Clinical trial results:
A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Active Psoriatic Arthritis

Summary

EudraCT number	2014-003697-17
Trial protocol	DE ES RO
Global end of trial date	17 January 2017

Results information

Result version number	v1 (current)
This version publication date	21 February 2018
First version publication date	21 February 2018

Trial information

Trial identification

Sponsor protocol code	CR105964

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02319759
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International N.V.
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, 2340
Public contact	Clinical Registry Group, Janssen-Cilag International N.V., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International N.V., 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	17 January 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this study were to evaluate the efficacy of guselkumab in subjects with active psoriatic arthritis (PsA) by assessing the reduction in signs and symptoms of PsA and to assess the safety and tolerability of guselkumab in subjects with active PsA.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki that are consistent with Good Clinical Practices and applicable regulatory requirements. The study protocol and amendment were reviewed by an Independent Ethics Committee (IEC) and Institutional Review Board (IRB). Subjects or their legally acceptable representatives provided their written consent to participate in the study after having been informed about the nature and purpose of the study, participation/termination conditions, and risks and benefits of treatment. Safety was evaluated throughout the study and included adverse events (AEs), including injection-site and allergic reactions, clinical laboratory tests, vital signs, physical examinations, concomitant medication review and early detection of active tuberculosis (TB). An independent data monitoring committee was commissioned for this study to review unblinded data at regularly scheduled intervals.

Background therapy:

Stable dose of methotrexate [less than or equal to (<=) 25 milligram per week (mg/week)], oral corticosteroids [<=10 milligram (mg) of prednisone/day or equivalent], or nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics were permitted but not required.

Evidence for comparator: -

Actual start date of recruitment	27 March 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Poland: 25
Country: Number of subjects enrolled	Romania: 5
Country: Number of subjects enrolled	Russian Federation: 89
Country: Number of subjects enrolled	United States: 11
Worldwide total number of subjects	149
EEA total number of subjects	43

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)	136
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

251 were screened; 149 were randomized into placebo (n=49) and guselkumab (n=100) treatment groups. Eligible Subjects had PsA for at least 6 months who met ClASsification criteria for Psoriatic Arthritis (CASPAR) criteria, >= 3 swollen and 3 tender joints,with C-reactive protein (CRP) level of >= 0.3 mg/dL, and >=3% body surface area of psoriasis.

Period 1

Period 1 title	W0 - W16: placebo-controlled
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were randomized to receive subcutaneous (SC) injection of placebo for guselkumab at Weeks (W) 0, 4, 12, and 20, and guselkumab 100 mg at Weeks 24, 28, 36, and 44. Subjects who met the early escape (EE) criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the psoriatic arthritis (PsA) indication.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo at Weeks 0, 4, 12, and 20.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	CNTO1275
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Early escaped subjects received ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects in the placebo group crossed over and received 100 mg guselkumab at Weeks 24, 28, 36, and 44.

Arm title	Guselkumab

Arm description:

Subjects were randomized to receive SC injection of guselkumab 100 milligram (mg) at Weeks 0, 4, 12,

20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 100 mg guselkumab at Weeks 0, 4, 12, 20, 28, 36, and 44.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	CNTO1275
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Early escaped subjects received ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo at Weeks 24 for maintaining the blind.

Number of subjects in period 1	Placebo	Guselkumab
Started	49	100
Subjects Early escaped (EE) at Week 16	17 [1]	10 [2]
Completed	48	99
Not completed	1	1
unspecified	-	1
Lack of efficacy	1	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 17 subjects who early escaped from placebo to ustekinumab at Week 16 were considered as completers at Week 16.
[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 10 subjects who early escaped from guselkumab to ustekinumab at Week 16 were considered as completers at Week 16.

Period 2

Period 2 title	W16 - W24: placebo-controlled
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were randomized to receive SC injection of placebo at Weeks 0, 4, 12, and 20, and guselkumab 100 mg at Weeks 24, 28, 36, and 44. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo at Weeks 0, 4, 12, and 20.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	CNTO1275
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Early escaped subjects received ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects in the placebo group crossed over and received 100 mg guselkumab at Weeks 24, 28, 36, and 44.

Arm title	Guselkumab

Arm description:

Subjects were randomized to receive SC injection of guselkumab 100 mg at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 100 mg guselkumab at Weeks 0, 4, 12, 20, 28, 36, and 44.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo at Weeks 24 for maintaining the blind.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	CNTO1275
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Early escaped subjects received ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Number of subjects in period 2[3]	Placebo	Guselkumab
Started	31	89
Subjects EE to Ustekinumab at W16	17 [4]	10 [5]
Cross-over to/continue Guselkumab at W24	29	86
Completed	29	86
Not completed	2	3
Consent withdrawn by subject	-	2
Lost to follow-up	1	-
Lack of efficacy	1	1

Notes:

[3] - 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: Subjects who early escaped at Week 16 were included in the completers in the preceding period but were not included in the number of subjects starting this period.
[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 17 subjects who early escaped from placebo to ustekinumab at Week 16 were counted in the previous period, but not in this period.
[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: 10 subjects who early escaped from guselkumab to ustekinumab at Week 16 were counted in the previous period, but not counted in this period.

Period 3

Period 3 title	W24 - W56: Active Treatment & Follow-up
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Crossover (Placebo to Guselkumab)

Arm description:

Subjects remained in the placebo group at Week 24 crossed over to receive guselkumab at at Weeks 24, 28, 36, and 44.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects remaining in the placebo group at Week 24 crossed over to receive guselkumab 100 mg at Weeks 24, 28, 36 and 44.

Arm title	Guselkumab

Arm description:

Subjects were randomized to receive SC injection of guselkumab 100 mg at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	CNTO1959
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 100 mg guselkumab at Weeks 0, 4, 12, 20, 28, 36, and 44.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	CNTO1275
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Early escaped subjects received ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo at Weeks 24 for maintaining the blind.

Number of subjects in period 3	Crossover (Placebo to Guselkumab)	Guselkumab
Started	29	86
Completed	28	84
Not completed	1	2
Consent withdrawn by subject	1	-
Adverse event, non-fatal	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive subcutaneous (SC) injection of placebo for guselkumab at Weeks (W) 0, 4, 12, and 20, and guselkumab 100 mg at Weeks 24, 28, 36, and 44. Subjects who met the early escape (EE) criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the psoriatic arthritis (PsA) indication.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects were randomized to receive SC injection of guselkumab 100 milligram (mg) at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.	

Reporting group values	Placebo	Guselkumab	Total
Number of subjects	49	100	149
Title for AgeCategorical Units: subjects			
Adults (18-64 years)	47	89	136
From 65 to 84 years	2	11	13
Title for AgeContinuous Units: years			
arithmetic mean	44.2	47.4	
standard deviation	± 12.43	± 12.83	-
Title for Gender Units: subjects			
Female	25	48	73
Male	24	52	76
Tender Joints Count TJC (0-68) Units: Units on a scale			
arithmetic mean	20.1	20.7	
standard deviation	± 12.45	± 12.16	-
Swollen Joints Count SJC (0-66) Units: Units on a scale			
arithmetic mean	10.6	11.9	
standard deviation	± 7.51	± 7.60	-
C-Reactive Protein (CRP) Units: Milligram per deciliter (mg/dL)			
median	0.91	0.94	
inter-quartile range (Q1-Q3)	0.4 to 2.0	0.5 to 1.8	-
Psoriatic Area and Severity Index (PASI) score (0-72) Units: Units on a scale			
arithmetic mean	9.88	12.03	
standard deviation	± 7.977	± 10.520	-
Body Surface Area (BSA) Units: Percentage			
arithmetic mean	13.6	17.2	
standard deviation	± 12.53	± 15.57	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive subcutaneous (SC) injection of placebo for guselkumab at Weeks (W) 0, 4, 12, and 20, and guselkumab 100 mg at Weeks 24, 28, 36, and 44. Subjects who met the early escape (EE) criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the psoriatic arthritis (PsA) indication.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects were randomized to receive SC injection of guselkumab 100 milligram (mg) at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive SC injection of placebo at Weeks 0, 4, 12, and 20, and guselkumab 100 mg at Weeks 24, 28, 36, and 44. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects were randomized to receive SC injection of guselkumab 100 mg at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.	
Reporting group title	Crossover (Placebo to Guselkumab)
Reporting group description:	
Subjects remained in the placebo group at Week 24 crossed over to receive guselkumab at at Weeks 24, 28, 36, and 44.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects were randomized to receive SC injection of guselkumab 100 mg at Weeks 0, 4, 12, 20, 28, 36, and 44, and placebo at Week 24. Subjects who met the EE criterion at week 16 switched to open-label therapy with ustekinumab 45 mg or 90 mg at Weeks 16, 20, 32, and 44 based on the approved dosage for the PsA indication.	

Primary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 24

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 24
End point description:	
ACR 20 response is defined as >=20% improvement in TJC(68 joints) and SJC(66 joints) and in 3 of following 5 assessments: Subject’s assessment of pain (VAS) 0-100mm scale, 0=no pain to 100=worst possible pain),Subject’s global assessment of disease activity (VAS)(scale ranges from 0= Excellent to 100= poor), Physician’s global assessment of disease activity (VAS) (scale ranges from 0=no arthritis activity to 100=extremely active arthritis),Subject’s assessment of physical function as measured by HAQ-DI (scale ranges from 0= no difficulty to 3= inability to do task in that area), Serum CRP. Full analysis set (FAS) for efficacy endpoints through Week 24 include all randomized subjects who received at least 1 dose of study drug and analyzed based on their assigned treatment regardless of their actual treatment received. Subjects set to non-responders if they met treatment failure (TF), early escape (EE) criteria at week 16 or had data missing.	
End point type	Primary
End point timeframe:	
Week 24	

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[1]	100[2]		
Units: Percentage of subjects				
number (not applicable)	18.4	58.0		

Notes:

[1] - FAS population

[2] - FAS population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab v Placebo
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	39.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.3
upper limit	54.1

Secondary: Percentage of Subjects who Achieved a Psoriatic Area and Severity Index (PASI) 75 Response at Week 24

End point title	Percentage of Subjects who Achieved a Psoriatic Area and Severity Index (PASI) 75 Response at Week 24

End point description:

A PASI 75 response is defined as >= 75% improvement in PASI score from baseline. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from (0 [best] - 72 [worst]). The combination of redness, scaling, and thickness, as well as overall body involvement determine the PASI score. PASI response through Week 24 is based on the imputed PASI values with last observation carry forward (LOCF) for EE and missing data. Subjects with missing baseline were excluded from the analysis. Here, 'N' number of participants analysed are those who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48[3]	98[4]		
Units: Percentage of subjects				
number (not applicable)	12.5	78.6		

Notes:

[3] - FAS population

[4] - FAS population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	66.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.8
upper limit	78.4

Secondary: Change from Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) Score at Week 24

End point title	Change from Baseline in the Disability Index of the Health Assessment Questionnaire (HAQ-DI) Score at Week 24

End point description:

The HAQ-DI score is an evaluation of the functional status for a subject. The 20- question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range: 0-3 where 0 = least difficulty and 3 = extreme difficulty. Based on the imputed HAQ-DI scores using last observation carry forward for EE and missing data.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[5]	100[6]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline	1.34 (± 0.542)	1.42 (± 0.621)		

Change at Week 24	-0.06 (± 0.530)	-0.42 (± 0.512)		

Notes:

[5] - FAS Population

[6] - FAS Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	LS Mean Difference
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.471
upper limit	-0.148
Variability estimate	Standard error of the mean
Dispersion value	0.082

Secondary: Percentage of Subjects who Achieved an ACR 20 Response at Week 16

End point title	Percentage of Subjects who Achieved an ACR 20 Response at Week 16

End point description:

ACR 20 response is defined as >=20% improvement in TJC(68 joints) and SJC(66 joints) and in 3 of following 5 assessments: Subject's assessment of pain (VAS) 0-100mm scale, 0=no pain to 100=worst possible pain),Subject's global assessment of disease activity (VAS)(scale ranges from 0= Excellent to 100= poor), Physician's global assessment of disease activity (VAS)(scale ranges from 0=no arthritis activity to 100=extremely active arthritis), Subject's assessment of physical function as measured by HAQ-DI (scale ranges from 0-no difficulty to 3-inability to perform a task in that area), and Serum C-reactive protein (CRP). Subjects were set to non-responders if they met TF criteria prior to week 16 or had data missing.

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	49[7]	100[8]		
Units: Percentage of subjects				
number (not applicable)	16.3	60.0		

Notes:
[7] - FAS Population
[8] - FAS population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	43.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.6
upper limit	57.6

Secondary: Percentage of Subjects who Achieved an ACR 50 Response at Week 24	
End point title	Percentage of Subjects who Achieved an ACR 50 Response at Week 24

End point description:

ACR 20 response is defined as >=20% improvement in TJC(68 joints) and SJC(66 joints) and in 3 of following 5 assessments: Subject's assessment of pain (VAS) 0-100mm scale, 0=no pain to 100=worst possible pain),Subject's global assessment of disease activity (VAS)(scale ranges from 0= Excellent to 100= poor), Physician's global assessment of disease activity (VAS)(scale ranges from 0=no arthritis activity to 100=extremely active arthritis), Subject's assessment of physical function as measured by HAQ-DI (scale ranges from 0-no difficulty to 3-inability to perform a task in that area), and Serum C-reactive protein (CRP). Subjects were set to non-responders if they met TF, EE criteria prior to week 16 or had data missing.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[9]	100[10]		
Units: Percentage of Subjects				
number (not applicable)	10.2	34.0		

Notes:
[9] - FAS Population
[10] - FAS Population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	23.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.3
upper limit	36.3

Secondary: Percent (%) Change from Baseline in Enthesitis Scores at Week 24 Among Subjects with Enthesitis at Baseline

End point title	Percent (%) Change from Baseline in Enthesitis Scores at Week 24 Among Subjects with Enthesitis at Baseline

End point description:

Enthesitis were assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in participants with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Here, N 'number of subjects analysed' signifies that those subjects who had enthesitis at baseline and were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31[11]	76[12]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))	-33.33 (-100.0 to 0.0)	-100.00 (-100.0 to -10.0)		

Notes:

[11] - Full Analysis Set with Enthesitis at Baseline

[12] - Full Analysis Set with Enthesitis at Baseline

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab

Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Wilcoxon rank sum test

Secondary: Percent Change from Baseline in Dactylitis Scores at Week 24 Among Subjects with Dactylitis at Baseline

End point title	Percent Change from Baseline in Dactylitis Scores at Week 24 Among Subjects with Dactylitis at Baseline

End point description:

Presence and severity of dactylitis were assessed in both hands and feet using a scoring system from 0 to 3 (0 – no dactylitis, 1 – mild dactylitis, 2 – moderate dactylitis, and 3 – severe dactylitis). The results for each digit were summed to produce a final score. The Dactylitis index ranges from 0 to 60. Higher score indicates more severe dactylitis. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Here, N 'number of subjects analyzed' signifies that those subjects who had Dactylitis at baseline and were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[13]	58[14]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))	-33.33 (-66.7 to 0.0)	-100.00 (-100.00 to -50.0)		

Notes:

[13] - Full Analysis Set with Dactylitis at Baseline

[14] - Full Analysis Set with Dactylitis at Baseline

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon rank sum test

Secondary: Percentage of Subjects who Achieved ACR 20, ACR 50, and ACR 70 Response Through Week 24

End point title	Percentage of Subjects who Achieved ACR 20, ACR 50, and ACR 70 Response Through Week 24

End point description:

ACR 20, 50 and 70 responses were defined as >= 20, 50 and 70 % improvement, respectively, in both TJC (68 joints) and SJC (66 joints) and >= 20, 50 and 70% improvement respectively in 3 of following 5 assessments: Subject's assessment of pain (VAS) 0-100mm scale, 0=no pain to 100=worst possible pain),Subject's global assessment of disease activity (VAS)(scale ranges from 0= Excellent to 100= poor), Physician's global assessment of disease activity (VAS)(scale ranges from 0=no arthritis activity to 100=extremely active arthritis), Subject's assessment of physical function as measured by HAQ-DI (scale ranges from 0-no difficulty to 3-inability to perform a task in that area), and Serum C-reactive protein (CRP). Subjects were set to non-responders if they met TF, EE criteria prior to week 16 or had data missing.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	100		
Units: Percentage of subjects				
number (not applicable)				
Week 4: ACR 20	0	21		
Week 4: ACR 50	0	0.1		
Week 4: ACR 70	0	0		
Week 8: ACR 20	22.4	42.0		
Week 8: ACR 50	6.1	12.0		
Week 8: ACR 70	2.0	4.0		
Week 12: ACR 20	12.2	49.0		
Week 12: ACR 50	6.1	15.0		
Week 12: ACR 70	0	7.0		
Week 16: ACR 50	6.1	30.0		
Week 16: ACR 70	4.1	9.0		
Week 20: ACR 20	22.4	63.0		
Week 20: ACR 50	10.2	37.0		
Week 20: ACR 70	2.0	11.0		
Week 24: ACR 70	2.0	14.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 20, ACR 50, and ACR 70 Response from Week 24 to 56

End point title	Percentage of Subjects who Achieved ACR 20, ACR 50, and ACR 70 Response from Week 24 to 56[15]

End point description:

ACR 20, 50, 70 responses are defined as >=20, 50, 70% improvement, respectively, in TJC(68 joints) and SJC(66 joints) and in 3 of following 5 assessments: Subject's assessment of pain (VAS) 0-100mm scale, 0=no pain to 100=worst possible pain),Subject's global assessment of disease activity (VAS)(scale ranges from 0= Excellent to 100= poor), Physician's global assessment of disease activity (VAS)(scale ranges from 0=no arthritis activity to 100=extremely active arthritis), Subject's assessment of physical function as measured by HAQ-DI (scale ranges from 0= no difficulty to 3= inability to do task

that area), and Serum CRP. Post Week 24 Efficacy Analysis Set (EAS) included all randomized subjects who did not EE to ustekinumab at Week 16 and did not discontinue study treatment prior to or at Week 24. No data imputation rules applied after Week 24. Here 'n' signifies number of subjects analyzed at specific time-points.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 36, 44 and 56

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[16]	86[17]		
Units: Percentage of subjects				
number (not applicable)				
Week 24: ACR 20 (n= 86, 29)	31.0	66.3		
Week 24: ACR 50 (n= 86, 29)	17.2	39.5		
Week 24: ACR 70 (n= 86, 29)	3.4	16.3		
Week 28: ACR 20 (n= 85, 28)	57.1	75.3		
Week 28: ACR 50 (n= 85, 28)	28.6	44.7		
Week 28: ACR 70 (n= 85, 28)	14.3	30.6		
Week 32: ACR 20 (n= 84, 28)	60.7	75.0		
Week 32: ACR 50 (n= 84, 28)	42.9	51.2		
Week 32: ACR 70 (n= 84, 28)	21.4	29.8		
Week 36: ACR 20 (n= 84, 28)	71.4	73.8		
Week 36: ACR 50 (n= 84, 28)	46.4	48.8		
Week 36: ACR 70 (n= 84, 27)	29.6	31.0		
Week 44: ACR 20 (n= 84, 28)	75.0	77.4		
Week 44: ACR 50 (n= 84, 28)	46.4	46.4		
Week 44: ACR 70 (n= 84, 28)	25.0	26.2		
Week 56: ACR 20 (n= 83, 27)	81.5	73.5		
Week 56: ACR 50 (n= 83, 27)	66.7	53.0		
Week 56: ACR 70 (n= 83, 28)	28.6	32.5		

Notes:

[16] - Post Week 24 EAS population

[17] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Selected ACR Components Through Week 24

End point title	Percent Change from Baseline in Selected ACR Components Through Week 24

End point description:

The selected ACR components were: TJC, SJC and CRP. LOCF method was used for missing data and to replace the data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[18]	100[19]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
%Change at Week 4 (SJC)	-18.18 (-41.2 to 0.0)	-28.42 (-60.0 to 0.0)		
%Change at Week 8 (SJC)	-33.33 (-50.0 to 0.0)	-51.47 (-84.7 to -11.1)		
%Change at Week 12 (SJC)	-29.41 (-50.0 to 0.0)	-64.50 (-93.8 to -30.0)		
%Change at Week 16 (SJC)	-16.67 (-66.7 to 7.7)	-71.43 (-100.0 to -33.3)		
%Change at Week 20 (SJC)	-16.67 (-66.7 to 4.3)	-80.00 (-100.0 to -42.2)		
%Change at Week 24 (SJC)	-11.76 (-59.1 to 11.8)	-84.11 (-100.0 to -43.2)		
%Change at Week 4 (TJC)	-10.00 (-30.8 to 7.7)	-17.71 (-42.5 to 0.0)		
%Change at Week 8 (TJC)	-18.75 (-46.8 to 15.4)	-40.59 (-67.9 to -17.3)		
%Change at Week 12 (TJC)	-13.33 (-46.7 to 15.4)	-45.80 (-78.0 to -25.0)		
%Change at Week 16 (TJC)	3.23 (-37.5 to 35.7)	-60.00 (-83.3 to -21.1)		
%Change at Week 20 (TJC)	14.29 (-50.0 to 39.5)	-65.37 (-87.5 to -27.9)		
%Change at Week 24 (TJC)	-5.56 (-53.1 to 30.8)	-70.00 (-89.6 to -23.7)		
%Change at Week 4 (CRP)	-8.35 (-26.3 to 23.3)	-20.13 (-57.1 to 14.1)		
%Change at Week 8 (CRP)	5.24 (-32.7 to 57.3)	-41.08 (-63.7 to 2.0)		
%Change at Week 12 (CRP)	-3.95 (-41.3 to 51.2)	-42.95 (-69.8 to 10.7)		
%Change at Week 16 (CRP)	-1.05 (-40.5 to 52.5)	-44.21 (-72.4 to -1.4)		
%Change at Week 20 (CRP)	7.94 (-33.9 to 53.7)	-52.99 (-74.5 to -12.7)		
%Change at Week 24 (CRP)	7.94 (-30.3 to 93.5)	-42.64 (-77.7 to 2.3)		

Notes:

[18] - FAS Population

[19] - FAS Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in Selected ACR Components from Week 24 to Week 56

End point title	Percent Change from Baseline in Selected ACR Components from Week 24 to Week 56[20]

End point description:

The selected ACR components were TJC, SJC and CRP. Based on observed data in the post Week 24 efficacy analysis population, here 'n' is defined as "number of subjects analyzed'' at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 36, 44 and 56

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[21]	86[22]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
SJC %Change: Week 24 (n= 29, 86)	-33.33 (-80.0 to -11.8)	-85.71 (-100.0 to -63.3)		
SJC % Change: Week 28 (n= 28, 85)	-69.05 (-83.3 to -32.7)	-93.75 (-100.0 to -60.9)		
SJC % Change: Week 32 (n= 28, 84)	-84.91 (-95.8 to -50.0)	-100.00 (-100.00 to -73.9)		
SJC % Change: Week 36 (n= 28, 84)	-79.14 (-100.0 to -57.7)	-93.93 (-100.0 to -66.7)		
SJC % Change: Week 44 (n= 28, 84)	-86.11 (-100.0 to -64.6)	-94.56 (-100.0 to -70.6)		
SJC % Change: Week 56 (n= 27, 83)	-100.00 (-100.00 to -63.6)	-100.00 (-100.00 to -75.0)		
TJC % Change: Week 24 (n=29, 86)	-50.00 (-74.5 to -14.9)	-72.00 (-90.0 to -45.8)		
TJC % Change: Week 28 (n=28, 85)	-65.99 (-83.3 to -17.0)	-74.36 (-91.3 to -50.0)		
TJC % Change: Week 32 (n=28, 84)	-71.76 (-86.1 to -27.7)	-79.66 (-92.3 to -50.0)		
TJC % Change: Week 36 (n=28, 84)	-81.67 (-91.2 to -27.1)	-73.32 (-94.6 to -50.5)		
TJC % Change: Week 44 (n=28, 84)	-86.06 (-93.5 to -50.0)	-77.22 (-97.0 to -49.0)		
TJC % Change: Week 56 (n=27, 83)	-80.00 (-93.8 to -51.2)	-77.27 (-100.0 to -58.8)		
CRP % Change: Week 24 (n= 29, 86)	6.19 (-30.3 to 93.5)	-43.62 (-79.0 to 3.7)		
CRP % Change: Week 28 (n= 28, 84)	-35.63 (-52.7 to -1.6)	-52.70 (-79.6 to -1.7)		
CRP % Change: Week 32 (n= 28, 84)	-42.61 (-60.8 to -21.8)	-50.63 (-78.7 to -4.1)		
CRP % Change: Week 36 (n= 28, 85)	-38.90 (-70.0 to -13.3)	-53.22 (-81.4 to -6.0)		
CRP % Change: Week 44 (n= 28, 84)	-53.43 (-76.9 to -36.5)	-53.36 (-75.7 to -10.3)		
CRP % Change: Week 56 (n= 28, 84)	-51.26 (-81.5 to -37.8)	-54.91 (-79.3 to -25.7)		

Notes:

[21] - Post Week 24 EAS population

[22] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HAQ-DI score Through Week 24

End point title	Change from Baseline in HAQ-DI score Through Week 24

End point description:

The HAQ-DI score is an evaluation of the functional status for a subject. The 20- question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range: 0-3 where 0 = least difficulty and 3 = extreme difficulty. LOCF method was used to impute missing values. Last observation at or prior EE was used to replace data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[23]	100[24]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
HAQ-DI: Baseline	1.34 (± 0.542)	1.42 (± 0.621)		
Change at Week 4	-0.02 (± 0.329)	-0.17 (± 0.322)		
Change at Week 8	-0.07 (± 0.440)	-0.32 (± 0.442)		
Change at Week 12	-0.05 (± 0.450)	-0.33 (± 0.390)		
Change at Week 16	-0.05 (± 0.428)	-0.38 (± 0.397)		
Change at Week 20	-0.08 (± 0.479)	-0.41 (± 0.453)		

Notes:

[23] - FAS population

[24] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HAQ-DI Score from Week 24 to Week 56

End point title	Change from Baseline in HAQ-DI Score from Week 24 to Week 56[25]

End point description:

The HAQ-DI score is an evaluation of the functional status for a subject. The 20- question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range: 0-3 where 0 = least difficulty and 3 = extreme difficulty. Based on observed data in the post Week 24 Efficacy Analysis Set. Here 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 36, 44 and 56

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[26]	86[27]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n= 29, 86)	-0.19 (± 0.581)	-0.46 (± 0.530)		
Change at Week 28 (n= 28, 85)	-0.40 (± 0.646)	-0.51 (± 0.571)		
Change at Week 32 (n= 28, 84)	-0.50 (± 0.624)	-0.56 (± 0.595)		
Change at Week 36 (n= 28, 84)	-0.59 (± 0.650)	-0.53 (± 0.618)		
Change at Week 44 (n= 28, 84)	-0.63 (± 0.612)	-0.54 (± 0.598)		
Change at Week 56 (n= 28, 83)	-0.67 (± 0.558)	-0.55 (± 0.621)		

Notes:

[26] - Post Week 24 EAS population

[27] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a HAQ-DI response (>= 0.30 Improvement from Baseline in HAQ-DI Score) Through Week 24

End point title	Percentage of Subjects Achieving a HAQ-DI response (>= 0.30 Improvement from Baseline in HAQ-DI Score) Through Week 24

End point description:

The HAQ-DI score is an evaluation of the functional status for a subject. The 20- question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range: 0-3 where 0 = least difficulty and 3 = extreme difficulty. HAQ-DI response is defined as at least 0.30 improvement from baseline in HAQ-DI score and based on

the imputed HAQ-DI score using LOCF for missing data and early escape.

End point type	Secondary

End point timeframe:

Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[28]	100[29]		
Units: Percentage of subjects				
number (not applicable)				
Week 4	12.2	29.0		
Week 8	26.5	43.0		
Week 12	22.4	47.0		
Week 16	20.4	50.0		
Week 20	22.4	48.0		
Week 24	28.6	51.0		

Notes:

[28] - FAS Population

[29] - FAS Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a HAQ-DI response (>= 0.30 Improvement from Baseline in HAQ-DI Score) from Week 24 to Week 56

End point title	Percentage of Subjects Achieving a HAQ-DI response (>= 0.30 Improvement from Baseline in HAQ-DI Score) from Week 24 to Week 56[30]

End point description:

The HAQ-DI score is an evaluation of the functional status for a subject. The 20- question instrument assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0, indicating no difficulty, to 3, indicating inability to perform a task in that area. Overall score was computed as the sum of domain scores and divided by the number of domains answered. Total possible score range: 0-3 where 0 = least difficulty and 3 = extreme difficulty. HAQ-DI response is defined as at least 0.30 improvement from baseline in HAQ-DI score and is based on observed values in the post week 24 efficacy analysis set. Here, N 'number of subjects analyzed' signifies that these subjects were evaluable for this endpoint and ‘n’ signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 36, 44 and 56

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[31]	86[32]		
Units: Percentage of subjects				
number (not applicable)				
Week 24 (n=29, 86)	44.8	55.8		
Week 28 (n=28, 85)	53.6	60.0		
Week 32 (n=28, 84)	57.1	56.0		
Week 36 (n=28, 84)	64.3	59.5		
Week 44 (n=28, 84)	71.4	61.9		
Week 56 (n=28, 83)	75.0	59.0		

Notes:

[31] - Post Week 24 EAS population

[32] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in the Dactylitis Score Among Subjects With Dactylitis at Baseline Through Week 24

End point title	Percent Change from Baseline in the Dactylitis Score Among Subjects With Dactylitis at Baseline Through Week 24

End point description:

Presence and severity of dactylitis were assessed in both hands and feet using a scoring system from 0 to 3 (0 – no dactylitis, 1 – mild dactylitis, 2 – moderate dactylitis, and 3 – severe dactylitis). The results for each digit were summed to produce a final score. The Dactylitis index ranges from 0 to 60. Higher score indicates more severe dactylitis. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Week 4, 8, 16

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[33]	100[34]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
% change at Week 4	-33.33 (-50.0 to 0.0)	-32.46 (-100.0 to 0.0)		
% change at Week 8	-50.00 (-100.0 to 0.0)	-75.00 (-100.0 to -10.0)		
% change at Week 16	-50.00 (-80.0 to 0.0)	-100.00 (-100.0 to -33.3)		

Notes:

[33] - FAS Population

[34] - FAS Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in the Dactylitis Score Among Subjects With Dactylitis at Baseline from Week 24 to Week 56

End point title	Percent Change from Baseline in the Dactylitis Score Among Subjects With Dactylitis at Baseline from Week 24 to Week 56[35]

End point description:

Presence and severity of dactylitis were assessed in both hands and feet using a scoring system from 0 to 3 (0 – no dactylitis, 1 – mild dactylitis, 2 – moderate dactylitis, and 3 – severe dactylitis). The results for each digit were summed to produce a final score. The Dactylitis index ranges from 0 to 60. Higher score indicates more severe dactylitis. Based on observed values in post Week 24 efficacy analysis set among subjects with dactylitis at baseline. Here 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16[36]	50[37]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
% change at Week 24 (n= 16, 50)	-45.00 (-70.8 to 0.0)	-100.00 (-100.00 to -80.0)		
% change at Week 28 (n= 16, 49)	-70.83 (-100.0 to -22.5)	-100.00 (-100.0 to -66.7)		
% change at Week 32 (n= 16, 49)	-100.00 (-100.00 to 79.2)	-100.00 (-100.00 to -70.0)		
% change at Week 44 (n= 16, 49)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -100.00)		
% change at Week 56 (n= 16, 48)	-100.00 (-100.00 to -100.00)	-100.00 (-100.00 to -95.0)		

Notes:

[36] - Post Week 24 EAS with Dactylitis at Baseline

[37] - Post Week 24 EAS with Dactylitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with One or More Digits with Dactylitis Through Week 24 in Subjects with Dactylitis at Baseline

End point title	Percentage of Subjects with One or More Digits with Dactylitis Through Week 24 in Subjects with Dactylitis at Baseline

End point description:

Presence and severity of dactylitis were assessed in both hands and feet using a scoring system from 0 to 3 (0 – no dactylitis, 1 – mild dactylitis, 2 – moderate dactylitis, and 3 – severe dactylitis). The results for each digit were summed to produce a final score. The Dactylitis index ranges from 0 to 60. Higher score indicates more severe dactylitis. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Week 4, 8, 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[38]	58[39]		
Units: Percentage of subjects				
number (not applicable)				
Week 4	91.3	72.4		
Week 8	69.6	56.9		
Week 16	78.3	48.3		
Week 24	82.6	44.8		

Notes:

[38] - FAS population with Dactylitis at Baseline

[39] - FAS population with Dactylitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with One or More Digits with Dactylitis from Week 24 to Week 56 in Subjects with Dactylitis at Baseline

End point title	Percentage of Subjects with One or More Digits with Dactylitis from Week 24 to Week 56 in Subjects with Dactylitis at Baseline[40]

End point description:

Presence and severity of dactylitis were assessed in both hands and feet using a scoring system from 0 to 3 (0 – no dactylitis, 1 – mild dactylitis, 2 – moderate dactylitis, and 3 – severe dactylitis). The results for each digit were summed to produce a final score. The Dactylitis index ranges from 0 to 60. Higher score indicates more severe dactylitis. Based on observed values in post Week 24 efficacy analysis set, among subjects with dactylitis at baseline. Here ‘n’ signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16[41]	50[42]		
Units: Percentage of subjects				
number (not applicable)				
Week 24 (n= 16, 50)	81.3	40.0		
Week 28 (n= 16, 49)	62.5	38.8		
Week 32 (n= 16, 49)	31.3	36.7		
Week 44 (n= 16, 49)	12.5	20.4		
Week 56 (n= 16, 48)	6.3	25.0		

Notes:

[41] - Post Week 24 FAS with Dactylitis at Baseline

[42] - Post Week 24 FAS with Dactylitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in the Enthesitis Score Through Week 24 in Subjects with Enthesitis at Baseline

End point title	Percent Change from Baseline in the Enthesitis Score Through Week 24 in Subjects with Enthesitis at Baseline

End point description:

Enthesitis were assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in participants with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Here, N 'number of subjects analyzed' signifies that these subjects were evaluated with Enthesitis at Baseline for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31[43]	76[44]		
Units: Percent Change				
median (inter-quartile range (Q1-Q3))				
% change at Week 4	0.00 (-50.0 to 0.0)	-18.33 (-79.2 to 0.0)		
% change at Week 8	0.00 (-60.0 to 0.0)	-58.33 (-100.0 to 0.0)		
% change at Week 16	0.00 (-50.0 to 0.0)	-70.83 (-100.0 to 0.0)		
% change at Week 24	-33.33 (-100.0 to 0.0)	-100.00 (-100.0 to -10.0)		

Notes:

[43] - FAS population

[44] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in the Enthesitis Score from Week 24 to Week 56 in Subjects with Enthesitis at Baseline

End point title	Percent Change from Baseline in the Enthesitis Score from Week 24 to Week 56 in Subjects with Enthesitis at Baseline[45]

End point description:

Enthesitis were assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in participants with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). Based on observed values in the post Week 24 efficacy analysis set with enthesitis at baseline. Here 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18[46]	67[47]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
% change at Week 24 (n= 18, 67)	-50.00 (-100.0 to 0.0)	-100.00 (-100.0 to -50.0)		
% change at Week 28 (n= 17, 67)	-60.00 (-100.0 to -40.0)	-100.00 (-100.0 to -50.0)		
% change at Week 32 (n= 17, 66)	-100.00 (-100.0 to -60.0)	-100.00 (-100.00 to -66.7)		
% change at Week 44 (n= 17, 66)	-100.00 (-100.00 to -60.0)	-100.00 (-100.00 to -50.0)		
% change at Week 56 (n= 16, 65)	-100.00 (-100.00 to -35.0)	-100.00 (-100.00 to -50.0)		

Notes:

[46] - Post Week 24 EAS with Enthesitis at Baseline

[47] - Post Week 24 EAS with Enthesitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Enthesitis in Subjects with Enthesitis at Baseline Through Week 24

End point title	Percentage of Subjects with Enthesitis in Subjects with Enthesitis at Baseline Through Week 24

End point description:

Enthesitis were be assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in participants with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Here, N 'number of subjects analyzed' signifies that these subjects were evaluated with Enthesitis at Baseline for this endpoint.

End point type	Secondary

End point timeframe:

Week 4, 8, 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31[48]	76[49]		
Units: Percentage of subjects				
number (not applicable)				
Week 4	87.1	76.3		
Week 8	87.1	59.2		
Week 16	83.9	53.9		
Week 24	71.0	43.4		

Notes:

[48] - Subjects in FAS with Enthesitis at Baseline

[49] - Subjects in FAS with Enthesitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Enthesitis in Subjects with Enthesitis at Baseline from Week 24 to Week 56

End point title	Percentage of Subjects with Enthesitis in Subjects with Enthesitis at Baseline from Week 24 to Week 56[50]

End point description:

Enthesitis were assessed using the Leeds Enthesitis Index (LEI). The LEI was developed to assess enthesitis in participants with PsA, and evaluates the presence (score of 1) or absence of pain (score of 0) by applying local pressure to Lateral elbow epicondyle, left and right, Medial femoral condyle, left and

right, and Achilles tendon insertion, left and right. LEI scores ranging from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). Based on the observed values in the post Week 24 efficacy analysis set with enthesitis at baseline. Here, N 'number of subjects analyzed' signifies that these subjects were evaluated with Enthesitis at Baseline for this endpoint in the post Week 24 efficacy analysis set and 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18[51]	67[52]		
Units: Percentage of Subjects				
number (not applicable)				
Week 24 (n=18, 67)	66.7	38.8		
Week 28 (n=17, 67)	64.7	44.8		
Week 32 (n=17, 66)	35.3	31.8		
Week 44 (n=17, 66)	47.1	37.9		
Week 56 (n=16, 65)	37.5	29.2		

Notes:

[51] - Post week 24 EAS with Enthesitis at Baseline

[52] - Post week 24 in EAS with Enthesitis at Baseline

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) Score Through Week 24

End point title	Change from Baseline in Psoriatic Arthritis Disease Activity Score (PASDAS) Score Through Week 24

End point description:

PASDAS is calculated using variables: patient global VAS (arthritis, psoriasis rescaled to 0 [excellent]–100[Poor]),physician global VAS (rescaled to 0 [no arthritis]–100 [extremely active arthritis]),66 SJC 68 TJC, CRP level (mg/L), enthesitis (measured by LEI and rescaled to 0 [nontenderness]–6 [tenderness] range), tender dactylitis count (scoring each digit from 0 [no dactylitis]–3[severe dactylitis] and recoding to 0–1, with score >0 equaled 1), and PCS scale of 36-item short form health survey (SF-36). The score ranges from 0 to10. Smaller values mean better condition; a negative change from baseline shows improvement. LOCF method was used to impute missing data and Last Observation at or prior EE was used to replace the data after EE for participants who met EE

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[53]	100[54]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline	6.33 (± 1.032)	6.62 (± 1.094)		
Change at Week 16	-0.45 (± 1.099)	-2.24 (± 1.458)		
Change at Week 24	-0.49 (± 1.333)	-2.50 (± 1.587)		

Notes:

[53] - FAS population

[54] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PASDAS Score from Week 24 to 44

End point title	Change from Baseline in PASDAS Score from Week 24 to 44[55]

End point description:

PASDAS is calculated using variables: patient global VAS (arthritis, psoriasis rescaled to 0 [excellent]–100[Poor]),physician global VAS (rescaled to 0 [no arthritis]–100 [extremely active arthritis]),66 SJC 68 TJC, CRP level (mg/L), enthesitis (measured by LEI and rescaled to 0 [nontenderness]–6 [tenderness] range), tender dactylitis count (scoring each digit from 0 [no dactylitis]–3[severe dactylitis] and recoding to 0–1, with score >0 equaled 1), and PCS scale of 36-item short form health survey (SF-36). The score ranges from 0 to10. Smaller values mean better condition; a negative change from baseline shows improvement. Based on observed data in the post Week 24 efficacy analyisis set. Here‘n’ signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[56]	86[57]		
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=28, 86)	-1.05 (± 1.440)	-2.80 (± 1.454)		
Change at Week 44 (n=28, 83)	-3.17 (± 1.524)	-3.15 (± 1.570)		

Notes:

[56] - Post Week 24 EAS population

[57] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Grappa Composite Score (GRACE) Index Through Week 24

End point title	Change from Baseline in Grappa Composite Score (GRACE) Index Through Week 24

End point description:

GRACE index is GRAPPA composite score, which is [1- Arithmetic Mean of the Desirability Function(AMDF)]*10. AMDF is calculated using the following parameters: TJC (0-68), SJC (0-66), HAQ(0-3), Patient's global assessment of disease activity by VAS(arthritis and psoriasis, 0-100 mm), Patient's assessment of skin disease activity by VAS (0-100 mm), Patient's global assessment of disease activity(arthritis) by VAS(0-100 mm), PASI(0-72), Psoriatic arthritis Quality of Life Index (PsAQOL), derived as 25.355+ (2.367*HAQ)−(0.234*PCS)−(0.244*MCS). LOCF method was used to impute missing values. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for participants who met EE criteria. Subjects with missing baseline were excluded from the analysis. Here, 'n' signifies number of subjects analyzed at specific time-points.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[58]	100[59]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 48, 98)	5.94 (± 1.119)	6.15 (± 1.250)		
Change at Week 16 (n= 48, 98)	-0.29 (± 1.174)	-2.49 (± 1.614)		
Change at Week 24 (n= 48, 98)	-0.35 (± 1.394)	-2.73 (± 1.756)		

Notes:

[58] - FAS population

[59] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in GRACE Index from Week 24 to 44

End point title	Change from Baseline in GRACE Index from Week 24 to 44[60]

End point description:

GRACE index is GRAPPA composite score, which is [1- Arithmetic Mean of the Desirability Function(AMDF)]*10. AMDF is calculated using the following parameters: TJC (0-68), SJC (0-66), HAQ(0-3), Patient's global assessment of disease activity by VAS(arthritis and psoriasis, 0-100 mm), Patient's assessment of skin disease activity by VAS (0-100 mm), Patient's global assessment of disease activity(arthritis) by VAS(0-100 mm), PASI(0-72), Psoriatic arthritis Quality of Life Index (PsAQOL), derived as 25.355+ (2.367*HAQ)−(0.234*PCS)−(0.244*MCS). Based on observed values in the post Week 24 efficacy analysis set. Here, 'n' signifies number of subjects analyzed at specific time-points.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[61]	86[62]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n= 27, 85)	-0.91 (± 1.498)	-2.96 (± 1.717)		
Change at Week 44 (n= 27, 82)	-3.21 (± 1.698)	-3.26 (± 1.856)		

Notes:

[61] - Post week 24 EAS population

[62] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Week 16 and 24

End point title	Change from Baseline in modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Week 16 and 24

End point description:

The mCPDAI assesses 4 domains (joints, skin, entheses, and dactylitis) and calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0 [not involved in specific condition] to 3 (severe condition]) is assigned. Higher score range indicates severe condition. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for participants who met EE criteria. Subjects with missing baseline were excluded from the analysis. Here, ‘n’ signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[63]	100[64]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 48, 98)	6.9 (± 2.16)	7.8 (± 2.27)		
Change at Week 16 (n= 48, 98)	-0.5 (± 2.00)	-3.3 (± 2.52)		
Change at Week 24 (n= 48, 98)	-0.8 (± 2.26)	-3.9 (± 2.79)		

Notes:

[63] - FAS population

[64] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in mCPDAI Score at Week 24 and Week 44

End point title	Change from Baseline in mCPDAI Score at Week 24 and Week 44[65]

End point description:

The mCPDAI assesses 4 domains (joints, skin, entheses, and dactylitis) and calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0 [not involved in specific condition] to 3 (severe condition]) is assigned. Higher score range indicates severe condition. Based on observed values in the Post Week 24 Efficacy Analysis Set. Here 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[66]	86[67]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n= 27, 85)	-1.6 (± 2.27)	-4.3 (± 2.70)		
Change at Week 44 (n= 27, 82)	-4.4 (± 2.79)	-5.0 (± 2.48)		

Notes:

[66] - Post week 24 EAS population

[67] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Disease Activity Index for Psoriatic Arthritis (DAPSA) Index Through Week 24

End point title	Change from Baseline in Disease Activity Index for Psoriatic Arthritis (DAPSA) Index Through Week 24

End point description:

DAPSA is calculated as the sum of the following components: tender joint count (0 [non-tenderness]–68 [tenderness]), swollen joint count (0[not swollen]–66 [swollen]), CRP level (milligram per deciliter [mg/dL]), patient VAS for pain (0 [no pain]–10 [the worst possible pain]), and patient VAS for global

disease activity (arthritis, 0[Excellent] –10[Poor]). Higher score indicates more severe condition. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for participants who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 12, 16, 20 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[68]	100[69]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline	45.16 (± 19.990)	47.38 (± 20.645)		
Change at Week 4	-5.62 (± 13.030)	-10.03 (± 11.207)		
Change at Week 8	-8.25 (± 15.158)	-16.65 (± 15.948)		
Change at Week 12	-6.84 (± 16.334)	-18.84 (± 16.266)		
Change at Week 16	-4.98 (± 16.045)	-21.26 (± 17.811)		
Change at Week 20	-4.70 (± 17.408)	-22.56 (± 19.918)		
Change at Week 24	-4.97 (± 20.114)	-23.08 (± 20.206)		

Notes:

[68] - FAS population

[69] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DAPSA Index from Week 24 to Week 56

End point title	Change from Baseline in DAPSA Index from Week 24 to Week 56[70]

End point description:

DAPSA is calculated as the sum of the following components: tender joint count (0 [non-tenderness]–68 [tenderness]), swollen joint count (0[not swollen]–66 [swollen]), CRP level (milligram per deciliter [mg/dL]), patient VAS for pain (0 [no pain]–10 [the worst possible pain]), and patient VAS for global disease activity (arthritis, 0[Excellent] –10[Poor]). Higher score indicates more severe condition. Based on observed data in the Post Week 24 Efficacy Analysis Set. Here ‘n’ signifies the number of subjects analyzed at specific time-points.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 36, 44 and 56

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[71]	86[72]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=29, 86)	-12.99 (± 22.328)	-26.93 (± 18.238)		
Change at Week 28 (n=28, 85)	-20.85 (± 21.434)	-29.71 (± 18.911)		
Change at Week 32 (n=28, 84)	-26.12 (± 21.309)	-30.59 (± 19.720)		
Change at Week 36 (n=28, 85)	-27.37 (± 22.480)	-30.43 (± 18.114)		
Change at Week 44 (n=28, 84)	-29.54 (± 20.785)	-30.55 (± 18.188)		
Change at Week 56 (n=28, 84)	-31.98 (± 20.359)	-32.02 (± 18.328)		

Notes:

[71] - Post week 24 EAS population

[72] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a Minimal Disease Activity (MDA) at Week 16 and 24

End point title	Percentage of Subjects who Achieved a Minimal Disease Activity (MDA) at Week 16 and 24

End point description:

MDA defines a satisfactory state of disease activity that includes 5 domains of PsA (joint symptoms, skin psoriasis, patient's perspective of pain and disease activity, physical function and enthesitis). Subjects were classified as achieving MDA if they fulfilled 5 of 7 outcome measures: tender joint count <= 1; swollen joint count <=1; PASI <=1; patient pain VAS score of <=15; patient global disease activity on arthritis and psoriasis VAS score of <=20; Health Assessment Questionnaire score <=0.5; and tender entheseal points <=1. Subjects were set to non-responders if they met TF, EE criteria prior to week 16 or had data missing.

End point type	Secondary

End point timeframe:

Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[73]	100[74]		
Units: Percentage of subjects				
number (not applicable)				
Week 16	0	18.0		
Week 24	2.0	23.0		

Notes:

[73] - FAS population

[74] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a MDA at Week 24 and 44

End point title	Percentage of Subjects who Achieved a MDA at Week 24 and 44[75]

End point description:

MDA defines a satisfactory state of disease activity that includes 5 domains of PsA (joint symptoms, skin psoriasis, patient's perspective of pain and disease activity, physical function and enthesitis). Subjects were classified as achieving MDA if they fulfilled 5 of 7 outcome measures: tender joint count <= 1; swollen joint count <=1; PASI <=1; patient pain VAS score of <=15; patient global disease activity on arthritis and psoriasis VAS score of<=20; Health Assessment Questionnaire score <=0.5; and tender entheseal points <=1. Based on observed data in the Post Week 24 Efficacy Analysis Set. Here, 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[75] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[76]	86[77]		
Units: Percentage of subjects				
number (not applicable)				
Week 24 (n= 29, 86)	3.4	26.7		
Week 44 (n= 28, 84)	28.6	34.5		

Notes:

[76] - Post week 24 EAS population

[77] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Component Summary Scores (PCS) and Mental Component Summary Scores (MCS) of the 36-item Short Form Healthy Survey (SF-36) at Week 16 and 24

End point title	Change from Baseline in Physical Component Summary Scores (PCS) and Mental Component Summary Scores (MCS) of the 36-item Short Form Healthy Survey (SF-36) at Week 16 and 24

End point description:

SF-36 questionnaire is health related quality of life (QOL) instrument and consists of 36 questions with 8 multi-item scales: Limitations in physical functioning (health problems); Limitations in usual role activities (physical health problems); Bodily pain; Limitations in General mental health (psychological distress and well-being); Limitations in usual role activities (personal or emotional problems); Limitations in social functioning (physical or mental health problems); Limitations in Vitality (energy and fatigue); General health perception. Each scale was scored from 0 to 100 with higher scores= better health. Based on scale scores, summary scores, PCS and MCS were derived using algorithm. Summary MCS and PCS score is also scaled from 0 to 100 and normalized based on general population with higher scores= better health. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[78]	100[79]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
PCS: Baseline	34.39 (± 8.014)	33.46 (± 7.093)		
PCS: Change at Week 16	-0.44 (± 5.025)	5.86 (± 7.315)		
PCS: Change at Week 24	0.46 (± 6.513)	6.59 (± 7.465)		
MCS: Baseline	45.99 (± 12.523)	43.27 (± 11.481)		
MCS: Change at Week 16	1.14 (± 7.075)	4.80 (± 8.952)		
MCS: Change at Week 24	0.42 (± 6.737)	4.95 (± 9.064)		

Notes:

[78] - FAS population

[79] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PCS and MCS of the 36-item Short Form Healthy Survey (SF-36) at Week 24 to 44

End point title	Change from Baseline in PCS and MCS of the 36-item Short Form Healthy Survey (SF-36) at Week 24 to 44[80]

End point description:

SF-36 questionnaire is health related quality of life (QOL) instrument and consists of 36 questions with 8 multi-item scales: Limitations in physical functioning (health problems); Limitations in usual role activities (physical health problems); Bodily pain; Limitations in General mental health (psychological distress and well-being); Limitations in usual role activities (personal or emotional problems); Limitations in social functioning (physical or mental health problems); Limitations in Vitality (energy and fatigue); General health perception. Each scale was scored from 0 to 100 with higher scores= better health. Based on scale scores, summary scores, PCS and MCS were derived using algorithm. Summary MCS and PCS score is also scaled from 0 to 100 and normalized based on general population with higher scores= better health. Based on observed data in the Post Week 24 Efficacy Analysis set. Here, 'n' signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[81]	86[82]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
PCS: Change at Week 24 (n= 28, 86)	2.13 (± 7.365)	7.40 (± 7.448)		
PCS: Change at Week 44 (n= 28, 84)	8.02 (± 8.647)	8.34 (± 8.783)		
MCS: Change at Week 24 (n= 28, 86)	0.51 (± 6.770)	5.45 (± 9.081)		
MCS: Change at Week 44 (n= 28, 84)	5.53 (± 9.013)	4.56 (± 9.548)		

Notes:

[81] - Post week 24 EAS population

[82] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Norm-based scores of SF-36 Scales at Week 16 and 24

End point title	Change from Baseline in Norm-based scores of SF-36 Scales at Week 16 and 24

End point description:

SF-36 questionnaire is health related quality of life (QOL) instrument and consists of 36 questions with 8 multi-item scales: Limitations in physical functioning (health problems); Limitations in usual role activities (physical health problems); Bodily pain; Limitations in General mental health (psychological distress and well-being); Limitations in usual role activities (personal or emotional problems); Limitations in social functioning (physical or mental health problems); Limitations in Vitality (energy and fatigue); General health perception. Each scale was scored from 0 to 100 and normalized based on general population, with higher scores= better health. LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[83]	100[84]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical functioning: Baseline	34.61 (± 9.396)	32.95 (± 8.854)		
Physical functioning: Change at Week 16	-0.31 (± 6.657)	6.30 (± 7.255)		

Physical functioning: Change at Week 24	-0.04 (± 8.227)	6.93 (± 8.009)		
Role-physical: Baseline	36.90 (± 7.879)	34.99 (± 7.776)		
Role-physical: Change at Week 16	-0.23 (± 5.674)	4.22 (± 7.146)		
Role-physical: Change at Week 24	-0.09 (± 6.813)	4.69 (± 7.961)		
Bodily pain: Baseline	35.82 (± 6.255)	34.72 (± 6.294)		
Bodily pain: Change at Week 16	0.21 (± 5.675)	6.56 (± 7.832)		
Bodily pain: Change at Week 24	0.81 (± 6.445)	7.56 (± 8.288)		
General health: Baseline	38.57 (± 8.758)	37.27 (± 7.597)		
General health: Change at Week 16	0.74 (± 5.857)	6.19 (± 7.964)		
General health: Change at Week 24	1.49 (± 7.274)	6.48 (± 7.676)		
Vitality: Baseline	42.29 (± 10.576)	41.22 (± 10.012)		
Vitality: Change at Week 16	0.73 (± 7.779)	5.85 (± 8.138)		
Vitality: Change at Week 24	1.46 (± 7.254)	6.39 (± 8.861)		
Social functioning: Baseline	41.99 (± 9.837)	39.39 (± 10.157)		
Social functioning: Change at Week 16	-0.82 (± 8.272)	5.87 (± 9.346)		
Social functioning: Change at Week 24	-0.82 (± 7.613)	6.22 (± 10.426)		
Role-emotional: Baseline	43.02 (± 10.133)	40.05 (± 11.476)		
Role-emotional: Change at Week 16	1.14 (± 8.774)	4.77 (± 9.643)		
Role-emotional: Change at Week 24	0.64 (± 8.754)	4.67 (± 9.393)		
Mental health: Baseline	42.33 (± 11.818)	39.80 (± 10.621)		
Mental health: Change at Week 16	1.28 (± 7.007)	5.10 (± 8.683)		
Mental health: Change at Week 24	0.21 (± 7.020)	5.68 (± 8.877)		

Notes:

[83] - FAS population

[84] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Norm-based scores of SF-36 Scales at Week 24 and 44

End point title	Change from Baseline in Norm-based scores of SF-36 Scales at Week 24 and 44[85]

End point description:

SF-36 questionnaire is health related quality of life (QOL) instrument and consists of 36 questions with 8 multi-item scales: Limitations in physical functioning (health problems); Limitations in usual role activities (physical health problems); Bodily pain; Limitations in General mental health (psychological distress and well-being); Limitations in usual role activities (personal or emotional problems); Limitations in social functioning (physical or mental health problems); Limitations in Vitality (energy and fatigue); General health perception. Each scale was scored from 0 to 100 and normalized based on general population, with higher scores= better health. Based on observed values in the Post Week 24 Efficacy Analysis set. Here, N 'number of subjects analyzed' signifies that these subjects were evaluable for this endpoint and ‘n’ signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[85] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[86]	86[87]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Physical function: Change at Week 24(n=28,86)	1.09 (± 8.953)	7.54 (± 8.228)		
Physical function: Change at Week 44(n=28,84)	8.41 (± 9.969)	8.50 (± 8.633)		
Role-physical: Change at Week 24(n=28,86)	1.92 (± 7.119)	5.74 (± 7.480)		
Role-physical: Change at Week 44(n=28,84)	6.82 (± 9.198)	6.66 (± 7.664)		
Bodily pain: Change at Week 24(n=28,86)	2.88 (± 6.856)	8.39 (± 8.332)		
Bodily pain: Change at Week 44(n=28,84)	9.42 (± 8.914)	8.95 (± 9.952)		
General health: Change at Week 24(n=28,86)	1.94 (± 8.185)	7.05 (± 7.657)		
General health: Change at Week 44(n=28,84)	6.25 (± 8.998)	6.74 (± 8.496)		
Vitality: Change at Week 24 (n=28,86)	1.49 (± 7.387)	7.39 (± 8.727)		
Vitality: Change at Week 44 (n=28,84)	7.53 (± 10.802)	7.11 (± 9.891)		
Social function: Change at Week 24(n=28,86)	-0.18 (± 7.776)	6.41 (± 10.919)		
Social function: Change at Week 44(n=28,84)	6.09 (± 10.151)	5.73 (± 10.357)		
Role-emotion: Change at Week 24(n=28,86)	2.11 (± 7.891)	5.30 (± 9.013)		
Role-emotion: Change at Week 44(n=28,84)	5.47 (± 9.160)	5.68 (± 9.635)		
Mental health: Change at Week 24(n=28,86)	0.19 (± 7.465)	6.30 (± 8.994)		
Mental health: Change at Week 44(n=28,84)	7.29 (± 9.952)	5.42 (± 8.978)		

Notes:

[86] - Post week 24 EAS Population

[87] - Post week 24 EAS Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Routine Assessment of Patient Index Data 3 (RAPID3) Score at Week 16 and 24

End point title	Change from Baseline in Routine Assessment of Patient Index Data 3 (RAPID3) Score at Week 16 and 24

End point description:

RAPID3 scores were designed for usual clinical care, although they also may be useful for clinical research. The 3 Core Data Set measures on multi-dimensional health assessment questionnaire (MDHAQ), for function (FN), pain, and patient global estimate, were each scored 0-10 and recorded on the MDHAQ. The scores for each domain were then added together to give a final score range of 0–30 (with a positive change indicating worsening of disease activity). LOCF method was used to impute missing values. Last Observation at or prior EE was used to replace the data after EE for participants who met EE criteria.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[88]	100[89]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline	16.51 (± 4.991)	17.06 (± 5.300)		
Change at Week 16	-0.19 (± 4.405)	-5.41 (± 5.307)		
Change at Week 24	-0.57 (± 5.123)	-5.81 (± 5.968)		

Notes:

[88] - FAS population

[89] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in RAPID3 Score at Week 24 and 44

End point title	Change from Baseline in RAPID3 Score at Week 24 and 44[90]

End point description:

RAPID3 scores were designed for usual clinical care, although they also may be useful for clinical research. The 3 Core Data Set measures on multi-dimensional health assessment questionnaire (MDHAQ), for function (FN), pain, and patient global estimate, were each scored 0-10 and recorded on the MDHAQ. The scores for each domain were then added together to give a final score range of 0–30 (with a positive change indicating worsening of disease activity). Based on observed data in the Post Week 24 Efficacy Analysis Set. Here ‘n’ signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24 and 44

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[91]	86[92]		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=28, 86)	-2.28 (± 5.244)	-6.36 (± 6.205)		
Change at Week 44 (n=28, 84)	-7.60 (± 6.588)	-7.48 (± 6.310)		

Notes:

[91] - Post week 24 EAS population

[92] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Greater Than or Equal to 50%, 75%, 90%, and Equal to 100% Improvement in PASI Response from Baseline Through Week 24

End point title	Percentage of Subjects Achieving Greater Than or Equal to 50%, 75%, 90%, and Equal to 100% Improvement in PASI Response from Baseline Through Week 24

End point description:

The PASI is a system used for assessing and grading severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A PASI 50, 75, 90 and 100 responses is defined as >= 50, 75, 90 and 100 percent (%) improvement respectively in PASI score from baseline. LOCF method was used for missing PASI values and the last observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Subjects with missing baseline PASI were excluded in the analysis. here 'n' signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 4, 8, 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49[93]	100[94]		
Units: Percentage of subjects				
number (not applicable)				
W4:>=100% improvement (n=48,98)	0	3.1		
W4:>=90% improvement (n=48,98)	0	9.2		
W4:>=75% improvement (n=48,98)	4.2	16.3		
W4:>=50% improvement (n=48,98)	12.5	43.9		
W8:>=100% improvement (n=48,98)	2.1	12.2		
W8:>=90% improvement (n=48,98)	2.1	27.6		
W8:>=75% improvement (n=48,98)	4.2	42.9		
W8:>=50% improvement (n=48,98)	10.4	67.3		
W16:>=100% improvement (n=48,98)	6.3	31.6		
W16:>=90% improvement (n=48,98)	6.3	53.1		
W16:>=75% improvement (n=48,98)	8.3	71.4		

W16:>=50% improvement (n=48,98)	27.1	81.6		
W24:>=100% improvement (n=48,98)	6.3	39.8		
W24:>=90% improvement (n=48,98)	6.3	66.3		
W24:>=75% improvement (n=48,98)	12.5	78.6		
W24:>=50% improvement (n=48,98)	29.2	86.7		

Notes:

[93] - FAS population

[94] - FAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving a Greater Than or Equal to 50%, 75%, 90%, and Equal to 100% Improvement in PASI Response from Baseline from Week 24 to 56

End point title	Percentage of Subjects Achieving a Greater Than or Equal to 50%, 75%, 90%, and Equal to 100% Improvement in PASI Response from Baseline from Week 24 to 56[95]

End point description:

The PASI is a system used for assessing and grading severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). A PASI 50, 75, 90 and 100 responses is defined as >= 50, 75, 90 and 100 percent (%) improvement respectively in PASI score from baseline. Based on observed values in the Post Week 24 Efficacy Analysis set. Subjects with missing baseline were excluded in the analysis. Here 'n' signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[96]	86[97]		
Units: Percentage of Subjects				
number (not applicable)				
W 24: PASI 50 responders (n= 29, 86)	37.9	89.5		
W 24: PASI 75 responders (n= 29, 86)	20.7	82.6		
W 24: PASI 90 responders (n= 29, 86)	10.3	70.9		
W 24: Subjects with PASI=0 (n= 29, 86)	10.3	44.2		
W 28: PASI 50 responders (n= 28, 84)	60.7	95.2		
W 28: PASI 75 responders (n= 28, 84)	35.7	84.5		
W 28: PASI 90 responders (n= 28, 84)	25.0	72.6		
W 28: Subjects with PASI=0 (n= 28, 84)	17.9	53.6		
W 32: PASI 50 responders (n= 28, 83)	78.6	92.8		
W 32: PASI 75 responders (n= 28, 83)	67.9	86.7		
W 32: PASI 90 responders (n= 28, 83)	50.0	80.7		

W 32: Subjects with PASI=0 (n= 28, 83)	35.7	62.7		
W 44: PASI 50 responders (n= 28, 83)	89.3	94.0		
W 44: PASI 75 responders (n= 28, 83)	82.1	90.4		
W 44: PASI 90 responders (n= 28, 83)	75.0	81.9		
W 44: Subjects with PASI=0 (n= 28, 83)	67.9	63.9		
W 56: PASI 50 responders (n= 27, 82)	96.3	92.7		
W 56: PASI 75 responders (n= 27, 82)	81.5	85.4		
W 56: PASI 90 responders (n= 27, 82)	74.1	78.0		
W 56: Subjects with PASI=0 (n= 27, 82)	55.6	57.3		

Notes:

[96] - Post week 24 EAS population

[97] - Post week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in PASI Through Week 24

End point title	Percent Change from Baseline in PASI Through Week 24

End point description:

The PASI is a system used for assessing and grading severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). LOCF method was used to impute missing data and the Last Observation at or prior EE was used to replace the data after EE for subjects who met EE criteria. Subjects with missing baseline were excluded in the analysis. Here, N 'number of participants analyzed' signifies that these participants were evaluable for this endpoint and ‘n’ signifies the number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 4, 8, 16 and 24

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48[98]	98[99]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
% change at Week 4 (n= 48, 98)	0.00 (-16.0 to 17.0)	-41.49 (-64.7 to -12.2)		
% change at Week 8 (n= 48, 98)	1.58 (-20.2 to 24.9)	-66.67 (-93.6 to -41.9)		
% change at Week 16 (n= 48, 98)	-1.10 (-50.0 to 35.9)	-90.55 (-100.0 to -65.6)		
% change at Week 24 (n= 48, 98)	-7.89 (-54.2 to 34.0)	-96.21 (-100.0 to -82.6)		

Notes:

[98] - FAS Population

[99] - FAS Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline in PASI from Week 24 to 56

End point title	Percent Change from Baseline in PASI from Week 24 to 56[100]

End point description:

The PASI is a system used for assessing and grading severity of psoriatic lesions and their response to therapy. The PASI produces a numeric score that can range from 0 (no disease) to 72 (maximal disease). Based on observed data in the Post Week 24 Efficacy Analysis Set. Subjects with missing baseline were excluded in the analysis. Here 'n' signifies number of subjects analyzed at specific timepoints.

End point type	Secondary

End point timeframe:

Week 24, 28, 32, 44 and 56

Notes:

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The placebo arm at baseline is not applicable for the endpoints post Week 24, as all remaining placebo subjects crossed over to receive guselkumab at Week 24. Therefore the reporting group is renamed as "Crossover (placebo to Guselkumab)".

End point values	Crossover (Placebo to Guselkumab)	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[101]	86[102]		
Units: Percent change				
median (inter-quartile range (Q1-Q3))				
% change at Week 24 (n= 28, 85)	-34.26 (-72.9 to 26.9)	-97.85 (-100.0 to -87.2)		
% change at Week 28 (n= 27, 83)	-57.69 (-94.3 to -39.4)	-100.00 (-100.0 to -88.2)		
% change at Week 32 (n= 27, 82)	-90.61 (-100.0 to -62.5)	-100.00 (-100.0 to -94.0)		
% change at Week 44 (n= 27, 82)	-100.00 (-100.0 to -91.0)	-100.00 (-100.0 to -95.4)		
% change at Week 56 (n= 26, 81)	-100.00 (-100.00 to -91.0)	-100.00 (-100.00 to -91.4)		

Notes:

[101] - Post Week 24 EAS population

[102] - Post Week 24 EAS population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 56

Adverse event reporting additional description:

Safety analysis set includes all subjects randomized at Week 0 who received at least (partial or complete) dose of study agent administration and were analyzed according to the actual treatment received (at the time of onset of AE event) after randomization, regardless of treatments they were randomized to.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1/19.1

Reporting groups

Reporting group title	Week (W) 0 to 24: Placebo

Reporting group description:

Include subjects who were randomized in the placebo group and received at least one injection of placebo. AEs that occurred between Week 0 and Week 24 while subjects were on placebo were included in this group. For subjects who early escaped to ustekinumab at Week 16, AEs that occurred after early escape were excluded.

Reporting group title	W0 to 24: Guselkumab

Reporting group description:

Include subjects who were randomized in the guselkumab group and received at least one injection of guselkumab. AEs that occurred between Week 0 and Week 24 while subjects were on guselkumab were included in this group. For subjects who early escaped to ustekinumab at Week 16, AEs that occurred after early escape were excluded.

Reporting group title	W24 to 44: Crossover (Placebo to Guselkumab)

Reporting group description:

Include subjects who remained in the placebo group and crossed over to guselkumab 100 mg at Week 24. AEs that occurred between Week 24 and Week 44 while subjects were on guselkumab were included in this group.

Reporting group title	W24 to 44: Guselkumab

Reporting group description:

Include subjects who were randomized in the guselkumab group and received at least one injection of guselkumab. AEs that occurred between Week 24 and Week 44 while subjects were on guselkumab were included in this group. For subjects who early escaped to ustekinumab at Week 16, AEs that occurred after early escape were excluded.

Reporting group title	W44 to 56: Crossover (Placebo to Guselkumab)

Reporting group description:

Include subjects who remained in the placebo group and crossed over to guselkumab 100 mg at Week 24. AEs that occurred during the follow-up period (12 weeks from the last study agent administration) were included in this group.

Reporting group title	W44 to 56: Guselkumab

Reporting group description:

Include subjects who were randomized in the guselkumab group and received at least one injection of guselkumab. AEs that occurred during the follow-up period (12 weeks from the last study agent administration) were included in this group. For subjects who early escaped to ustekinumab at Week 16, AEs that occurred after early escape were excluded.

Serious adverse events	Week (W) 0 to 24: Placebo	W0 to 24: Guselkumab	W24 to 44: Crossover (Placebo to Guselkumab)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)	1 / 100 (1.00%)	0 / 29 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Joint Injury			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (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
Radius Fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (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
Eye disorders			
Pupils Unequal			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (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
Ulcerative Keratitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	W24 to 44: Guselkumab	W44 to 56: Crossover (Placebo to Guselkumab)	W44 to 56: Guselkumab
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 100 (5.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Joint Injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (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
Radius Fracture			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (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
Eye disorders			
Pupils Unequal			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (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
Ulcerative Keratitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (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
Musculoskeletal and connective tissue disorders			

Osteoarthritis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Week (W) 0 to 24: Placebo	W0 to 24: Guselkumab	W24 to 44: Crossover (Placebo to Guselkumab)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 49 (32.65%)	35 / 100 (35.00%)	4 / 29 (13.79%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Uterine Leiomyoma			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
General disorders and administration site conditions			
Influenza Like Illness			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Injection Site Erythema			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Local Swelling			

subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Pregnancy of Partner			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Postmenopausal Haemorrhage			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 49 (2.04%)	2 / 100 (2.00%)	2 / 29 (6.90%)
occurrences (all)	1	2	2
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	2 / 29 (6.90%)
occurrences (all)	0	2	2
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	1 / 29 (3.45%)
occurrences (all)	0	2	1
C-Reactive Protein Increased			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Liver Function Test Abnormal			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Liver Function Test Increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Morphology Abnormal			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Neutrophil Count Decreased			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Transaminases Increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Weight Increased			

subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Burns Second Degree			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Chest Injury			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Foot Fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Humerus Fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Morton's Neuralgia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 49 (0.00%)	4 / 100 (4.00%)	0 / 29 (0.00%)
occurrences (all)	0	4	0
Neutropenia			
subjects affected / exposed	0 / 49 (0.00%)	4 / 100 (4.00%)	0 / 29 (0.00%)
occurrences (all)	0	4	0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Pupils Unequal			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Pancreatic Disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gallbladder Disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Hepatitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Hepatomegaly			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Liver Disorder			

subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Scab			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Renal Colic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Joint Effusion			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Pain in Extremity			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Psoriatic Arthropathy			

subjects affected / exposed	1 / 49 (2.04%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	1	2	0
Spinal Pain			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Tendonitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 49 (2.04%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Diverticulitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal Infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Herpes Simplex			
subjects affected / exposed	1 / 49 (2.04%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Herpes Zoster			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0

Influenza			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 49 (10.20%)	7 / 100 (7.00%)	0 / 29 (0.00%)
occurrences (all)	8	8	0
Oral Herpes			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Rhinotracheitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Subcutaneous Abscess			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Tooth Infection			
subjects affected / exposed	1 / 49 (2.04%)	0 / 100 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 49 (2.04%)	1 / 100 (1.00%)	1 / 29 (3.45%)
occurrences (all)	1	1	1
Urinary Tract Infection			
subjects affected / exposed	0 / 49 (0.00%)	2 / 100 (2.00%)	0 / 29 (0.00%)
occurrences (all)	0	2	0

Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 49 (0.00%)	1 / 100 (1.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	W24 to 44: Guselkumab	W44 to 56: Crossover (Placebo to Guselkumab)	W44 to 56: Guselkumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 100 (22.00%)	1 / 29 (3.45%)	8 / 100 (8.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Uterine Leiomyoma			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Influenza Like Illness			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Local Swelling			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Pregnancy of Partner			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Postmenopausal Haemorrhage			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Rhinitis Allergic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Sinus Congestion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	2 / 100 (2.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Aspartate Aminotransferase Increased			

subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
C-Reactive Protein Increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Liver Function Test Abnormal			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Liver Function Test Increased			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Morphology Abnormal			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Weight Increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Burns Second Degree			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Chest Injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Foot Fracture			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Humerus Fracture			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Procedural Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Morton's Neuralgia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 100 (1.00%)	1 / 29 (3.45%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Neutropenia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Pupils Unequal			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pancreatic Disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Gallbladder Disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hepatic Steatosis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Hepatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Liver Disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Renal Colic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Joint Effusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Psoriatic Arthropathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Tendonitis			

subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 100 (3.00%)	0 / 29 (0.00%)	2 / 100 (2.00%)
occurrences (all)	3	0	2

Oral Herpes			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Respiratory Tract Infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rhinotracheitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Subcutaneous Abscess			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Tooth Infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 100 (2.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 29 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 29 (0.00%) 0	0 / 100 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 February 2015	The overall reasons for the amendment is to provide additional treatment options for subjects with ongoing disease activity after Week 24, to collect Ribonucleic acid (RNA) and stool samples to evaluate the mechanism of action of guselkumab, and to add additional results from the CNTO1275ARA2001 study to support the CNTO1959PSA2001 study design.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Study results were limited by small sample size, relatively short duration of follow-up to detect rare AEs. Lack of an active comparator limited comparison with other PsA therapies.

Notes: