Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind Placebo-controlled Study Evaluating the Efficacy and Safety of CNTO 1959 (Guselkumab) Delivered via a SelfDose Device in the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis

Summary

EudraCT number	2016-002022-37
Trial protocol	PL
Global end of trial date	07 February 2018

Results information

Result version number	v1 (current)
This version publication date	09 January 2019
First version publication date	09 January 2019

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO3006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02905331
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	1000 U.S. 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)	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	07 February 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy of guselkumab delivered using the SelfDose device for the treatment of subjects with moderate to severe plaque-type psoriasis and to assess the safety and tolerability of guselkumab delivered using the SelfDose device in subjects with moderate to severe plaque-type psoriasis.

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. The safety assessments included included adverse events (AEs), including injection site and allergic reactions, clinical laboratory tests (hematology, serum chemistry panel, lipid panel), physical examinations, vital signs (pulse rate, blood pressure), electronic columbia-suicide severity rating scale (eC-SSRS) questionnaires, concomitant medication review, early detection of tuberculosis (TB).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 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	Canada: 24
Country: Number of subjects enrolled	Poland: 25
Country: Number of subjects enrolled	United States: 29
Worldwide total number of subjects	78
EEA total number of subjects	25

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)	72
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 85 subjects were screened, of which 78 were enrolled and treated (62 subjects in the guselkumab group and 16 subjects in the placebo group).

Period 1

Period 1 title	Placebo Controlled Period(Week[wk] 0-16)
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	Placebo

Arm description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at weeks 0, 4, and 12 during placebo-controlled period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received placebo SC injection at Weeks 0, 4, and 12.

Arm title	Guselkumab

Arm description:

Subjects received guselkumab 100 mg SC injection at weeks 0, 4 and 12.

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

Dosage and administration details:

Subjects received guselkumab 100 mg injection at weeks 0, 4, and 12.

Number of subjects in period 1	Placebo	Guselkumab
Started	16	62
Completed	13	61
Not completed	3	1
Adverse event, non-fatal	1	-
Lost to follow-up	-	1
Lack of efficacy	2	-

Period 2

Period 2 title	Active Treatment and Follow up (wk16-40)
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	Placebo to Guselkumab

Arm description:

Subjects who received placebo up to Week 12 during placebo controlled period were then crossed over at Week 16 to receive guselkumab 100 mg SC injection at weeks 16, 20 and 28.

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

Dosage and administration details:

Subjects who received placebo up to Week 12 during placebo controlled period were crossed over at Week 16 to receive guselkumab 100 mg SC injection at weeks 16, 20 and 28.

Arm title	Guselkumab

Arm description:

Subjects received guselkumab 100 mg SC injection at weeks 20 and 28. Subjects received placebo at Week 16 to maintain the study blind.

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

Dosage and administration details:

Subjects received placebo matched with guselkumab 100 mg SC injection at Week 16 to maintain the study blind.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received guselkumab 100 mg SC injection at weeks 20 and 28.

Number of subjects in period 2	Placebo to Guselkumab	Guselkumab
Started	13	61
Completed	13	53
Not completed	0	8
Consent withdrawn by subject	-	2
Unspecified	-	6

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to guselkumab subcutaneous (SC) injection at weeks 0, 4, and 12 during placebo-controlled period.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects received guselkumab 100 mg SC injection at weeks 0, 4 and 12.	

Reporting group values	Placebo	Guselkumab	Total
Number of subjects	16	62	78
Title for AgeCategorical			
Units: subjects			
Adults (18-64 years)	14	58	72
From 65 to 84 years	2	4	6
Title for AgeContinuous			
Units: years			
arithmetic mean	45.4	46.2	
standard deviation	± 15.7	± 12.92	-
Title for Gender			
Units: subjects			
Female	4	21	25
Male	12	41	53

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to guselkumab subcutaneous (SC) injection at weeks 0, 4, and 12 during placebo-controlled period.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects received guselkumab 100 mg SC injection at weeks 0, 4 and 12.	
Reporting group title	Placebo to Guselkumab
Reporting group description:	
Subjects who received placebo up to Week 12 during placebo controlled period were then crossed over at Week 16 to receive guselkumab 100 mg SC injection at weeks 16, 20 and 28.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects received guselkumab 100 mg SC injection at weeks 20 and 28. Subjects received placebo at Week 16 to maintain the study blind.	

Primary: Percentage of Subjects who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

End point title	Percentage of Subjects who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16
End point description:	
The IGA documents the investigator's assessment of subjects psoriasis at given time point. Overall lesions graded for induration, erythema, and scaling. Subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Subjects who achieved IGA score of cleared (0) or minimal (1) were considered IGA cleared or minimal responders. Non-responder imputation was applied for subjects who met treatment failure rules, as well as for remaining missing data after treatment failure. Subjects who discontinued study drug due to lack of efficacy, an adverse event (AE) of worsening of psoriasis, or who started protocol-prohibited medication during study that could improve psoriasis were considered as treatment failures for study. Full analysis set (FAS) included all randomized subjects who received at least 1 study drug injection. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they actually received.	
End point type	Primary
End point timeframe:	
Week 16	

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)	0	80.6		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact

Primary: Percentage of Subjects who Achieved a Psoriasis Area and Severity Index (PASI) 90 Response at Week 16

End point title	Percentage of Subjects who Achieved a Psoriasis Area and Severity Index (PASI) 90 Response at Week 16

End point description:

PASI used for assessing, grading severity of psoriatic lesions, their response to therapy. PASI, body divided into 4 regions: head, trunk, upper, lower extremities. Each area was assessed separately for percentage(%) of area involved, which translates to numeric score ranges from 0 (no involvement) to 6 (90 to 100% involvement) and for erythema, induration, scaling, each are rated on a scale of 0 (none) to 4 (severe). PASI produces numeric score ranges from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 represents subjects who achieved at least 90% improvement from baseline in PASI score. Non-responder imputation was applied for subjects who met treatment failure rules, also for remaining missing data after treatment failure. FAS: all randomized subjects received at least 1 study drug injection. Subjects analyzed as per assigned treatment to which they were randomized, regardless treatment received.

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)	0	75.8		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact

Secondary: Percentage of Subjects who Achieve an IGA Score of Cleared (0) at Week 16

End point title	Percentage of Subjects who Achieve an IGA Score of Cleared (0) at Week 16

End point description:

The IGA documents the investigator's assessment of subjects psoriasis at given time point. Overall lesions graded for induration, erythema, and scaling. Subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Subjects who achieved an IGA score of cleared (0) were considered IGA cleared responders. Non-responder imputation was applied for subjects who met treatment failure rules, as well as for remaining missing data after treatment failure. FAS included all randomized subjects who received at least 1 study drug injection. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they actually received.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)	0	56.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieve a PASI 100 Response at Week 16

End point title	Percentage of Subjects who Achieve a PASI 100 Response at Week 16

End point description:

The PASI assessing, grading severity of psoriatic lesions, their response to therapy. In PASI, the body divided into 4 regions: head, trunk, upper extremities, and lower extremities. Each area was assessed separately % of area involved, which translates to numeric score that ranges from 0(no involvement) to 6(90 to 100% involvement) and for erythema, induration, scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. Higher score indicates more severe disease. Subjects with 100% improvement in PASI from baseline (PASI score=0) were considered PASI 100 responders. Non-responder imputation was applied for subjects who met treatment failure rules, as well as for remaining missing data after treatment failure. FAS: all randomized subjects who received at least 1 study drug injection. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they actually received.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)	0	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved an IGA Score of Mild or Better (less than or equal to [<=] 2) at Week 16

End point title	Percentage of Subjects who Achieved an IGA Score of Mild or Better (less than or equal to [<=] 2) at Week 16

End point description:

The IGA documents the investigator's assessment of subjects psoriasis at given time point. Overall lesions graded for induration, erythema, and scaling. Subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Subjects who achieved IGA score of cleared (0), minimal (1) or mild (2) were considered IGA mild or better responders. Non-responder imputation was applied for subjects who met treatment failure rules, as well as for remaining missing data after treatment failure. FAS included all randomized subjects who received at least 1 study drug injection. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they actually received.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)	0	93.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieve a PASI 50 Response and a PASI 75 Response at Week 16

End point title	Percentage of Subjects who Achieve a PASI 50 Response and a PASI 75 Response at Week 16

End point description:

PASI used for assessing, grading severity of psoriatic lesions, their response to therapy. PASI, the body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area was assessed separately for % of area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 to 100% involvement), for erythema, induration, scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. Higher

score indicates more severe disease. Subjects with >=50% and >= 75% improvement in PASI from baseline were considered PASI 50, PASI 75 responders. Non-responder imputation was applied for subjects who met treatment failure rules, also for remaining missing data after treatment failure. FAS: all randomized subjects who received at least 1 study drug injection. Subjects were analyzed as per assigned treatment to which they were randomized, regardless of treatment received.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)				
PASI 50 responders	0	93.5		
PASI 75 responders	0	88.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement From Baseline in PASI Score at Week 16

End point title	Percent Improvement From Baseline in PASI Score at Week 16

End point description:

Percent Improvement defined as improvement in PASI from baseline. PASI used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI, body divided into 4 regions:head,trunk,upper extremities,lower extremities. Each area was assessed separately for % of area involved which translates to numeric score ranges from 0(indicates no involvement) to 6(90 to 100% involvement), and for erythema, induration, and scaling, which are each rated on scale of 0 to 4. PASI produces numeric score ranges from 0(no psoriasis) to 72. Higher score shows more severe disease. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they received. FAS:all randomized subjects who received at least 1 study drug injection. 'N'(number of subjects analyzed):number of subjects evaluable for this outcome measure. Imputation was applied only for subjects who met treatment failure and their percent improvement was imputed as 0.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	61		
Units: Percent improvement				
arithmetic mean (standard deviation)	8.72 (± 18.229)	91.53 (± 16.756)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement From Baseline in PASI Score Through Week 40

End point title	Percent Improvement From Baseline in PASI Score Through Week 40

End point description:

Percent Improvement defined as improvement in PASI from baseline. PASI used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI, body divided into 4 regions:head,trunk,upper extremities,lower extremities. Each area was assessed separately for % of area involved which translates to numeric score ranges from 0(indicates no involvement) to 6(90 to 100% involvement), and for erythema, induration, and scaling, which are each rated on scale of 0 to 4. PASI produces numeric score ranges from 0(no psoriasis) to 72. Higher score shows more severe disease. Subjects were analyzed according to assigned treatment to which they were randomized, regardless of treatment they received. FAS:all randomized subjects who received at least 1 study drug injection. Here n is number of subjects who were analyzed at specific timepoint. Imputation was applied only for subjects who met treatment failure and their percent improvement was imputed as 0.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 12, 20, 24, 28, 32, and Week 40 (4 weeks beyond the recommended every 8 weeks [q8w] dosing interval)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percent improvement				
arithmetic mean (standard deviation)				
Week 4 (n=16,62)	5.58 (± 13.970)	40.99 (± 26.377)		
Week 8 (n=16,62)	10.45 (± 21.540)	71.76 (± 26.984)		
Week 12 (n=16,61)	13.76 (± 24.143)	84.97 (± 20.520)		
Week 20 (n=13,61)	62.65 (± 20.760)	94.77 (± 13.179)		
Week 24 (n=13,59)	88.74 (± 12.092)	95.89 (± 10.164)		
Week 28 (n=13,60)	95.68 (± 6.162)	96.30 (± 7.504)		
Week 32 (n=13,58)	96.16 (± 5.602)	96.64 (± 7.143)		
Week 40 (n=13,55)	97.70 (± 3.443)	92.47 (± 13.289)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved an IGA Score of cleared (0), cleared (0) or minimal (1) and mild or better (<=2) Through Week 40

End point title	Percentage of Subjects who Achieved an IGA Score of cleared (0), cleared (0) or minimal (1) and mild or better (<=2) Through Week 40

End point description:

IGA documents investigator's assessment of subjects psoriasis at given time point. Overall lesions graded for induration, erythema, scaling. Subject's psoriasis was assessed as cleared(0), minimal(1), mild(2), moderate(3), or severe(4). Subjects who achieved IGA score of cleared(0) were considered IGA cleared responders. Those who achieved IGA score of cleared(0) or minimal(1) were considered IGA cleared or minimal responders while those achieved IGA score of cleared(0), minimal(1), or mild(2) were considered IGA mild or better responders. Subjects were analyzed as per assigned treatment to which they were randomized, regardless of treatment they received. From week 20, subjects in placebo group, only included subjects who crossed over to receive guselkumab at week 16. It included FAS. n (number analyzed) signify number of subjects who were analyzed at specific timepoint. Non-responder imputation was used to impute missing data or after subjects who met treatment failure criteria.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 20, 24, 28, 32, and Week 40 (4 weeks beyond the recommended q8w dosing interval)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)				
Week 4: IGA of cleared(0) (n=16,62)	0	4.8		
Week 4: IGA of cleared(0) or minimal(1) (n=16,62)	0	19.4		
Week 4: IGA of mild or better (<=2) (n=16,62)	0	54.8		
Week 8: IGA of cleared(0) (n=16,62)	0	19.4		
Week 8: IGA of cleared(0) or minimal(1) (n=16,62)	0	56.5		
Week 8: IGA of mild or better (<=2) (n=16,62)	12.5	85.5		
Week 12: IGA of cleared(0) (n=16,62)	0	35.5		
Week 12: IGA of cleared(0) or minimal(1) (n=16,62)	0	67.7		
Week 12: IGA of mild or better (<=2) (n=16,62)	0	91.9		
Week 20: IGA of cleared(0) (n=13,62)	0	67.7		
Week 20: IGA of cleared(0) or minimal(1) (n=13,62)	46.2	85.5		
Week 20: IGA of mild or better (<=2) (n=13,62)	92.3	93.5		
Week 24: IGA of cleared(0) (n=13,62)	38.5	71.0		
Week 24: IGA of cleared(0) or minimal(1) (n=13,62)	100.0	87.1		
Week 24: IGA of mild or better (<=2) (n=13,62)	100.0	88.7		
Week 28: IGA of cleared(0) (n=13,62)	61.5	64.5		

Week 28: IGA of cleared(0) or minimal(1) (n=13,62)	100.0	87.1		
Week 28: IGA of mild or better (<=2) (n=13,62)	100.0	95.2		
Week 32: IGA of cleared(0) (n=13,62)	69.2	66.1		
Week 32: IGA of cleared(0) or minimal(1) (n=13,62)	92.3	82.3		
Week 32: IGA of mild or better (<=2) (n=13,62)	100.0	100.0		
Week 40: IGA of cleared(0) (n=13,62)	61.5	53.2		
Week 40: IGA of cleared(0) or minimal(1) (n=13,62)	92.3	71.0		
Week 40:IGA of mild or better (<=2) (n=13,62)	100.0	79.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved PASI 100 responses, PASI 90 responses, PASI 75 responses, and PASI 50 responses

End point title	Percentage of Subjects who Achieved PASI 100 responses, PASI 90 responses, PASI 75 responses, and PASI 50 responses

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. PASI produces numeric score that can range from 0 (no psoriasis) to 72. Higher score indicates more severe disease. Subjects with 100% improvement in PASI from baseline(PASI score=0) was considered PASI 100 responders. Subjects with >=90%, >=75%, >=50% improvement in PASI from baseline were considered PASI 90, PASI 75, PASI 50 responders. Non-responder imputation was applied for subjects who met treatment failure rules, also for remaining missing data after treatment failure. FAS:all randomized subjects who received at least 1 study drug injection. Subjects were analyzed as per assigned treatment to which they were randomized, regardless of treatment received. Here, n(number analyzed) signifies number of subjects who were analyzed at specific timepoint, for each arm. Non-responder imputation was used to impute missing data or after subjects who met treatment failure criteria.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 20, 24, 28, 32, and Week 40 (4 weeks beyond the recommended q8w dosing interval)

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	62		
Units: Percentage of subjects				
number (not applicable)				
Week 4: 100% improvement (n=16,62)	0	3.2		
Week 4: >= 90% improvement (n=16,62)	0	4.8		
Week 4: >= 75% improvement (n=16,62)	0	12.9		
Week 4: >= 50% improvement (n=16,62)	0	33.9		
Week 8: 100% improvement (n=16,62)	0	16.1		

Week 8: >= 90% improvement (n=16,62)	0	33.9		
Week 8: >= 75% improvement (n=16,62)	0	56.5		
Week 8: >= 50% improvement (n=16,62)	6.3	80.6		
Week 12: 100% improvement (n=16,62)	0	30.6		
Week 12: >= 90% improvement (n=16,62)	0	54.8		
Week 12: >= 75% improvement (n=16,62)	0	77.4		
Week 12: >= 50% improvement (n=16,62)	12.5	90.3		
Week 16: 100% improvement (n=16,62)	0	50.0		
Week 16: >=90% improvement (n=16,62)	0	75.8		
Week 16: >=75% improvement (n=16,62)	0	88.7		
Week 16: >=50% improvement (n=16,62)	0	93.5		
Week 20: 100% improvement (n=13,62)	0	66.1		
Week 20: >=90% improvement (n=13,62)	7.7	85.5		
Week 20: >=75% improvement (n=13,62)	30.8	91.9		
Week 20: >=50% improvement (n=13,62)	69.2	95.2		
Week 24: 100% improvement (n=13,62)	30.8	71.0		
Week 24: >=90% improvement (n=13,62)	61.5	82.3		
Week 24: >=75% improvement (n=13,62)	84.6	88.7		
Week 24: >=50% improvement (n=13,62)	100.0	95.2		
Week 28: 100% improvement (n=13,62)	53.8	64.5		
Week 28: >=90% improvement (n=13,62)	84.6	85.5		
Week 28: >=75% improvement (n=13,62)	100.0	95.2		
Week 28: >50% improvement (n=13,62)	100.0	96.8		
Week 32: 100% improvement (n=13,62)	61.5	64.5		
Week 32: >=90% improvement (n=13,62)	84.6	85.5		
Week 32: >=75% improvement (n=13,62)	100.0	90.3		
Week 32: >=50% improvement (n=13,62)	100.0	93.5		
Week 40: 100% improvement (n=13,62)	53.8	53.2		
Week 40: >=90% improvement (n=13,62)	100.0	66.1		
Week 40: >=75% improvement (n=13,62)	100.0	79.0		
Week 40: >=50% improvement (n=13,62)	100.0	79.0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to Week 40	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	Placebo (Week 0-16)
Reporting group description: Subjects received placebo matched to guselkumab subcutaneous (SC) injection at weeks 0, 4, and 12 during placebo-controlled period.	
Reporting group title	Guselkumab (Week 0-16)
Reporting group description: Subjects received guselkumab 100 mg SC injection at weeks 0, 4, and 12.	
Reporting group title	Placebo to Guselkumab (Week 16-40)
Reporting group description: Subjects who received placebo during placebo controlled period was crossed over to receive guselkumab 100 mg SC injection at weeks 16, 20 and 28.	
Reporting group title	Guselkumab (Week 16-40)
Reporting group description: Subjects received placebo at Week 16, and 100 mg guselkumab at Week 20 and 28.	

Serious adverse events	Placebo (Week 0-16)	Guselkumab (Week 0-16)	Placebo to Guselkumab (Week 16-40)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	2 / 62 (3.23%)	2 / 13 (15.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
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			
Chest Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 62 (1.61%)	0 / 13 (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

Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 62 (1.61%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	0 / 13 (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			
Diverticulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
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	Guselkumab (Week 16-40)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 61 (1.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest Discomfort			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest Pain			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			

Drug Hypersensitivity			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo (Week 0-16)	Guselkumab (Week 0-16)	Placebo to Guselkumab (Week 16-40)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 16 (75.00%)	38 / 62 (61.29%)	8 / 13 (61.54%)
Investigations			
Hepatic Enzyme Increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Cardiac disorders			
Left Ventricular Hypertrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Injection Site Bruising			
subjects affected / exposed	1 / 16 (6.25%)	2 / 62 (3.23%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Injection Site Coldness			

subjects affected / exposed	3 / 16 (18.75%)	14 / 62 (22.58%)	2 / 13 (15.38%)
occurrences (all)	3	21	2
Injection Site Erythema			
subjects affected / exposed	1 / 16 (6.25%)	7 / 62 (11.29%)	0 / 13 (0.00%)
occurrences (all)	1	12	0
Injection Site Induration			
subjects affected / exposed	2 / 16 (12.50%)	7 / 62 (11.29%)	1 / 13 (7.69%)
occurrences (all)	3	8	1
Injection Site Oedema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Injection Site Pain			
subjects affected / exposed	7 / 16 (43.75%)	25 / 62 (40.32%)	3 / 13 (23.08%)
occurrences (all)	12	50	4
Injection Site Pruritus			
subjects affected / exposed	2 / 16 (12.50%)	8 / 62 (12.90%)	1 / 13 (7.69%)
occurrences (all)	2	9	1
Injection Site Swelling			
subjects affected / exposed	1 / 16 (6.25%)	7 / 62 (11.29%)	1 / 13 (7.69%)
occurrences (all)	1	9	1
Gastrointestinal disorders			
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Postmenopausal Haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Vaginal Cyst			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Productive Cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			

Urticaria Pressure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 16 (6.25%)	1 / 62 (1.61%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Psoriatic Arthropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Furuncle			
subjects affected / exposed	0 / 16 (0.00%)	0 / 62 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Tooth Abscess			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Tooth Infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 62 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	5 / 62 (8.06%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	3 / 62 (4.84%)	1 / 13 (7.69%)
occurrences (all)	0	3	1

Non-serious adverse events	Guselkumab (Week 16-40)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 61 (39.34%)		
Investigations			
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Left Ventricular Hypertrophy			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
General disorders and administration site conditions			
Injection Site Bruising			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Injection Site Coldness			
subjects affected / exposed	7 / 61 (11.48%)		
occurrences (all)	7		
Injection Site Erythema			
subjects affected / exposed	4 / 61 (6.56%)		
occurrences (all)	4		
Injection Site Induration			
subjects affected / exposed	2 / 61 (3.28%)		
occurrences (all)	2		
Injection Site Oedema			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Injection Site Pain			

subjects affected / exposed occurrences (all) Injection Site Pruritus subjects affected / exposed occurrences (all) Injection Site Swelling subjects affected / exposed occurrences (all)	11 / 61 (18.03%) 14 2 / 61 (3.28%) 2 3 / 61 (4.92%) 3		
Gastrointestinal disorders Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	 0 / 61 (0.00%) 0		
Reproductive system and breast disorders Postmenopausal Haemorrhage subjects affected / exposed occurrences (all) Vaginal Cyst subjects affected / exposed occurrences (all)	 0 / 61 (0.00%) 0 0 / 61 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Productive Cough subjects affected / exposed occurrences (all)	 0 / 61 (0.00%) 0		
Skin and subcutaneous tissue disorders Urticaria Pressure subjects affected / exposed occurrences (all)	 0 / 61 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Insomnia	 0 / 61 (0.00%) 0 0 / 61 (0.00%) 0		

subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Psoriatic Arthropathy			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Furuncle			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Tooth Abscess			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Tooth Infection			
subjects affected / exposed	2 / 61 (3.28%)		
occurrences (all)	2		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 61 (9.84%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 November 2016	The overall reason for the amendment is to include the following major changes: 1) The electronic Columbia-Suicide Severity Rating Scale (eC-SSRS) assessment was added to the protocol as requested by the US Food and Drug Administration (FDA). 2) Clarification was added that all shampoos used to treat psoriasis must be included in the list of all therapies, other than the study drug, that must be recorded in the subject electronic case report form (eCRF). 3) An exclusion criterion was modified to allow subjects who have completed antiviral treatment for hepatitis C virus to participate.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported