Clinical trial results:
A Randomized Double-blind Pharmacokinetic Study of Ustekinumab in Pediatric Subjects with Moderately to Severely Active Crohn's Disease

Summary

EudraCT number	2016-001956-22
Trial protocol	BE DE PL FR Outside EU/EEA
Global end of trial date	18 March 2022

Results information

Result version number	v1 (current)
This version publication date	04 October 2022
First version publication date	04 October 2022

Trial information

Trial identification

Sponsor protocol code	CNTO1275CRD1001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02968108
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development LLC
Sponsor organisation address	920 Route 202, South Raritan NJ, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000311-PIP04-13
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the pharmacokinetics (PK) of ustekinumab in subjects from 2 through less than (<) 18 years old and determine if it was similar to that observed in adults with moderately to severely active Crohn's disease, to assess the safety, immunogenicity, and the efficacy of ustekinumab in the treatment of moderately to severely active Crohn's disease, including assessment of improvement in the endoscopic appearance of the mucosa. The objective of the long-term extension (LTE) period of study CNTO1275CRD1001 was to evaluate the PK, efficacy, safety, and immunogenicity of ustekinumab in pediatric subjects 2 to <18 years old with moderately to severely active Crohn's disease.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Poland: 10
Country: Number of subjects enrolled	United States: 10
Worldwide total number of subjects	44
EEA total number of subjects	29

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)	10
Adolescents (12-17 years)	34
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 45 randomised subjects, 44 were treated in double-blind (DB) period (23 in Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg and 21 in 9 mg/kg or 390 mg + 2 mg/kg or 90 mg). In long-term extension (LTE) period, 34 subjects were treated (18 in Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg and 16 in 9 mg/kg or 390 mg + 2 mg/kg or 90 mg).

Period 1

Period 1 title	DB Period (Through Week 16)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg

Arm description:

Subjects received single intravenous (IV) ustekinumab induction dose of 3 milligrams per kilogram (mg/kg) (for body weight [BW] less than [<]40 kg) or 130 mg (for BW greater than or equal to [>=]40 kg) at Week 0, followed by single subcutaneous (SC) maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 3 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Ustekinumab 3 mg/kg (if body weight <40 kg).

Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 90 mg (if body weight >=40 kg).

Investigational medicinal product name	Ustekinumab 2 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 2 mg/kg (if body weight <40 kg).

Investigational medicinal product name	Ustekinumab 130 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion

Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Ustekinumab 130 mg (if body weight >=40 kg).

Arm title	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg

Arm description:

Subjects received single IV ustekinumab induction dose of 9 mg/kg (for BW <40 kg) or 390 mg (for BW >=40 kg) at Week 0, followed by single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 9 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Ustekinumab 9 mg/kg (if body weight <40 kg).

Investigational medicinal product name	Ustekinumab 2 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 2 mg/kg (if body weight <40 kg).

Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 90 mg (if body weight >=40 kg).

Investigational medicinal product name	Ustekinumab 390 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Ustekinumab 390 mg (if body weight >=40 kg).

Number of subjects in period 1	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg
Started	23	21
Completed	22	18
Not completed	1	3
Consent withdrawn by subject	1	-
Unspecified	-	3

Period 2

Period 2 title	LTE Period: Week 16 Post Dose - Week 268
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Ustekinumab 3mg/kg or 130mg in DB then 2mg/kg or 90mg in LTE

Arm description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) every 8 weeks (Q8W) from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 90 mg (for BW >=40 kg).

Investigational medicinal product name	Ustekinumab 2 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 2 mg/kg (for BW <40 kg).

Arm title	Ustekinumab 9mg/kg or 390mg in DB then 2mg/kg or 90mg in LTE

Arm description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) Q8W from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Ustekinumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 90 mg (for BW >=40 kg).

Investigational medicinal product name	Ustekinumab 2 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab 2 mg/kg (for BW <40 kg).

Number of subjects in period 2[1]	Ustekinumab 3mg/kg or 130mg in DB then 2mg/kg or 90mg in LTE	Ustekinumab 9mg/kg or 390mg in DB then 2mg/kg or 90mg in LTE
Started	18	16
Completed	6	2
Not completed	12	14
Consent withdrawn by subject	5	5
Unspecified	7	9

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: Out of 40 subjects who completed the DB period, only 34 subjects entered the LTE period, as 6 subjects discontinued the study before initiation of LTE period.

Baseline characteristics

Reporting groups	
Reporting group title	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg
Reporting group description:	
Subjects received single intravenous (IV) ustekinumab induction dose of 3 milligrams per kilogram (mg/kg) (for body weight [BW] less than [<]40 kg) or 130 mg (for BW greater than or equal to [>=]40 kg) at Week 0, followed by single subcutaneous (SC) maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.	
Reporting group title	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg
Reporting group description:	
Subjects received single IV ustekinumab induction dose of 9 mg/kg (for BW <40 kg) or 390 mg (for BW >=40 kg) at Week 0, followed by single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.	

Reporting group values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg	Total
Number of subjects	23	21	44
Title for AgeCategorical Units: subjects			
Children (2-11 years)	6	4	10
Adolescents (12-17 years)	17	17	34
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	13.2	13.6	
standard deviation	± 2.89	± 2.62	-
Title for Gender Units: subjects			
Female	17	9	26
Male	6	12	18

End points

End points reporting groups

Reporting group title	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg

Reporting group description:

Subjects received single intravenous (IV) ustekinumab induction dose of 3 milligrams per kilogram (mg/kg) (for body weight [BW] less than [<]40 kg) or 130 mg (for BW greater than or equal to [>=]40 kg) at Week 0, followed by single subcutaneous (SC) maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Reporting group title	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg

Reporting group description:

Subjects received single IV ustekinumab induction dose of 9 mg/kg (for BW <40 kg) or 390 mg (for BW >=40 kg) at Week 0, followed by single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Reporting group title	Ustekinumab 3mg/kg or 130mg in DB then 2mg/kg or 90mg in LTE

Reporting group description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) every 8 weeks (Q8W) from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Reporting group title	Ustekinumab 9mg/kg or 390mg in DB then 2mg/kg or 90mg in LTE

Reporting group description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) Q8W from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Primary: Serum Concentrations of Ustekinumab at Week 16

End point title	Serum Concentrations of Ustekinumab at Week 16[1]

End point description:

Serum concentrations of ustekinumab at Week 16 was reported. Pharmacokinetics (PK) analysis set included all randomised subjects who received at least 1 administration of ustekinumab and who had one or more PK blood samples obtained after the first ustekinumab dose and were analysed according to the actual treatment received. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Week 16

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	13		
Units: micrograms (mcg)/millilitre (mL)				
arithmetic mean (standard deviation)	1.47 (± 1.323)	1.80 (± 2.356)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Clinical Response Measured by the Pediatric Crohn's Disease Activity Index (PCDAI) Score at Weeks 8 and 16

End point title	Percentage of Subjects with Clinical Response Measured by the Pediatric Crohn's Disease Activity Index (PCDAI) Score at Weeks 8 and 16

End point description:

Clinical response was defined as a reduction from baseline in the PCDAI score of greater than or equal to (>=)15 points. PCDAI is an index used to measure disease activity of pediatric subjects with Crohn's Disease assessing abdominal pain, stool frequency, subjects functioning, hematocrit, erythrocyte sedimentation rate, albumin, weight, height, abdominal tenderness or mass, perirectal disease, and extraintestinal manifestations. It ranges from 0 to 100; higher scores indicate more active disease. Efficacy analysis set included all randomised subjects who received at least 1 administration of ustekinumab analysed according to the assigned treatment.

End point type	Secondary

End point timeframe:

Week 8 and Week 16

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	21		
Units: Percentage of Subjects				
number (not applicable)				
Week 8	47.8	47.6		
Week 16	52.2	52.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Clinical Remission Measured by the PCDAI Score at Weeks 8 and 16

End point title	Percentage of Subjects with Clinical Remission Measured by the PCDAI Score at Weeks 8 and 16

End point description:

Clinical remission was defined as a reduction from baseline in the PCDAI score of less than or equal to (<=)10 points. PCDAI is an index used to measure disease activity of pediatric subjects with Crohn's Disease assessing abdominal pain, stool frequency, subjects functioning, hematocrit, erythrocyte

sedimentation rate, albumin, weight, height, abdominal tenderness or mass, perirectal disease, and extraintestinal manifestations. It ranges from 0 to 100; higher scores indicate more active disease. Efficacy analysis set included all randomised subjects who received at least 1 administration of ustekinumab analysed according to the assigned treatment.

End point type	Secondary

End point timeframe:

Week 8 and Week 16

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	21		
Units: Percentage of Subjects				
number (not applicable)				
Week 8	21.7	19.0		
Week 16	21.7	28.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Endoscopic Response at Week 16

End point title	Percentage of Subjects with Endoscopic Response at Week 16

End point description:

Endoscopic response was defined as a reduction from induction baseline in simple endoscopic score for Crohn's disease (SES-CD) score >=50 percent (%). SES-CD is a validated instrument reflecting an endoscopist global appraisal of mucosal lesions in Crohn's disease. SES-CD grades lesions by location (5 bowel segments:ileum, right colon, transverse colon, left colon, and rectum) using 4 endoscopic variables:ulcer size, extent of ulcerated surface, extent of affected surface, and presence/type of narrowing. The total SES-CD was calculated as the sum of the 4 variables for the 5 bowel segments: rectum, left colon, transverse colon, right colon, and ileum.Scores range from 0 to 60, with higher scores indicating more severe disease. Efficacy analysis set included all randomised subjects who received at least 1 administration of ustekinumab analysed according to the assigned treatment. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Percentage of Subjects				
number (not applicable)	31.6	27.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Endoscopic Remission at Week 16

End point title	Percentage of Subjects with Endoscopic Remission at Week 16

End point description:

Endoscopic remission was defined as a reduction from induction baseline in SES-CD score of <=2 %. SES-CD is a validated instrument reflecting an endoscopist global appraisal of mucosal lesions in Crohn's disease. SES-CD grades lesions by location (5 bowel segments: ileum, right colon, transverse colon, left colon, and rectum) using 4 endoscopic variables: ulcer size, extent of ulcerated surface, extent of affected surface, and presence/type of narrowing. The total SES-CD was calculated as the sum of the 4 variables for the 5 bowel segments: rectum, left colon, transverse colon, right colon, and ileum. Scores range from 0 to 60, with higher scores indicating more severe disease. Efficacy analysis set included all randomised subjects who received at least 1 administration of ustekinumab analysed according to the assigned treatment. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Percentage of Subjects				
number (not applicable)	15.8	11.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Clinically Meaningful Endoscopic Improvement at Week 16

End point title	Percentage of Subjects with Clinically Meaningful Endoscopic Improvement at Week 16

End point description:

Clinically meaningful endoscopic improvement is defined as a reduction in SES-CD of >=3 from baseline. SES-CD is a validated instrument reflecting an endoscopist global appraisal of mucosal lesions in Crohn's disease. SES-CD grades lesions by location (5 bowel segments: ileum, right colon, transverse colon, left colon, and rectum) using 4 endoscopic variables: ulcer size, extent of ulcerated surface, extent of affected surface, and presence/type of narrowing. The total SES-CD was calculated as the sum of the 4 variables for the 5 bowel segments: rectum, left colon, transverse colon, right colon, and ileum. Scores

range from 0 to 60, with higher scores indicating more severe disease. Efficacy analysis set included all randomised subjects who received at least 1 administration of ustekinumab analysed according to the assigned treatment. Here, 'N' (number of subjects analysed) signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At Week 16

End point values	Ustekinumab 3 mg/kg or 130 mg + 2 mg/kg or 90 mg	Ustekinumab 9 mg/kg or 390 mg + 2 mg/kg or 90 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Percentage of Subjects				
number (not applicable)	42.1	33.3		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Double-blind (DB) period: From Week 0 (Day 1) up to Week 16 (prior to SC dose) and Long-term extension (LTE) period: From Week 16 (post SC dose) up to Week 268

Adverse event reporting additional description:

Safety analysis set included all randomised subjects who received at least one administration of ustekinumab and analysed according to the actual treatment received.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	DB Period: Ustekinumab 3mg/kg or 130mg +2mg/kg or 90mg

Reporting group description:

Subjects received single intravenous (IV) ustekinumab induction dose of 3 milligrams per kilogram (mg/kg) (for body weight [BW] less than [<]40 kg) or 130 mg (for BW greater than or equal to [>=]40 kg) at Week 0, followed by single subcutaneous (SC) maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Reporting group title	LTE Period: Ustekinumab 9 mg/kg or 390mg then 2 mg/kg or 90mg

Reporting group description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) every 8 weeks (Q8W) from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Reporting group title	LTE Period: Ustekinumab 3 mg/kg or 130mg then 2 mg/kg or 90mg

Reporting group description:

After completion of DB period (prior to Week 16 SC dose), subjects received single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) every 8 weeks (Q8W) from Week 16 up to Week 268 or upon availability of Study CNTO1275ISD3001 or completed 20 weeks safety follow-up post last dose or terminated study participation, whichever occurred first.

Reporting group title	DB Period: Ustekinumab 9mg/kg or 390mg +2mg/kg or 90mg

Reporting group description:

Subjects received single IV ustekinumab induction dose of 9 mg/kg (for BW <40 kg) or 390 mg (for BW >=40 kg) at Week 0, followed by single SC maintenance dose of ustekinumab 2 mg/kg (for BW <40 kg) or 90 mg (for BW >=40 kg) at Week 8 in the DB period. The duration of DB period was up to prior SC dose administration at Week 16.

Serious adverse events	DB Period: Ustekinumab 3mg/kg or 130mg +2mg/kg or 90mg	LTE Period: Ustekinumab 9 mg/kg or 390mg then 2 mg/kg or 90mg	LTE Period: Ustekinumab 3 mg/kg or 130mg then 2 mg/kg or 90mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 23 (26.09%)	4 / 16 (25.00%)	7 / 18 (38.89%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
General Physical Health Deterioration			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	0 / 18 (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
Pyrexia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	2 / 23 (8.70%)	4 / 16 (25.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	1 / 3	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			

subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	0 / 18 (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
Large Intestinal Stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	0 / 18 (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
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	DB Period: Ustekinumab 9mg/kg or 390mg +2mg/kg or 90mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
General Physical Health Deterioration			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Vision Blurred			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anal Ulcer			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Crohn's Disease			

subjects affected / exposed	1 / 21 (4.76%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal Obstruction				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large Intestinal Stenosis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small Intestinal Obstruction				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Myalgia				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	DB Period: Ustekinumab 3mg/kg or 130mg +2mg/kg or 90mg	LTE Period: Ustekinumab 9 mg/kg or 390mg then 2 mg/kg or 90mg	LTE Period: Ustekinumab 3 mg/kg or 130mg then 2 mg/kg or 90mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 23 (78.26%)	14 / 16 (87.50%)	18 / 18 (100.00%)
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Chest Pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Face Oedema			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	1 / 23 (4.35%)	4 / 16 (25.00%)	3 / 18 (16.67%)
occurrences (all)	1	11	3
Influenza Like Illness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pyrexia			

subjects affected / exposed	3 / 23 (13.04%)	3 / 16 (18.75%)	4 / 18 (22.22%)
occurrences (all)	3	6	4
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Menstrual Discomfort			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	3 / 23 (13.04%)	3 / 16 (18.75%)	4 / 18 (22.22%)
occurrences (all)	3	3	4
Dyspnoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	2
Nasal Congestion			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	2 / 18 (11.11%)
occurrences (all)	1	1	2
Oropharyngeal Pain			
subjects affected / exposed	1 / 23 (4.35%)	2 / 16 (12.50%)	4 / 18 (22.22%)
occurrences (all)	1	2	5
Respiratory Depression			

subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sinus Congestion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Upper Respiratory Tract Congestion			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	3
Insomnia			
subjects affected / exposed	0 / 23 (0.00%)	3 / 16 (18.75%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Mood Altered			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Sleep Disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Investigations			
Blood Bilirubin Increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood Bilirubin Unconjugated Increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood Iron Decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
C-Reactive Protein Increased			

subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Full Blood Count Abnormal			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haemoglobin Decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hepatic Enzyme Abnormal			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Heart Rate Increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Liver Function Test Increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Neutrophil Count Increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	2
Sars-Cov-2 Test Positive			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vitamin D Decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Weight Decreased			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Weight Increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
White Blood Cell Count Increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	2
Injury, poisoning and procedural			

complications			
Ankle Fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Head Injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Joint Injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ligament Sprain			
subjects affected / exposed	2 / 23 (8.70%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	2	1	1
Limb Injury			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Skin Abrasion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Road Traffic Accident			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sunburn			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Spinal Compression Fracture			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nervous system disorders			

Dizziness Postural			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	5 / 23 (21.74%)	5 / 16 (31.25%)	8 / 18 (44.44%)
occurrences (all)	5	15	17
Sciatica			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 23 (26.09%)	0 / 16 (0.00%)	5 / 18 (27.78%)
occurrences (all)	6	0	5
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Microcytic Anaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			

Excessive Cerumen Production			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Eye disorders			
Dry Eye			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eczema Eyelids			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eye Pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypermetropia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Visual Impairment			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Keratitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 23 (0.00%)	4 / 16 (25.00%)	3 / 18 (16.67%)
occurrences (all)	0	5	4
Abdominal Pain Lower			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Anal Fissure			
subjects affected / exposed	2 / 23 (8.70%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Anal Fistula			

subjects affected / exposed	3 / 23 (13.04%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	3	1	5
Crohn's Disease			
subjects affected / exposed	4 / 23 (17.39%)	3 / 16 (18.75%)	8 / 18 (44.44%)
occurrences (all)	4	4	10
Constipation			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Dental Discomfort			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 23 (0.00%)	5 / 16 (31.25%)	1 / 18 (5.56%)
occurrences (all)	0	8	1
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Food Poisoning			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gingival Pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 23 (0.00%)	3 / 16 (18.75%)	3 / 18 (16.67%)
occurrences (all)	0	9	5
Large Intestinal Stenosis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Mucous Stools			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Nausea			

subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	2 / 18 (11.11%)
occurrences (all)	0	3	2
Periodontal Inflammation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tooth Impacted			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Toothache			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 23 (8.70%)	2 / 16 (12.50%)	5 / 18 (27.78%)
occurrences (all)	2	2	7
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	2 / 18 (11.11%)
occurrences (all)	0	6	2
Dry Skin			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Eczema			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Dyshidrotic Eczema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 23 (0.00%)	3 / 16 (18.75%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Hyperhidrosis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1

Photosensitivity Reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Neurodermatitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Psoriasis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Seborrhoeic Dermatitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Skin Mass			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin Striae			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Urticaria			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 23 (4.35%)	4 / 16 (25.00%)	1 / 18 (5.56%)
occurrences (all)	1	7	1
Back Pain			
subjects affected / exposed	0 / 23 (0.00%)	3 / 16 (18.75%)	2 / 18 (11.11%)
occurrences (all)	0	5	2
Arthritis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Chronic Recurrent Multifocal Osteomyelitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Joint Stiffness			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Neck Pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Osteitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pain in Extremity			
subjects affected / exposed	1 / 23 (4.35%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	2	2	1
Pain in Jaw			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sacral Pain			

subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Infections and infestations			
Body Tinea			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Anal Abscess			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Bronchitis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	1	1	4
Clostridium Difficile Infection			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Conjunctivitis			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Ear Infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Eczema Infected			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Gastroenteritis Viral			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Helicobacter Gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 23 (0.00%)	2 / 16 (12.50%)	2 / 18 (11.11%)
occurrences (all)	0	2	2

Localised Infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	2
Nasopharyngitis			
subjects affected / exposed	2 / 23 (8.70%)	5 / 16 (31.25%)	6 / 18 (33.33%)
occurrences (all)	2	8	12
Osteomyelitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Otitis Media			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Paronychia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 23 (4.35%)	3 / 16 (18.75%)	2 / 18 (11.11%)
occurrences (all)	1	3	2
Parotitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Sinusitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Staphylococcal Infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Tracheitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 23 (8.70%)	2 / 16 (12.50%)	8 / 18 (44.44%)
occurrences (all)	2	8	12
Urinary Tract Infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Viral Infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 23 (4.35%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 23 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypoproteinaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Iron Deficiency			
subjects affected / exposed	1 / 23 (4.35%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2

Non-serious adverse events	DB Period: Ustekinumab 9mg/kg or 390mg +2mg/kg or 90mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 21 (57.14%)		

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Chest Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Face Oedema			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	2		
Fatigue			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	4		
Influenza Like Illness			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	2		
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		

Menstrual Discomfort			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Nasal Congestion			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Respiratory Depression			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Sinus Congestion			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Congestion			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Mood Altered			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Sleep Disorder			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Investigations			
Blood Bilirubin Increased			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Blood Bilirubin Unconjugated Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Blood Iron Decreased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
C-Reactive Protein Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Full Blood Count Abnormal			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Haemoglobin Decreased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Hepatic Enzyme Abnormal			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Heart Rate Increased			

subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Liver Function Test Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Neutrophil Count Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Sars-Cov-2 Test Positive			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Vitamin D Decreased			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Weight Decreased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Weight Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
White Blood Cell Count Increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Ankle Fracture			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Concussion			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Head Injury			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Joint Injury			

subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Ligament Sprain			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Limb Injury			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Skin Abrasion			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Road Traffic Accident			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Spinal Compression Fracture			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	7		
Sciatica			

subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Microcytic Anaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Excessive Cerumen Production			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry Eye			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Eczema Eyelids			

subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Eye Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Hypermetropia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Visual Impairment			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Keratitis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Abdominal Pain Lower			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Anal Fissure			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Anal Fistula			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Crohn's Disease			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		
Constipation			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Dental Discomfort			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		

Diarrhoea				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Diarrhoea Haemorrhagic				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Food Poisoning				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Gastrooesophageal Reflux Disease				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Gingival Pain				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Large Intestinal Stenosis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Mucous Stools				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	2 / 21 (9.52%)			
occurrences (all)	2			
Periodontal Inflammation				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Tooth Impacted				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Toothache				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			

Vomiting			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Dry Skin			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Dyshidrotic Eczema			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Photosensitivity Reaction			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Neurodermatitis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Psoriasis			

subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Seborrhoeic Dermatitis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Skin Mass			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Skin Striae			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Arthritis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Chronic Recurrent Multifocal Osteomyelitis			

subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Joint Stiffness			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Musculoskeletal Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Neck Pain			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Osteitis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Pain in Extremity			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Pain in Jaw			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Sacral Pain			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Body Tinea			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Anal Abscess			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		

Clostridium Difficile Infection				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Conjunctivitis				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Ear Infection				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Eczema Infected				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Gastroenteritis Viral				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Helicobacter Gastritis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Localised Infection				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Osteomyelitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Otitis Media				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			

Paronychia				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Parotitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Staphylococcal Infection				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Upper Respiratory Tract Infection				
subjects affected / exposed	2 / 21 (9.52%)			
occurrences (all)	2			
Urinary Tract Infection				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences (all)	0			
Viral Infection				
subjects affected / exposed	1 / 21 (4.76%)			
occurrences (all)	1			
Viral Upper Respiratory Tract Infection				

subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Hypoproteinaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Iron Deficiency			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 August 2017	This amendment was implemented to include individual stopping criteria for drug-induced liver injury; addition of these criteria is a regulatory authority request.
11 March 2021	This amendment was implemented to include language for the long-extension basket study (CNTO1275ISD3001) portion of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported