsening in any measure.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	54.5 (42.5 to 66.6)	75.7 (65.7 to 85.8)	74.6 (64.2 to 85.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change from Baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

End point title	Adjusted Change from Baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

End point description:

In participants with baseline evidence of Psoriatic Arthritis Spondylitis, symptoms are evaluated using the BASDAI, which consists of a 0 to 100 scale measuring discomfort, pain, and fatigue in response to 6 questions pertaining to the 5 major symptoms of ankylosing spondylitis:
• Fatigue (medical)
• Spinal pain
• Joint pain and swelling
• Areas of localized tenderness
• Morning stiffness duration
• Morning stiffness severity
A higher count indicates worse disease.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	19	16	
Units: Score on a scale				
arithmetic mean (standard error)	-1.7 (± 0.55)	-2.0 (± 0.48)	-2.2 (± 0.57)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change From Baseline in the Mental Component Summary (MCS) Score of the Short Form Health Survey-36 (SF-36) Questionnaire

End point title	Adjusted Change From Baseline in the Mental Component Summary (MCS) Score of the Short Form Health Survey-36 (SF-36) Questionnaire

End point description:

The SF-36 is a patient-reported outcome measure, which includes 36 items in a Likert-type format to measure the following 8 health dimensions over the past week: 1) limitations in physical activities, such as bathing or dressing 2) limitations in social activities because of physical or emotional problems 3) limitations in usual role activities because of physical health problems 4) bodily pain 5) general mental health (psychological distress and well-being) 6) limitations in usual role activities because of emotional problems 7) vitality (energy and fatigue) and 8) general health perceptions.
The 8 health dimensions assessed are grouped into 2 main components, physical and mental. Each of the 8 dimensions contribute to both the Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score.
PCS and MCS scores range from 0 to 100, with high scores indicating a better health status.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	0.7 (± 1.00)	3.6 (± 0.97)	3.5 (± 1.01)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change From Baseline in the Psoriatic Arthritis Impact of Disease (PsAID) 12 Score

End point title	Adjusted Change From Baseline in the Psoriatic Arthritis Impact of Disease (PsAID) 12 Score

End point description:

PsAID is a 12-item self-report that measures psoriatic arthritis symptoms and impact of disease. Each item is scored on a 0 to 10 numeric rating scale, and each item contributes differently to the final score. Weighted scores for each item are summed and divided by 20 to generate the final score, ranging from 0 to 10 (higher values indicate worse health).
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	-1.0 (± 0.26)	-2.1 (± 0.26)	-2.3 (± 0.26)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change From Baseline in the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) Score

End point title	Adjusted Change From Baseline in the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) Score

End point description:

The FACIT-Fatigue instrument is a questionnaire used to evaluate a range of self-reported symptoms over the past week, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one’s ability to execute daily activities and function normally in family or social roles. Fatigue is divided into the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities. The questionnaire is composed of 13 questions (Short Form 13a) and each question is scored from 1 to 5. The final score results from the sum of the scores of the 13 questions, and ranges from 13 (most desirable outcome) to

65 (least desirable outcome).
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	67	65	
Units: Score on a scale				
arithmetic mean (standard error)	2.8 (± 1.17)	5.6 (± 1.16)	7.2 (± 1.18)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Change From Baseline in the Work Limitation Questionnaire (WLQ) Score

End point title	Adjusted Change From Baseline in the Work Limitation Questionnaire (WLQ) Score

End point description:

The Work Limitation Questionnaire (WLQ) is a 25-item self-report that measures the on-the-job impact of chronic health conditions and treatment over the past 2 weeks. It focuses on assessing limitations while performing specific job demands from the following 4 domains:
1) Time management: difficulty with handling time and scheduling demands (5 items)
2) Physical demands: ability to perform job tasks that involve bodily strength, movement, endurance, coordination, and flexibility (6 items)
3) Mental-interpersonal demands: cognitively demanding tasks and on-the-job social interactions (9 items)
4) Output demands: concerns reduced work productivity (5 items).
Final score ranges from 0 (limited none of the time) to 100 (limited all of the time). The score can be used to calculate a percent of lost work productivity due to a particular disease state.
Adjusted change represents a change from baseline based on statistical model.

End point type	Secondary

End point timeframe:

From baseline (day of the first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Score on a scale				
arithmetic mean (standard error)	-1.2 (± 0.69)	-1.9 (± 0.67)	-2.7 (± 0.70)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Health Assessment Questionnaire-Disability Index (HAQ-DI) 0.35 Response

End point title	Percentage of Participants Achieving Health Assessment Questionnaire-Disability Index (HAQ-DI) 0.35 Response

End point description:

The HAQ-DI is measured by the use of a patient-reported outcome measure questionnaire, assessing the degree of difficulty a person has experienced during the past week in 8 domains of daily living activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and other activities. Each activity category consists of 2 to 3 questions (total of 20 questions). For reach question the level of activity is scored from 0 ("no difficulty") to 3 ("unable to do"). For each activity category, the highest score reported in the 2 or 3 questions pertinent to that category represents the category score. Scores from the 8 categories are then summed and divided by 8 to generate the final score. The final score can range from 0 (most desirable outcome) to 3 (least desirable outcome).
A HAQ-DI 0.35 responder is defined as a participant with an improvement from baseline in HAQ-DI score of at least 0.35.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: Percent of Participants				
number (confidence interval 95%)	15.2 (6.5 to 23.8)	38.6 (27.2 to 50.0)	40.3 (28.6 to 52.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving the Psoriasis Area and Severity Index (PASI) 90 Response

End point title	Percentage of Participants Achieving the Psoriasis Area and Severity Index (PASI) 90 Response

End point description:

The PASI is a measure of the average erythema, induration thickness and scaling of psoriatic skin lesions (each graded on a 0 to 4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. The PASI 90 response rate represents the percentage of participants who experienced at least a 90% improvement in PASI score as compared with the baseline value. PASI assessment was performed by trained professionals.

End point type	Secondary

End point timeframe:

16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	59	52	
Units: Percent of Participants				
number (confidence interval 95%)	9.3 (1.5 to 17.0)	20.3 (10.1 to 30.6)	34.6 (21.7 to 47.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Electrocardiogram (ECG) Results

End point title	Change from Baseline in Electrocardiogram (ECG) Results

End point description:

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	70	67	
Units: msec				
arithmetic mean (standard deviation)				
PR Interval, Aggregate	3.9 (± 16.40)	3.2 (± 17.83)	-2.9 (± 37.09)	
QRS Duration, Aggregate	-0.5 (± 9.07)	3.9 (± 11.58)	-1.1 (± 13.55)	
QT Interval, Aggregate	1.4 (± 27.47)	2.7 (± 28.56)	1.5 (± 26.81)	
QTcB Interval, Aggregate	2.8 (± 41.79)	-6.7 (± 24.46)	0.4 (± 20.34)	
QTcF Interval, Aggregate	-0.6 (± 29.83)	2.4 (± 29.62)	4.4 (± 22.96)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Electrocardiogram (ECG) Heart Rate

End point title	Change from Baseline in Electrocardiogram (ECG) Heart Rate

End point description:

End point type	Secondary

End point timeframe:
From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	63	59	
Units: beats/min				
arithmetic mean (standard deviation)	-0.7 (± 8.28)	-1.0 (± 9.84)	0.0 (± 8.82)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Diastolic Blood Pressure

End point title	Change from Baseline in Vital Signs - Diastolic Blood Pressure

End point description:

End point type	Secondary

End point timeframe:
From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: mmHg				
arithmetic mean (standard deviation)	1.1 (± 8.67)	-0.9 (± 6.10)	-1.7 (± 7.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Heart Rate

End point title	Change from Baseline in Vital Signs - Heart Rate

End point description:

End point type	Secondary

End point timeframe:
From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: beats/min				
arithmetic mean (standard deviation)	0.7 (± 9.40)	-2.5 (± 9.02)	0.8 (± 8.56)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Respiratory Rate

End point title	Change from Baseline in Vital Signs - Respiratory Rate

End point description:

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: breaths/min				
arithmetic mean (standard deviation)	0.0 (± 1.88)	-0.2 (± 1.46)	0.2 (± 1.16)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Systolic Blood Pressure

End point title	Change from Baseline in Vital Signs - Systolic Blood Pressure

End point description:

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: mmHg				
arithmetic mean (standard deviation)	1.6 (± 11.05)	-0.6 (± 10.95)	-1.5 (± 11.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Temperature

End point title	Change from Baseline in Vital Signs - Temperature

End point description:

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	64	60	
Units: Celsius degree (C)				
arithmetic mean (standard deviation)	-0.05 (± 0.307)	-0.07 (± 0.364)	-0.06 (± 0.323)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Signs - Weight

End point title	Change from Baseline in Vital Signs - Weight

End point description:

End point type	Secondary

End point timeframe:

From baseline (day of first dose) to 16 weeks after first dose

End point values	Placebo	BMS-986165 6 mg	BMS-986165 12 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	63	60	
Units: Kg				
arithmetic mean (standard deviation)	-0.24 (± 3.690)	0.18 (± 2.646)	0.43 (± 2.823)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was assessed from date of first dose to study completion.
Serious Adverse events and other adverse events were assessed from date of first dose to 30 days following date of last dose (up to approximately 13 months).

Adverse event reporting additional description:

All participants receiving treatment either only in Part A or in Part A + Part B

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Only Part A:Placebo

Reporting group description:

In Part A, Placebo matching BMS-986165.

Reporting group title	Only Part A:BMS-986165 12 mg QD

Reporting group description:

In Part A, BMS-986165 12 mg administered QD for 16 weeks.

Reporting group title	Only Part A:BMS-986165 6 mg QD

Reporting group description:

In Part A, BMS-986165 6 mg administered QD for 16 weeks.

Reporting group title	BMS-986165 6 mg in Part A and Part B

Reporting group description:

In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, BMS-986165 at 6 mg

Reporting group title	Part A: BMS-986165 6 mg QD - Part B: Ustekinumab SQ

Reporting group description:

In Part A, BMS-986165 6 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ.

Reporting group title	BMS-986165 12 mg in Part A and Part B

Reporting group description:

In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, BMS-986165 at 12 mg

Reporting group title	Part A: BMS-986165 12 mg QD - Part B: Ustekinumab SQ

Reporting group description:

In Part A, BMS-986165 12 mg administered QD for 16 weeks. In Part B, Ustekinumab SQ

Reporting group title	Part A: Placebo + Part B: Ustekinumab SQ

Reporting group description:

In Part A, Placebo matching BMS-986165. In Part B, Ustekinumab SQ.

Serious adverse events	Only Part A:Placebo	Only Part A:BMS-986165 12 mg QD	Only Part A:BMS-986165 6 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 11 (18.18%)	0 / 9 (0.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Metastatic carcinoid tumour			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (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
Injury, poisoning and procedural complications			
Chest injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
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			

Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
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	BMS-986165 6 mg in Part A and Part B	Part A: BMS-986165 6 mg QD - Part B: Ustekinumab SQ	BMS-986165 12 mg in Part A and Part B
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)	3 / 47 (6.38%)	0 / 16 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic carcinoid tumour			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Chest injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Road traffic accident			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (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
Psoriatic arthropathy			

subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
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	Part A: BMS-986165 12 mg QD - Part B: Ustekinumab SQ	Part A: Placebo + Part B: Ustekinumab SQ	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 42 (9.52%)	0 / 55 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic carcinoid tumour			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Chest injury			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (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			
Pneumonia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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	Only Part A:Placebo	Only Part A:BMS-986165 12 mg QD	Only Part A:BMS-986165 6 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)	7 / 9 (77.78%)	7 / 10 (70.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal neoplasm			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Mesenteric neoplasm			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Post thrombotic syndrome			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Injection site discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pulmonary mass			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	2	0

Haemoglobin decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Eye injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 11 (9.09%)	1 / 9 (11.11%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
Paraesthesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Eosinophilia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Noninfective sialoadenitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Diverticulum intestinal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Flatulence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal inflammation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Haemorrhoids			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Ileal ulcer			

subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Subileus			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nail bed inflammation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	2 / 11 (18.18%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Rash macular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Rash vesicular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Psoriatic arthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Furuncle			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 9 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 9 (11.11%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	BMS-986165 6 mg in Part A and Part B	Part A: BMS-986165 6 mg QD - Part B: Ustekinumab SQ	BMS-986165 12 mg in Part A and Part B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	30 / 47 (63.83%)	11 / 16 (68.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mesenteric neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 13 (15.38%)	3 / 47 (6.38%)	0 / 16 (0.00%)
occurrences (all)	2	3	0
Post thrombotic syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	3 / 16 (18.75%)
occurrences (all)	1	0	6
Injection site discomfort			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 13 (7.69%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)	2 / 47 (4.26%)	1 / 16 (6.25%)
occurrences (all)	1	2	1
Pulmonary mass			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Respiratory disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	2 / 16 (12.50%)
occurrences (all)	8	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 13 (15.38%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	6	0	1

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	3
Body temperature increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Blood pressure increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Eye injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Palpitations			

subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 13 (15.38%)	6 / 47 (12.77%)	0 / 16 (0.00%)
occurrences (all)	3	9	0
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Eosinophilia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	2	1	2
Conjunctival haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Macular fibrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eye haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			

Aphthous ulcer			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
Mouth ulceration			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	3	0	1
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Noninfective sialoadenitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	3 / 47 (6.38%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Diverticulum intestinal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastrointestinal inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ileal ulcer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Subileus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Hepatomegaly			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	1 / 13 (7.69%)	2 / 47 (4.26%)	1 / 16 (6.25%)
occurrences (all)	2	2	2
Erythema			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Nail bed inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 13 (7.69%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Intertrigo			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Rash macular			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rosacea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1

Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Muscle discomfort			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 13 (0.00%)	3 / 47 (6.38%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	6 / 47 (12.77%)	2 / 16 (12.50%)
occurrences (all)	2	8	2
Upper respiratory tract infection			
subjects affected / exposed	2 / 13 (15.38%)	3 / 47 (6.38%)	1 / 16 (6.25%)
occurrences (all)	2	3	2
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Ear infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Herpes simplex			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	3 / 47 (6.38%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Furuncle			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	1 / 13 (7.69%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	1	2	2
Oral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 13 (15.38%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	2	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Tonsillitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 47 (4.26%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Hyperuricaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 47 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 47 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 47 (2.13%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part A: BMS-986165 12 mg QD - Part B: Ustekinumab SQ	Part A: Placebo + Part B: Ustekinumab SQ	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 42 (73.81%)	34 / 55 (61.82%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	

Mesenteric neoplasm			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Post thrombotic syndrome			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 42 (4.76%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Pyrexia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Injection site discomfort			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Pulmonary mass			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Respiratory disorder			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	

Rhinorrhoea			
subjects affected / exposed	3 / 42 (7.14%)	0 / 55 (0.00%)	
occurrences (all)	3	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 42 (4.76%)	2 / 55 (3.64%)	
occurrences (all)	3	2	
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 42 (4.76%)	1 / 55 (1.82%)	
occurrences (all)	3	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 42 (4.76%)	1 / 55 (1.82%)	
occurrences (all)	2	1	
Body temperature increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Weight increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Blood pressure increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Haemoglobin decreased			
subjects affected / exposed	3 / 42 (7.14%)	0 / 55 (0.00%)	
occurrences (all)	5	0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Platelet count increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			

Eye injury			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 42 (2.38%)	6 / 55 (10.91%)	
occurrences (all)	1	7	
Dizziness			
subjects affected / exposed	1 / 42 (2.38%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Paraesthesia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	3 / 42 (7.14%)	0 / 55 (0.00%)	
occurrences (all)	3	0	
Anaemia			
subjects affected / exposed	2 / 42 (4.76%)	2 / 55 (3.64%)	
occurrences (all)	2	2	
Eosinophilia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	2	

Conjunctival haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Macular fibrosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Eye haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Mouth ulceration			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	0 / 42 (0.00%)	3 / 55 (5.45%)	
occurrences (all)	0	5	
Noninfective sialoadenitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	3	
Abdominal pain			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	2 / 42 (4.76%)	1 / 55 (1.82%)	
occurrences (all)	2	1	
Diverticulum intestinal			

subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Ileal ulcer			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Large intestine polyp			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Retching			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Subileus			

subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Hepatomegaly			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	4 / 42 (9.52%)	0 / 55 (0.00%)	
occurrences (all)	4	0	
Erythema			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Nail bed inflammation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Skin exfoliation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	2 / 42 (4.76%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Intertrigo			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Psoriasis			
subjects affected / exposed	0 / 42 (0.00%)	2 / 55 (3.64%)	
occurrences (all)	0	2	
Rash macular			

subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Rash papular			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Rash vesicular			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Rosacea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Muscle discomfort			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Osteoarthritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Psoriatic arthropathy			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	11 / 42 (26.19%)	7 / 55 (12.73%)	
occurrences (all)	14	7	
Upper respiratory tract infection			
subjects affected / exposed	0 / 42 (0.00%)	4 / 55 (7.27%)	
occurrences (all)	0	4	
COVID-19			
subjects affected / exposed	5 / 42 (11.90%)	0 / 55 (0.00%)	
occurrences (all)	5	0	
Ear infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Herpes simplex			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Bronchitis			
subjects affected / exposed	1 / 42 (2.38%)	2 / 55 (3.64%)	
occurrences (all)	1	2	
Furuncle			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	1 / 42 (2.38%)	0 / 55 (0.00%)	
occurrences (all)	1	0	
Oral infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	2 / 42 (4.76%)	1 / 55 (1.82%)	
occurrences (all)	3	1	

Respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	1 / 55 (1.82%)	
occurrences (all)	1	2	
Respiratory tract infection viral			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	3 / 42 (7.14%)	0 / 55 (0.00%)	
occurrences (all)	4	0	
Tonsillitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	2 / 42 (4.76%)	3 / 55 (5.45%)	
occurrences (all)	5	3	
Viral infection			
subjects affected / exposed	0 / 42 (0.00%)	3 / 55 (5.45%)	
occurrences (all)	0	4	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 55 (1.82%)	
occurrences (all)	0	1	
Hyperuricaemia			
subjects affected / exposed	2 / 42 (4.76%)	1 / 55 (1.82%)	
occurrences (all)	2	1	
Hyperlipidaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			

subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 55 (1.82%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 September 2019	- Inclusion/Exclusion criteria - PK sampling and dosing schedule

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported