Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis including those Previously Treated with Biologic Anti-TNF Agent(s)

Summary

EudraCT number	2016-001163-37
Trial protocol	HU CZ ES DE PL
Global end of trial date	14 November 2019

Results information

Result version number	v1 (current)
This version publication date	30 November 2020
First version publication date	30 November 2020

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSA3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03162796
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202, P.O. Box 300, Raritan, United States, NJ 08869
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 December 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the efficacy of guselkumab treatment in subjects with active psoriatic arthritis (PsA) including those previously treated with biologic anti-tumor necrosis factor alpha (anti-TNF alpha) agent(s) by assessing the reduction in signs and symptoms of PsA.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practices and applicable regulatory requirements. The safety assessments included adverse events (AEs), clinical laboratory tests, physical examinations, vital signs, suicidal ideation or behavior (using the eC-SSRS questionnaires), concomitant medication review, and early detection of tuberculosis (TB).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 August 2017
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	Australia: 17
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Czechia: 12
Country: Number of subjects enrolled	Germany: 23
Country: Number of subjects enrolled	Spain: 12
Country: Number of subjects enrolled	Hungary: 16
Country: Number of subjects enrolled	Korea, Republic of: 4
Country: Number of subjects enrolled	Malaysia: 8
Country: Number of subjects enrolled	Poland: 107
Country: Number of subjects enrolled	Russian Federation: 64
Country: Number of subjects enrolled	Taiwan: 16
Country: Number of subjects enrolled	Ukraine: 70
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	381
EEA total number of subjects	170

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)	352
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 383 subjects were enrolled. Among them, 381 subjects received at least one dose of study drug (126 in placebo group, 127 in guselkumab 100 mg q8w group and 128 in guselkumab 100 mg q4w group). One subjects was randomized to guselkumab 100 mg q8w but not treated.

Pre-assignment

Screening details:

One subjects was accidentally randomized before completion of screening assessments. Subsequently, this subjects screen failed and was later re-screened and randomized using a new subjects number.Therefore, this subjects was counted twice in the number of subjects enrolled, but only once in the number of subjects randomized.

Period 1

Period 1 title	Placebo Controlled Period: Week 0 - 24
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Sponsor was also blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period.

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

Dosage and administration details:

Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through
Week 20 in the placebo controlled period (PCP).

Arm title	Guselkumab 100 mg q8w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4,

then every 8 weeks (q8w).

Arm title	Guselkumab 100 mg q4w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week
48.

Number of subjects in period 1	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	126	127	128
Completed	114	123	125
Not completed	12	4	3
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	3	-	1
Initiated prohibited medication	1	-	-
Adverse event, non-fatal	2	3	1
Unspecified	-	1	1
Lost to follow-up	1	-	-
Lack of efficacy	4	-	-

Period 2

Period 2 title	Active Treatment Period: Week 24 - 52
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Blinding implementation details:

Sponsor was also blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period.

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

Dosage and administration details:

Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through
Week 20 in the placebo controlled period (PCP).

Arm title	Guselkumab 100 mg q8w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w).

Arm title	Guselkumab 100 mg q4w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNTO1959
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week
48.

Number of subjects in period 2	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	114	123	125
Completed	107	116	124
Not completed	7	7	1
Consent withdrawn by subject	-	2	-
Adverse event, non-fatal	3	2	-
Lack of efficacy	4	3	1

Period 3

Period 3 title	Safety Follow-up: Week 52 - 60
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Blinding implementation details:

Sponsor was also blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Guselkumab 100 mg q8w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Guselkumab 100 mg q4w

Arm description:

Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 3	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	107	116	124
Completed	106	114	123
Not completed	1	2	1
Consent withdrawn by subject	1	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period.	
Reporting group title	Guselkumab 100 mg q8w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48.	
Reporting group title	Guselkumab 100 mg q4w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48.	

Reporting group values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Number of subjects	126	127	128
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	114	118	120
From 65-84 years	12	9	8
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	49	48.9	47.4
standard deviation	± 11.1	± 11.52	± 11.59
Sex: Female, Male Units: subjects			
Female	65	59	62
Male	61	68	66
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	2	0
Not Hispanic or Latino	122	124	128
Unknown or Not Reported	2	1	0
Region of Enrollment Units: Subjects			
AUSTRALIA	5	8	4
CANADA	8	3	4

CZECH REPUBLIC	5	4	3
GERMANY	3	10	10
HUNGARY	3	4	9
MALAYSIA	5	1	2
POLAND	37	36	34
RUSSIAN FEDERATION	22	19	23
SOUTH KOREA	3	1	0
SPAIN	5	6	1
TAIWAN	4	7	5
UKRAINE	19	22	29
UNITED STATES	7	6	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	12	10	7
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	0	0	0
White	112	116	121
More than one race	0	0	0
Unknown or Not Reported	2	0	0

Reporting group values	Total		
Number of subjects	381		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	352		
From 65-84 years	29		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: subjects			
Female	186		
Male	195		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4		
Not Hispanic or Latino	374		
Unknown or Not Reported	3		
Region of Enrollment Units: Subjects			

AUSTRALIA	17		
CANADA	15		
CZECH REPUBLIC	12		
GERMANY	23		
HUNGARY	16		
MALAYSIA	8		
POLAND	107		
RUSSIAN FEDERATION	64		
SOUTH KOREA	4		
SPAIN	12		
TAIWAN	16		
UKRAINE	70		
UNITED STATES	17		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	29		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	0		
White	349		
More than one race	0		
Unknown or Not Reported	2		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period.	
Reporting group title	Guselkumab 100 mg q8w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48.	
Reporting group title	Guselkumab 100 mg q4w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48.	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period.	
Reporting group title	Guselkumab 100 mg q8w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48.	
Reporting group title	Guselkumab 100 mg q4w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48.	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (PCP), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 48 in the active treatment period. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.	
Reporting group title	Guselkumab 100 mg q8w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) and placebo matched to guselkumab injections at other visits through Week 48. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.	
Reporting group title	Guselkumab 100 mg q4w
Reporting group description:	
Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 48. Subjects were followed-up for 8 weeks after Week 52 during safety follow-up period.	

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: >=20% improvement from baseline in both SJC(66 joints) and TJC(68 joints), and >=20% improvement from baseline in 3 of 5 assessments: patient’s assessment of pain using VAS(0-100mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform task), and CRP. TF criteria - discontinued study drug, initiated/increased dose of non-biologic DMARDs or oral corticosteroids, initiated prohibited psoriatic arthritis treatment. Analysis population is FAS1. Subjects who
achieved ACR 20 response at Week 24 and did not meet any TF criteria before Week 24 considered responders. Subjects who met 1/more TF criteria or with missing data considered non-responders.

End point type	Primary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)	22.2	52.0	59.4	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	29.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.6
upper limit	41.1

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w

Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	37.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.1
upper limit	48.2

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

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

End point description:

HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score is average of the computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning. Negative change from baseline indicates improvement of physical function. Analysis population is full analysis set-1 (FAS1). Data after meeting one or more treatment failure (TF) criteria were imputed as no change from baseline. Missing data were assumed to be missing at random (MAR) and imputed using multiple imputation (MI).

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.0743 (-0.1605 to 0.0119)	-0.3225 (-0.4082 to -0.2369)	-0.3968 (-0.4825 to -0.3112)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w

Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Square (LS) Mean Difference
Point estimate	-0.2483
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.364
upper limit	-0.1325

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.3226
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4385
upper limit	-0.2066

Secondary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 50 Response at Week 24

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 50 Response at Week 24

End point description:

ACR 50 defined as greater than or equal to (>=)50 percent (%) improvement from baseline in both SJC(66 joints) and TJC(68 joints), and >=50% improvement from baseline in 3 of 5 assessments: patient’s assessment of pain using visual analog scale (VAS; 0-100mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI; a 20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform a task in that area), and C-Reactive Protein (CRP). Analysis population is FAS1. Subjects who achieved ACR 50 response at Week 24 and did not meet any TF criteria before Week 24 considered as responders. Subjects who met 1 or more TF criteria or with missing data considered as nonresponders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)	8.7	29.9	35.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.1
upper limit	30.7

Notes:

[1] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	27.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.6
upper limit	36.8

Notes:

[2] - Nominal

Secondary: Percentage of Subjects With Psoriasis Response of IGA (Score: 0[Cleared] or 1[Minimal] and >=2 grade reduction from baseline) at Week 24

Subjects With >=3% Body Surface Area (BSA) Psoriatic Involvement and IGA Score of >=2 (Mild) at Baseline

End point title	Percentage of Subjects With Psoriasis Response of IGA (Score: 0[Cleared] or 1[Minimal] and >=2 grade reduction from baseline) at Week 24 Among Subjects With >=3% Body Surface Area (BSA) Psoriatic Involvement and IGA Score of >=2 (Mild) at Baseline

End point description:

A psoriasis Investigator's Global Assessment (IGA) response was defined as an IGA score of 0 (cleared) or 1 (minimal) and >=2 grade reduction from baseline in the IGA psoriasis score. The IGA documents the investigator's assessment of the patient's psoriasis and lesions are graded for induration, erythema and scaling, each using a 5 point scale: 0 (no evidence), 1 (minimal), 2 (mild), 3 (moderate), and 4 (severe). The IGA score of psoriasis was based upon the average of induration, erythema and scaling scores. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). FAS1 among the subjects with >=3% BSA psoriatic involvement and an IGA score of >=2 (mild) at baseline. Subjects who achieved psoriasis IGA response at Week 24 and did not meet any TF criteria before Week 24 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)	15.4	57.3	75.3	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	42
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.9
upper limit	55.1

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	60
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.3
upper limit	71.8

Secondary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 16

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 20 Response at Week 16

End point description:

ACR 20 response: >=20% improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and >=20% improvement from baseline in 3 of 5 assessments: patient's assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no pain and 100=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100=poor), physician's global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 20 response at Week 16 and did not meet any TF criteria before Week 16 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as nonresponders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)	25.4	52.0	60.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w

Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	26.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.3
upper limit	38.1

Notes:

[3] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	34.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.5
upper limit	46

Notes:

[4] - Nominal

Secondary: Change From Baseline in Disease Activity Score (DAS28) (C-reactive Protein [CRP]) Score at Week 24

End point title	Change From Baseline in Disease Activity Score (DAS28) (C-reactive Protein [CRP]) Score at Week 24

End point description:

The Disease Activity Index Score (DAS28) based on C-Reactive Protein (CRP) is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. The values are 0=best to 10=worst. Negative changes from baseline indicate improvement of arthritis. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.70 (-0.89 to -0.51)	-1.43 (-1.61 to -1.24)	-1.61 (-1.80 to -1.42)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	-0.48

Notes:

[5] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.16
upper limit	-0.66

Notes:

[6] - Nominal

Secondary: Percentage of Subjects who Achieve an American College of Rheumatology (ACR) 70 Response at Week 24

End point title	Percentage of Subjects who Achieve an American College of Rheumatology (ACR) 70 Response at Week 24

End point description:

ACR 70 response was defined as >= 70% improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and >=70% improvement from baseline in 3 of 5 assessments: patient’s assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no pain and 100=worst possible pain), patient’s global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician’s global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (a 20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform a task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 70 response at Week 24 and did not meet any TF criteria before Week 24 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)	5.6	11.8	20.3	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.069
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	13.1

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w

Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	14.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.9
upper limit	22.7

Secondary: Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 50 Response at Week 16

End point title	Percentage of Subjects who Achieved an American College of Rheumatology (ACR) 50 Response at Week 16

End point description:

ACR 50 response was defined as >=50% improvement from baseline in both swollen joint count (SJC; 66 joints) and tender joint count (TJC; 68 joints), and >=50% improvement from baseline in 3 of 5 assessments: patient’s assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no pain and 100=worst possible pain), patient’s global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician’s global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (a 20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform a task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 50 response at Week 16 and did not meet any TF criteria before Week 16 considered as responders. Subjects who met 1 or more TF criteria or with missing data considered as nonresponders.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)	12.7	22.8	26.6	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w

Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	19.3

Notes:

[7] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	13.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.4
upper limit	23.4

Notes:

[8] - Nominal

Secondary: Change From Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) Score at Week 24

End point title	Change From Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) Score at Week 24

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The PCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)	1.96 (0.69 to 3.24)	6.10 (4.83 to 7.37)	6.87 (5.60 to 8.14)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	4.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.42
upper limit	5.85

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	4.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.19
upper limit	6.63

Secondary: Percentage of Subjects With Resolution of Enthesitis at Week 24 Among

the Subjects With Enthesitis at Baseline	
End point title	Percentage of Subjects With Resolution of Enthesitis at Week 24 Among the Subjects With Enthesitis at Baseline

End point description:

Enthesitis was assessed using the Leeds Enthesitis Index (LEI), a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). A LEI score of 0 at a post baseline visit indicates resolution of enthesitis when baseline LEI greater than (>) 0. Analysis population is FAS1 among the subjects with enthesitis (LEI) at baseline. Subjects who achieved resolution of enthesitis at Week 24 and did not meet any TF criteria before Week 24 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	73	
Units: percentage of subjects				
number (not applicable)	27.3	40.3	47.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.094 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	27.5

Notes:

[9] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w

Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	19.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.9
upper limit	34.6

Notes:

[10] - Nominal

Secondary: Change From Baseline in Enthesitis Score (Based on LEI) at Week 24 Among the Subjects with Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score (Based on LEI) at Week 24 Among the Subjects with Enthesitis at Baseline

End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). Negative changes from baseline indicates improvement of enthesitis. Analysis population is FAS1 among the subjects with enthesitis (LEI) at baseline. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	73	
Units: units on a scale				
least squares mean (confidence interval 95%)	-1.01 (-1.37 to -0.66)	-1.35 (-1.72 to -0.98)	-1.75 (-2.13 to -1.38)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w

Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.185 [11]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	0.16

Notes:

[11] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004 [12]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	-0.24

Notes:

[12] - Nominal

Secondary: Change From Baseline in 36-Item Short Form Health Survey (SF-36) Mental Component Summary (MCS) Score at Week 24

End point title	Change From Baseline in 36-Item Short Form Health Survey (SF-36) Mental Component Summary (MCS) Score at Week 24

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The MCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)	2.37 (0.93 to 3.81)	3.20 (1.78 to 4.63)	3.60 (2.17 to 5.02)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.398 [13]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	2.77

Notes:

[13] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.214 [14]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	3.16

Notes:

[14] - Nominal

Secondary: Percentage of Subjects With Resolution of Dactylitis at Week 24 Among

the Subjects with Dactylitis at Baseline	
End point title	Percentage of Subjects With Resolution of Dactylitis at Week 24 Among the Subjects with Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. Higher score indicates more severe dactylitis. Resolution of dactylitis was defined as a dactylitis score of 0 with the baseline dactylitis score >0. Analysis population is FAS1 among the subjects with dactylitis at baseline. Subjects who achieved resolution of dactylitis at Week 24 and did not meet any TF criteria before Week 24 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	49	38	
Units: percentage of subjects				
number (not applicable)	49.1	65.3	63.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088 [15]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	16.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	34.8

Notes:

[15] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.212 [16]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	13.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	33.7

Notes:

[16] - Nominal

Secondary: Change From Baseline in Dactylitis Scores at Week 24 Among the Subjects with Dactylitis at Baseline

End point title	Change From Baseline in Dactylitis Scores at Week 24 Among the Subjects with Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. A higher score indicates more severe dactylitis. Negative change from baseline indicates improvement in dactylitis. Analysis population is FAS1 among the subjects with dactylitis at baseline. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	49	38	
Units: units on a scale				
least squares mean (confidence interval 95%)	-4.30 (-5.96 to -2.63)	-6.11 (-7.81 to -4.41)	-5.82 (-7.82 to -3.83)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg q8w

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.121 [17]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.12
upper limit	0.49

Notes:

[17] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v Guselkumab 100 mg q4w
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.225 [18]
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	0.95

Notes:

[18] - Nominal

Secondary: Percentage of Subjects who Achieved ACR 20 Response by Visit Over Time Through Week 24

End point title	Percentage of Subjects who Achieved ACR 20 Response by Visit Over Time Through Week 24

End point description:

ACR 20 response was defined as >=20% improvement from baseline in both SJC (66 joints) and TJC (68 joints), and >=20% improvement from baseline in 3 of 5 assessments: patient’s assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 20 response at a specific time point and did not meet any TF criteria before were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	7.9	15.7	20.3	
Week 8	18.3	36.2	39.1	
Week 12	27.0	43.3	53.1	
Week 16	25.4	52.0	60.2	
Week 20	30.2	51.2	62.5	
Week 24	22.2	52.0	59.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 50 Response by Visit Over Time Through Week 24

End point title	Percentage of Subjects who Achieved ACR 50 Response by Visit Over Time Through Week 24

End point description:

ACR 50 response was defined as >=50% improvement from baseline in both SJC (66 joints) and TJC (68 joints), and >=50% improvement from baseline in 3 of the 5 assessments: patient’s assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 50 response at a specific time point and did not meet any treatment failure (TF) criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as nonresponders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	2.4	1.6	3.1	
Week 8	7.9	7.9	10.9	
Week 12	10.3	20.5	24.2	
Week 16	12.7	22.8	26.6	

Week 20	13.5	29.1	37.5	
Week 24	8.7	29.9	35.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 70 Response by Visit Over Time Through Week 24

End point title	Percentage of Subjects who Achieved ACR 70 Response by Visit Over Time Through Week 24

End point description:

ACR 70 response was defined as >=70% improvement from baseline in both SJC (66 joints) and TJC (68 joints), and >=70% improvement from baseline in 3 of the 5 assessments: patient's assessment of pain using VAS (0-100 millimeters [mm], 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS1. Subjects who achieved ACR 70 response at a specific time point and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	0	0.8	0	
Week 8	1.6	3.1	2.3	
Week 12	4.8	7.1	6.3	
Week 16	5.6	7.9	7.8	
Week 20	7.1	11.8	17.2	
Week 24	5.6	11.8	20.3	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Components- Swollen Joint Count and Tender Joint Count Through Week 24

End point title	ACR Components- Swollen Joint Count and Tender Joint Count

	Through Week 24

End point description:

ACR components including swollen joint count (66 joints) and tender joint count (68 joints) were measured. Analysis population is FAS1. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: joints				
arithmetic mean (standard deviation)				
Week 4: Swollen Joint Count (n=124, 124, 128)	8.0 (± 7.71)	7.7 (± 7.89)	5.7 (± 4.89)	
Week 8: Swollen Joint Count (n=122, 125, 128)	6.6 (± 5.83)	6.2 (± 9.36)	4.4 (± 5.22)	
Week 12: Swollen Joint Count (n=123, 126, 127)	6.1 (± 6.41)	4.5 (± 6.63)	3.5 (± 5.60)	
Week 16: Swollen Joint Count (n=122, 123, 127)	5.9 (± 6.09)	3.8 (± 5.15)	2.7 (± 4.25)	
Week 20: Swollen Joint Count (n=118, 122, 126)	5.2 (± 5.72)	4.0 (± 6.28)	2.7 (± 4.87)	
Week 24: Swollen Joint Count (n=118, 123, 127)	4.9 (± 6.14)	3.8 (± 6.53)	2.8 (± 5.27)	
Week 4: Tender Joint Count (n=124, 124, 128)	17.0 (± 13.81)	16.3 (± 14.11)	14.4 (± 11.85)	
Week 8: Tender Joint Count (n=122, 125, 128)	15.8 (± 13.68)	13.5 (± 13.86)	12.2 (± 11.53)	
Week 12: Tender Joint Count (n=123, 126, 127)	15.1 (± 14.21)	11.5 (± 13.16)	9.7 (± 11.14)	
Week 16: Tender Joint Count (n=122, 123, 127)	15.5 (± 13.61)	10.3 (± 12.06)	9.0 (± 10.29)	
Week 20: Tender Joint Count (n=118, 122, 126)	13.4 (± 13.02)	9.9 (± 12.53)	7.9 (± 9.54)	
Week 24: Tender Joint Count (n=118, 123, 127)	13.2 (± 12.09)	9.9 (± 12.82)	8.4 (± 10.47)	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Components- Patient’s Assessment of Pain, Patient’s Global Assessment of Disease Activity, Physician’s Global Assessment of Disease Activity Through Week 24

End point title	ACR Components- Patient’s Assessment of Pain, Patient’s Global Assessment of Disease Activity, Physician’s Global Assessment of Disease Activity Through Week 24

End point description:

ACR components included patient’s assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no

pain and 100=worst possible pain), patient's global assessment (PtGA) of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician's global assessment (PGA) of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis). Analysis population is FAS1. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: millimeters				
arithmetic mean (standard deviation)				
Week4: Patient's Assessment of Pain(n=124,123,128)	5.74 (± 2.296)	5.49 (± 2.159)	5.18 (± 2.224)	
Week8: Patient's Assessment of Pain(n=123,126,128)	5.06 (± 2.257)	4.90 (± 2.310)	4.54 (± 2.397)	
Week12:Patient's Assessment of Pain(n=123,126,127)	4.96 (± 2.355)	4.35 (± 2.503)	4.09 (± 2.346)	
Week16:Patient's Assessment of Pain(n=122,124,127)	5.01 (± 2.417)	4.25 (± 2.471)	3.85 (± 2.462)	
Week20:Patient's Assessment of Pain(n=118,124,126)	4.98 (± 2.497)	4.00 (± 2.481)	3.51 (± 2.409)	
Week24:Patient's Assessment of Pain(n=118,123,127)	5.09 (± 2.379)	3.82 (± 2.470)	3.52 (± 2.502)	
Week4:PtGA of Disease Activity(n=124,123,128)	5.86 (± 2.281)	5.80 (± 2.181)	5.36 (± 2.200)	
Week8: PtGA of Disease Activity(n=123,126,128)	5.26 (± 2.271)	4.99 (± 2.381)	4.82 (± 2.384)	
Week12: PtGA of Disease Activity(n=123,126,127)	5.13 (± 2.398)	4.46 (± 2.459)	4.18 (± 2.441)	
Week16: PtGA of Disease Activity(n=122,124,127)	5.12 (± 2.379)	4.59 (± 2.541)	3.96 (± 2.458)	
Week20: PtGA of Disease Activity(n=118,124,126)	5.08 (± 2.596)	4.21 (± 2.604)	3.57 (± 2.443)	
Week24: PtGA of Disease Activity(n=118,123,127)	5.19 (± 2.419)	4.03 (± 2.603)	3.48 (± 2.412)	
Week4: PGA of Disease Activity(n=122,123,126)	5.53 (± 1.986)	4.94 (± 1.977)	4.72 (± 1.955)	
Week8: PGA of Disease Activity(n=122,125,128)	4.79 (± 2.197)	3.88 (± 2.299)	3.63 (± 2.035)	
Week12: PGA of Disease Activity(n=122,125,127)	4.31 (± 2.196)	3.47 (± 1.992)	3.08 (± 2.031)	
Week16: PGA of Disease Activity(n=120,123,124)	4.31 (± 2.296)	3.39 (± 2.260)	2.73 (± 2.022)	
Week20: PGA of Disease Activity(n=117,121,125)	3.96 (± 2.367)	2.90 (± 2.132)	2.44 (± 1.780)	
Week24: PGA of Disease Activity(n=117,122,127)	4.07 (± 2.361)	2.81 (± 2.169)	2.34 (± 1.889)	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Component- C-reactive Protein (CRP) Through Week 24

End point title	ACR Component- C-reactive Protein (CRP) Through Week 24

End point description:

ACR component including CRP was measured. Analysis population is FAS1. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: milligrams per deciliter (mg/dL)				
arithmetic mean (standard deviation)				
Week 4 (n=124, 123, 128)	1.220 (± 1.5753)	1.159 (± 1.7641)	0.785 (± 1.1917)	
Week 8 (n=120, 124, 127)	1.184 (± 1.8722)	1.059 (± 1.4736)	0.720 (± 1.2637)	
Week 12 (n=122, 123, 127)	1.138 (± 1.5889)	0.936 (± 1.3470)	0.629 (± 0.7882)	
Week 16 (n=120, 123, 124)	1.143 (± 1.6005)	0.996 (± 1.5296)	0.592 (± 0.7861)	
Week 20 (n=119, 124, 126)	1.105 (± 1.6401)	0.941 (± 1.5067)	0.592 (± 0.8831)	
Week 24 (n=119, 123, 127)	1.319 (± 3.0033)	0.894 (± 1.5386)	0.633 (± 1.0522)	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Component- Patient's Assessment of Physical Function as Assessed by HAQ-DI Scale Score at Weeks 4, 8, 12, 16, 20 and 24

End point title	ACR Component- Patient's Assessment of Physical Function as Assessed by HAQ-DI Scale Score at Weeks 4, 8, 12, 16, 20 and 24

End point description:

Patient's assessment of physical function was measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI). HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score is average of the computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning. Negative change from baseline indicates improvement of physical function. Analysis population is FAS1. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=124, 124, 128)	1.2188 (± 0.67806)	1.1371 (± 0.59755)	0.9824 (± 0.65278)	
Week 8 (n=123, 126, 128)	1.1331 (± 0.66928)	1.0188 (± 0.61463)	0.9150 (± 0.65488)	
Week 12 (n=123, 126, 127)	1.1169 (± 0.63813)	0.9831 (± 0.64058)	0.8012 (± 0.63060)	
Week 16 (n=122, 124, 127)	1.1035 (± 0.65372)	0.9375 (± 0.65845)	0.7776 (± 0.66011)	
Week 20 (n=118, 124, 126)	1.1049 (± 0.67838)	0.8730 (± 0.62347)	0.7619 (± 0.66491)	
Week 24 (n=118, 123, 127)	1.1133 (± 0.69279)	0.8770 (± 0.60691)	0.7264 (± 0.63225)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in ACR Components at Weeks 4, 8, 12, 16, 20 and 24

End point title	Percent Change From Baseline in ACR Components at Weeks 4, 8, 12, 16, 20 and 24

End point description:

ACR components include swollen joint count (66 joints), tender joint count (68 joints), patient's assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no pain and 100=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician's global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI; a 20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform a task in that area), and CRP. Analysis population is FAS1. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percent change				
arithmetic mean (standard deviation)				
Week 4: Swollen Joint Count (n=124, 124, 128)	-22.4 (± 49.78)	-27.5 (± 42.92)	-29.3 (± 50.85)	
Week 8: Swollen Joint Count (n=122, 125, 128)	-29.4 (± 50.57)	-45.3 (± 66.29)	-46.5 (± 53.81)	
Week 12: Swollen Joint Count (n=123, 126, 127)	-38.1 (± 55.69)	-60.0 (± 48.23)	-61.1 (± 42.62)	
Week 16: Swollen Joint Count (n=122, 123, 127)	-36.6 (± 56.25)	-65.8 (± 40.42)	-71.3 (± 34.69)	
Week 20: Swollen Joint Count (n=118, 122, 126)	-44.4 (± 54.01)	-66.2 (± 38.24)	-71.0 (± 40.88)	
Week 24: Swollen Joint Count (n=118, 123, 127)	-49.5 (± 45.66)	-66.6 (± 47.09)	-73.3 (± 37.95)	
Week 4: Tender Joint Count (n=124, 124, 124)	-15.4 (± 36.11)	-22.2 (± 36.99)	-17.2 (± 50.26)	
Week 8: Tender Joint Count (n=122, 125, 128)	-21.4 (± 41.36)	-35.7 (± 47.45)	-31.4 (± 47.13)	
Week 12: Tender Joint Count (n=123, 126, 127)	-24.5 (± 50.74)	-48.0 (± 40.24)	-47.9 (± 38.76)	
Week 16: Tender Joint Count (n=122, 123, 127)	-19.9 (± 50.84)	-52.6 (± 36.33)	-49.2 (± 57.97)	
Week 20: Tender Joint Count (n=118, 122, 126)	-30.8 (± 53.79)	-55.4 (± 40.17)	-59.4 (± 35.91)	
Week 24: Tender Joint Count (n=118, 123, 127)	-29.1 (± 53.54)	-53.7 (± 45.12)	-56.0 (± 41.76)	
Week4: Patient's Assessment of Pain(n=123,123,127)	2.98 (± 38.337)	-2.41 (± 43.139)	-9.12 (± 37.068)	
Week8: Patient's Assessment of Pain(n=122,126,127)	-7.41 (± 42.846)	-12.18 (± 46.920)	-19.41 (± 45.862)	
Week12:Patient's Assessment of Pain(n=122,126,126)	-7.82 (± 49.910)	-22.74 (± 45.048)	-27.28 (± 42.305)	
Week16:Patient's Assessment of Pain(n=121,124,126)	-7.86 (± 47.980)	-25.45 (± 47.860)	-29.74 (± 53.817)	
Week20:Patient's Assessment of Pain(n=117,124,125)	-8.31 (± 54.287)	-29.36 (± 46.581)	-38.45 (± 46.235)	
Week24:Patient's Assessment of Pain(n=117,123,126)	-5.35 (± 53.599)	-32.65 (± 45.343)	-38.97 (± 43.873)	
Week 4: PtGA of Disease Activity (n=124,123,128)	0.06 (± 37.022)	-9.57 (± 30.374)	-2.82 (± 58.438)	
Week 8: PtGA of Disease Activity (n=123, 126, 128)	-9.06 (± 43.197)	-20.08 (± 45.707)	-14.95 (± 46.672)	
Week12: PtGA of Disease Activity (n=123, 126, 127)	-10.00 (± 49.346)	-28.38 (± 40.863)	-26.84 (± 48.800)	
Week16: PtGA of Disease Activity (n=122, 124, 127)	-8.56 (± 55.279)	-26.93 (± 42.999)	-30.16 (± 47.486)	
Week20: PtGA of Disease Activity (n=118, 124, 126)	-11.67 (± 54.531)	-34.61 (± 40.905)	-38.76 (± 43.118)	
Week24: PtGA of Disease Activity (n=118, 123, 127)	-4.91 (± 65.728)	-37.16 (± 39.760)	-40.32 (± 42.037)	
Week 4: PGA of Disease Activity (n=122, 123, 126)	-10.50 (± 30.144)	-17.83 (± 34.370)	-22.42 (± 34.627)	
Week 8: PGA of Disease Activity (n=122, 125, 128)	-20.87 (± 38.908)	-36.57 (± 34.906)	-41.05 (± 31.682)	
Week 12: PGA of Disease Activity (n=122, 125, 127)	-30.47 (± 32.894)	-40.61 (± 37.367)	-48.87 (± 35.082)	

Week 16: PGA of Disease Activity (n=120, 123, 124)	-29.42 (± 36.058)	-45.04 (± 36.363)	-55.36 (± 32.848)	
Week 20: PGA of Disease Activity (n=117, 121, 125)	-36.48 (± 35.490)	-51.88 (± 34.491)	-59.57 (± 30.353)	
Week 24: PGA of Disease Activity (n=117, 122, 127)	-33.95 (± 34.349)	-53.43 (± 37.305)	-61.39 (± 31.234)	
Week 4: HAQ-DI Score (n=118, 121, 119)	4.3521 (± 61.86548)	-0.4964 (± 54.63888)	-5.9245 (± 53.44204)	
Week 8: HAQ-DI Score (n=117, 123, 119)	-3.3329 (± 48.15101)	-9.1556 (± 65.76295)	-11.3467 (± 69.07565)	
Week 12: HAQ-DI Score (n=119, 123, 118)	-2.1600 (± 88.42239)	-13.1115 (± 69.57297)	-21.6242 (± 65.32053)	
Week 16: HAQ-DI Score (n=116, 122, 118)	-3.2447 (± 109.78825)	-19.5421 (± 55.80512)	-27.7444 (± 68.28273)	
Week 20: HAQ-DI Score (n=112, 122, 118)	-10.5259 (± 44.67386)	-23.6139 (± 65.27566)	-26.2478 (± 74.38446)	
Week 24: HAQ-DI Score (n=112, 121, 118)	-7.3745 (± 61.62081)	-8.7950 (± 148.19861)	-31.1750 (± 72.70079)	
Week 4: CRP (n=124, 123, 128)	9.972 (± 66.9599)	-4.060 (± 76.1801)	-1.054 (± 102.5692)	
:Week 8: CRP (n=120, 124, 127)	10.402 (± 83.4766)	5.403 (± 111.6889)	11.791 (± 273.1510)	
Week 12: CRP (n=122, 123, 127)	9.295 (± 94.9020)	-2.507 (± 98.4549)	-7.908 (± 114.4983)	
Week 16: CRP (n=120, 123, 124)	82.057 (± 734.6577)	7.139 (± 134.6682)	2.759 (± 208.7305)	
Week 20: CRP (n=119, 124, 126)	5.768 (± 98.6914)	-11.151 (± 84.9807)	-14.684 (± 98.0041)	
Week 24: CRP (n=119, 123, 127)	31.628 (± 239.7722)	-7.404 (± 101.4807)	-6.112 (± 148.2088)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HAQ-DI Score at Weeks 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in HAQ-DI Score at Weeks 4, 8, 12, 16, 20 and 24

End point description:

HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score is average of the computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning. Negative change from baseline indicates improvement of physical function.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 4	0.0043 (-0.0562 to 0.0647)	-0.0571 (-0.1173 to 0.0031)	-0.1095 (-0.1695 to -0.0494)	
Week 8	-0.0781 (-0.1498 to -0.0064)	-0.1711 (-0.2423 to -0.0999)	-0.1907 (-0.2619 to -0.1194)	
Week 12	-0.1013 (-0.1783 to -0.0243)	-0.2174 (-0.2938 to -0.1410)	-0.3209 (-0.3973 to -0.2444)	
Week 16	-0.1131 (-0.1955 to -0.0307)	-0.2620 (-0.3438 to -0.1802)	-0.3393 (-0.4211 to -0.2575)	
Week 20	-0.1079 (-0.1935 to -0.0223)	-0.3293 (-0.4143 to -0.2443)	-0.3708 (-0.4558 to -0.2858)	
Week 24	-0.0743 (-0.1605 to -0.0119)	-0.3225 (-0.4082 to -0.2369)	-0.3968 (-0.4825 to -0.3112)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a Clinically Meaningful Improvement (>=0.35 improvement from baseline) in HAQ-DI Score by Visit Over Time Through Week 24 Among Subjects With HAQ-DI score >=0.35 at Baseline

End point title	Percentage of Subjects who Achieved a Clinically Meaningful Improvement (>=0.35 improvement from baseline) in HAQ-DI Score by Visit Over Time Through Week 24 Among Subjects With HAQ-DI score >=0.35 at Baseline

End point description:

HAQ-DI is 20 question instrument that assess 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=no difficulty, to 3=inability to perform task. Total HAQ score is average of computed categories scores ranging from 0-3, where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning. Negative change from baseline indicates improvement of physical function and decrease of 0.35 from baseline in HAQDI score indicates a meaningful improvement. FAS1 among the subjects with HAQ-DI Score >=0.35 at baseline. Subjects with HAQ-DI >=0.35 improvement from baseline at specific timepoint and did not meet any TF criteria before, considered responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	110	112	110	
Units: percentage of subjects				
number (not applicable)				
Week 4	20.0	26.8	30.9	
Week 8	25.5	40.2	38.2	
Week 12	27.3	45.5	51.8	
Week 16	30.9	46.4	57.3	
Week 20	28.2	50.9	56.4	
Week 24	29.1	50.9	57.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a DAS28 (CRP) Response by Visit Over Time Through Week 24

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Response by Visit Over Time Through Week 24

End point description:

DAS28 based on CRP is an index combining TJC(28 joints), SJC(28 joints), CRP and PtGA of disease activity. Set of 28 joint count is based on evaluation of shoulder, elbow, wrist, MCP1 to MCP5, PIP1 to PIP5 joints of both upper right and left extremity as well as knee joints of lower right and left extremities. DAS28(CRP) response criteria defined as follows: Good response: <=3.2 at visit and >1.2 improvement; Moderate response: >3.2 at visit and >1.2 improvement or <=5.1 at visit and >0.6-1.2 improvement; No response: <=0.6 improvement, or >5.1 at visit and <=1.2 improvement. The values are 0=best to 10=worst. DAS28(CRP) responder defined as achieving good or moderate DAS28 response at specific visit. Analysis population is FAS1. Subjects who achieved DAS28(CRP) response at specific timepoint and did not meet TF criteria before considered as responders at that timepoint. Subjects who met 1/more TF criteria before or with missing data at that time point considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	27.0	33.1	40.6	
Week 8	35.7	59.1	54.7	
Week 12	41.3	67.7	74.2	
Week 16	44.4	65.4	73.4	
Week 20	46.0	66.1	75.0	
Week 24	44.4	70.9	76.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a DAS28 (CRP) Remission by Visit Over Time Through Week 24

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Remission by Visit Over Time Through Week 24

End point description:

DAS28 based on CRP is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. The values are 0=best to 10=worst. DAS 28 (CRP) remission was defined as DAS 28 (CRP) value <2.6 at the analysis visit. Analysis population is FAS1. Subjects who achieved DAS28 (CRP) remission at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	3.2	7.9	7.8	
Week 8	7.9	11.0	11.7	
Week 12	9.5	22.0	21.9	
Week 16	7.9	19.7	25.0	
Week 20	17.5	25.2	36.7	
Week 24	12.7	23.6	35.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (CRP) Score at Weeks 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in DAS28 (CRP) Score at Weeks 4, 8, 12, 16, 20 and 24

End point description:

DAS28 based on CRP is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. The values are 0=best to 10=worst. Negative change from baseline indicates improvement of arthritis. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 4	-0.35 (-0.48 to -0.22)	-0.53 (-0.67 to -0.40)	-0.56 (-0.69 to -0.43)	
Week 8	-0.55 (-0.71 to -0.39)	-0.83 (-0.99 to -0.67)	-0.88 (-1.04 to -0.72)	
Week 12	-0.63 (-0.80 to -0.47)	-1.16 (-1.33 to -0.99)	-1.23 (-1.39 to -1.06)	
Week 16	-0.64 (-0.82 to -0.46)	-1.19 (-1.37 to -1.01)	-1.38 (-1.56 to -1.20)	
Week 20	-0.80 (-1.00 to -0.60)	-1.38 (-1.58 to -1.19)	-1.56 (-1.76 to -1.37)	
Week 24	-0.70 (-0.89 to -0.51)	-1.43 (-1.61 to -1.24)	-1.61 (-1.80 to -1.42)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) by Visit Over Time Through Week 24

End point title	Percentage of Subjects Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) by Visit Over Time Through Week 24

End point description:

The modified PsARC response was defined as improvement in at least 2 of the four criteria: >=30% decrease in swollen joint count, >=30% decrease in tender joint count, >=20% improvement in patient’s Global Assessment of Disease Activity (arthritis) using VAS (0-100 mm, 0=excellent and 100= poor), >=20% improvement in physician’s Global Assessment of Disease Activity using VAS (VAS: 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), and at least one of the 2 joint criteria with no deterioration in the other criteria. Analysis population is FAS1. Subjects who achieved a modified PsARC response at a specific time point and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 4	20.6	29.1	33.6	
Week 8	32.5	56.7	48.4	
Week 12	41.3	58.3	66.4	
Week 16	36.5	64.6	68.0	
Week 20	41.3	66.1	75.8	
Week 24	31.0	59.8	72.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Resolution of Enthesitis at Weeks 4, 8, 16, and 24 Among the Subjects With Enthesitis at Baseline

End point title	Percentage of Subjects who Achieved Resolution of Enthesitis at Weeks 4, 8, 16, and 24 Among the Subjects With Enthesitis at Baseline

End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). A LEI score of 0 at a post baseline visit indicates resolution of enthesitis when baseline LEI>0. FAS1 among the subjects with enthesitis at baseline. Subjects who achieved enthesitis resolution at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 16, and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	73	
Units: percentage of subjects				
number (not applicable)				
Week 4	22.1	18.1	27.4	
Week 8	23.4	30.6	30.1	

Week 16	37.7	34.7	45.2	
Week 24	27.3	40.3	47.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Enthesitis Score at Weeks 4, 8, 16 and 24 Among the Subjects with Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score at Weeks 4, 8, 16 and 24 Among the Subjects with Enthesitis at Baseline

End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). Negative changes from baseline indicate improvement of enthesitis. Analysis population is FAS1 among the subjects with enthesitis at baseline. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	73	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 4	-0.37 (-0.69 to -0.05)	-0.45 (-0.78 to -0.11)	-0.96 (-1.30 to -0.62)	
Week 8	-0.65 (-1.00 to -0.31)	-0.83 (-1.19 to -0.47)	-1.11 (-1.48 to -0.74)	
Week 16	-0.99 (-1.36 to -0.61)	-1.00 (-1.39 to -0.61)	-1.51 (-1.90 to -1.11)	
Week 24	-1.01 (-1.37 to -0.66)	-1.35 (-1.72 to -0.98)	-1.75 (-2.13 to -1.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Resolution of Dactylitis by Visit Over Time Through Week 24 Among the Subjects With Dactylitis at Baseline

End point title	Percentage of Subjects With Resolution of Dactylitis by Visit Over Time Through Week 24 Among the Subjects With

	Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. Higher score indicates more severe dactylitis. Resolution of dactylitis was defined as a dactylitis score of 0 with the baseline dactylitis score >0. FAS1 among the subjects with dactylitis at baseline. Subjects who achieved dactylitis resolution at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	49	38	
Units: percentage of subjects				
number (not applicable)				
Week 4	41.8	34.7	31.6	
Week 8	41.8	40.8	44.7	
Week 16	43.6	59.2	57.9	
Week 24	49.1	65.3	63.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Score at Weeks 4, 8, 16 and 24 Among the Subjects With Dactylitis at Baseline

End point title	Change From Baseline in Dactylitis Score at Weeks 4, 8, 16 and 24 Among the Subjects With Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. A higher score indicates more severe dactylitis. Negative changes from baseline indicate improvement in dactylitis. Analysis population is FAS1 among the subjects with dactylitis at baseline. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	49	38	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 4	-2.77 (-4.24 to -1.30)	-2.24 (-3.76 to -0.72)	-2.63 (-4.39 to -0.86)	
Week 8	-2.92 (-4.58 to -1.26)	-4.00 (-5.72 to -2.29)	-3.92 (-5.90 to -1.93)	
Week 16	-4.03 (-5.76 to -2.30)	-6.00 (-7.79 to -4.22)	-6.29 (-8.36 to -4.22)	
Week 24	-4.30 (-5.96 to -2.63)	-6.11 (-7.81 to -4.41)	-5.82 (-7.82 to -3.83)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Psoriatic Arthritis Disease Activity (PASDAS) Score at Weeks 8, 16 and 24

End point title	Change from Baseline in the Psoriatic Arthritis Disease Activity (PASDAS) Score at Weeks 8, 16 and 24

End point description:

PASDAS (score range of 0 to 10, where higher score indicated more severe disease) is a compositive score of overall disease activity combining PtGA of Disease Activity (arthritis and psoriasis, using VAS), PGA of Disease Activity using VAS, SJC (0-66 joints), TJC (0-68 joints), CRP (mg/L), enthesitis based on LEI (0–6), tender dactylitis count (scoring each digit from 0-3 and recoding to 0-1, where any score >0 equaled 1), and the PCS score of the SF-36 health survey. Cutoffs for disease activity were 3.2 (low) to 5.4 (high). Negative changes from baseline indicate improvement of overall disease activity. Analysis population is FAS1. Data after meeting 1/more TF criteria were imputed as no change from baseline. Missing data assumed to be MAR. The LS mean is based on Mixed-effect repeated measures (MMRM) model that included data from all visits for all subjects included in model.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	-0.759 (-0.961 to -0.556)	-1.315 (-1.518 to -1.113)	-1.428 (-1.628 to -1.228)	
Week 16	-0.980 (-1.221 to -0.739)	-1.779 (-2.019 to -1.539)	-2.083 (-2.322 to -1.843)	
Week 24	-0.959 (-1.212 to -0.707)	-2.124 (-2.376 to -1.871)	-2.407 (-2.657 to -2.156)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score at Weeks 16 and 24

End point title	Change From Baseline in Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score at Weeks 16 and 24

End point description:

GRACE index: composite PsA disease activity score converted from Arithmetic Mean of Desirability Function derived from TJC(0-68) and SJC(0-66), HAQ-DI (0-3), PtGA of disease activity on arthritis and psoriasis (0-100mm, 0=excellent and 100=poor), patient's assessment of skin disease activity (0-100mm, 0=excellent and 100=poor), PtGA of disease activity on arthritis(0-100mm, 0=excellent and 100=poor), PASI(0-72), and PsA Quality of Life Index (PsAQOL=25.355+[2.367*HAQ-DI]-[0.234*SF-PCS]-[0.244*SF-MCS]), Total score: 0-10, lower score=better response. Higher score: more active disease activity. Negative change from baseline indicates improvement of PsA disease activity. FAS1 where data after meeting 1/more TF criteria were imputed as no change from baseline. Missing data assumed to be MAR. LS mean based on MMRM model that included data from all visits for all subjects included in model. n= number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	-0.918 (-1.176 to -0.659)	-2.024 (-2.283 to -1.765)	-2.368 (-2.625 to -2.111)	
Week 24	-0.854 (-1.122 to -0.586)	-2.368 (-2.636 to -2.099)	-2.735 (-3.001 to -2.468)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Disease Activity Index for Psoriatic Arthritis (DAPSA) Score at Weeks 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in the Disease Activity Index for Psoriatic Arthritis (DAPSA) Score at Weeks 4, 8, 12, 16, 20 and 24

End point description:

DAPSA assessed the joint domain of psoriatic arthritis (PsA) and was derived from the sum of the following components: tender joint count (0–68), swollen joint count (0–66), CRP level (mg/dL, value <lower limit of quantification [LLOQ] is considered equal to half of the value of LLOQ for numerical calculations), patient assessment of pain (0–10 centimeter [cm] VAS, 0=no pain, 10=worst possible pain), and patient's global assessment of disease activity on arthritis (0 to 10 cm VAS, 0=excellent and 10=poor). A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. The assessment does not have a score range with an upper or lower bound. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR. The LS mean is based on MMRM model that included data from all visits for all subjects included in the model.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 4	-4.826 (-6.901 to -2.752)	-7.815 (-9.926 to -5.705)	-8.574 (-10.636 to -6.511)	
Week 8	-8.776 (-11.307 to -6.246)	-13.601 (-16.118 to -11.084)	-13.231 (-15.731 to -10.732)	
Week 12	-10.135 (-12.670 to -7.599)	-18.167 (-20.704 to -15.631)	-17.433 (-19.949 to -14.918)	
Week 16	-9.964 (-12.568 to -7.359)	-19.830 (-22.426 to -17.234)	-19.389 (-21.977 to -16.802)	
Week 20	-11.552 (-14.228 to -8.876)	-20.570 (-23.248 to -17.891)	-21.244 (-23.903 to -18.586)	
Week 24	-10.749 (-13.396 to -8.102)	-21.332 (-23.977 to -18.688)	-20.621 (-23.251 to -17.992)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

MDA was considered achieved if at least 5 of the following 7 criteria were met at the analysis visit: tender joint count less than or equal to (<=) 1; swollen joint count <=1; psoriasis activity and severity index <=1; patient's assessment of pain VAS score of <=15; patient's global assessment of disease activity VAS (arthritis and psoriasis) score of <=20; HAQ-DI <=0.5; and tender entheseal points <=1. Analysis population is FAS1. Subjects who achieved MDA at a specific timepoint and did not meet any TF

criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 16	7.1	15.7	18.0	
Week 24	11.1	22.8	30.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement from Baseline in BASDAI Score Through Week 24 Among the Subjects With Spondylitis and Peripheral Arthritis and BASDAI Score >0 at Baseline

End point title	Percentage of Subjects who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement from Baseline in BASDAI Score Through Week 24 Among the Subjects With Spondylitis and Peripheral Arthritis and BASDAI Score >0 at Baseline

End point description:

BASDAI is selfassessment tool with 6 questions relating to 5 major symptoms of ankylosing spondylitis: fatigue, spinal pain, joint pain, enthesitis, qualitative and quantitative morning stiffness. First 5 items scored on 10 centimeter(cm) VAS. Quantitative morning stiffness scored on 10cm VAS ranging from 0=0 hours to 10=2/more hours. The 2 scores for qualitative and quantitative morning stiffness were averaged, and total BASDAI score was average of 5 scores of each symptom, ranging from 0=none to 10=very severe. Higher scores indicate greater disease severity and improvement of 50% from baseline considered clinically meaningful. FAS1 with spondylitis and peripheral arthritis and BASDAI score >0 at baseline. Subjects with specified improvement in BASDAI at specific time point and did not meet TF criteria before, considered responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	24	20	
Units: percentage of subjects				
number (not applicable)				

Week 8: Subjects with >=20% Improvement	26.1	58.3	55.0	
Week 16: Subjects with >=20% Improvement	52.2	75.0	65.0	
Week 24: Subjects with >=20% Improvement	26.1	70.8	65.0	
Week 8: Subjects with >=50% Improvement	4.3	25.0	25.0	
Week 16: Subjects with >=50% Improvement	26.1	29.2	35.0	
Week 24: Subjects with >=50% Improvement	13.0	41.7	35.0	
Week 8: Subjects with >=70% Improvement	4.3	4.2	15.0	
Week 16: Subjects with >=70% Improvement	8.7	25.0	15.0	
Week 24: Subjects with >=70% Improvement	8.7	29.2	5.0	
Week 8: Subjects with >=90% Improvement	0	0	0	
Week 16: Subjects with >=90% Improvement	0	8.3	10.0	
Week 24: Subjects with >=90% Improvement	0	16.7	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score at Week 8, 16, and Week 24 Among Subjects with Spondylitis and Peripheral Arthritis at Baseline

End point title	Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score at Week 8, 16, and Week 24 Among Subjects with Spondylitis and Peripheral Arthritis at Baseline

End point description:

BASDAI is a tool with 6 questions relating to 5 major symptoms of ankylosing spondylitis: fatigue, spinal pain, joint pain, enthesitis, qualitative and quantitative morning stiffness. First 5 items scored on 10 cm VAS ranging from 0=none to 10=very severe. Quantitative morning stiffness scored on 10cm VAS ranging from 0=0 hours to 10=2/more hours. The 2 scores for qualitative and quantitative morning stiffness were averaged, and total BASDAI score was average of 5 scores of each symptom, ranging from 0=none to 10=very severe. Higher scores indicate greater disease severity and an improvement of 50% from baseline considered clinically meaningful. Analysis population is FAS1 among subjects with spondylitis and peripheral arthritis at baseline. Data after meeting 1/more TF criteria were imputed as no change from baseline. Missing data assumed to be MAR. The LS mean based on MMRM model that included data from all visits for all subjects included in model.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16, and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	24	20	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	-0.595 (-1.351 to -0.162)	-1.577 (-2.296 to -0.859)	-1.976 (-2.779 to -1.174)	
Week 16	-1.604 (-2.483 to -0.725)	-2.419 (-3.261 to -1.577)	-2.469 (-3.405 to -1.533)	
Week 24	-0.919 (-1.795 to -0.043)	-2.665 (-3.503 to -1.826)	-2.074 (-3.006 to -1.142)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with low or very low Disease Activity Based on Psoriatic Arthritis Disease Activity Score (PASDAS) by Visit Over Time Through Week 24

End point title	Percentage of Subjects with low or very low Disease Activity Based on Psoriatic Arthritis Disease Activity Score (PASDAS) by Visit Over Time Through Week 24

End point description:

PASDAS (score range of 0-10, where higher score indicated more severe disease) is a compositive score of overall disease activity combining PtGA of Disease Activity (arthritis and psoriasis, using VAS [0-100 mm, 0=excellent and 100=poor]), PGA of Disease Activity (using VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), SJC (0-66 joints), TJC (0-68 joints), CRP (mg/L), enthesitis based on LEI (0–6), tender dactylitis count (scoring each digit from 0–3 and recoding to 0–1, where any score > 0 equaled 1), and the PCS score of the SF-36 health survey. The cutoffs for disease activity were 3.2 (low) to 5.4 (high). Analysis population is FAS1. Subjects with low or very low disease activity at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8	4.0	10.2	14.8	
Week 16	8.7	22.0	27.3	
Week 24	11.1	30.7	36.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with low Disease Activity Based on Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score Index by Visit Over Time Through Week 24

End point title	Percentage of Subjects with low Disease Activity Based on Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score Index by Visit Over Time Through Week 24

End point description:

GRACE index is composite PsA disease activity score converted from AMDF, which was derived from TJC(0-68) and SJC(0-66), HAQ-DI(0-3), PtGA of disease activity on arthritis and psoriasis (0-100mm, 0=excellent and 100=poor), patient's assessment of skin disease activity (0-100mm, 0=excellent and 100=poor), PtGA of disease activity on arthritis (0-100mm, 0=excellent and 100=poor), PASI (0-72), and PsA Quality of Life Index (derived as PsAQOL =25.355+[2.367*HAQ-DI]–[0.234*SF-PCS]–[0.244*SF-MCS]), Total score from 0-10, where lower score=better response. Higher score=more active disease activity. Analysis population is FAS1. Subjects with low disease activity at specific timepoint and did not meet any TF criteria before, considered as responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 16	10.3	22.0	28.9	
Week 24	11.9	30.7	42.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with low Disease Activity or Remission Based on Disease Activity Index for Psoriatic Arthritis (DAPSA) by Visit Over Time Through Week 24

End point title	Percentage of Subjects with low Disease Activity or Remission Based on Disease Activity Index for Psoriatic Arthritis (DAPSA) by Visit Over Time Through Week 24

End point description:

DAPSA assessed the joint domain of PsA and was derived from the sum of the following components: tender joint count (0–68), swollen joint count (0–66), CRP level (mg/dL), patient assessment of pain (0–10 cm VAS, 0=no pain, 10=worst possible pain), and patient's global assessment of disease activity on arthritis (0 to 10 cm VAS, 0=excellent and 10=poor). A higher score indicates more active disease activity. The assessment does not have a score range with an upper or lower bound. Analysis population is FAS1. Subjects with low disease activity or remission at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

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

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Baseline	1.6	2.4	0.8	
Week 4	10.3	8.7	13.3	
Week 8	13.5	17.3	25.0	
Week 12	18.3	27.6	37.5	
Week 16	13.5	29.9	36.7	
Week 20	22.2	37.8	46.1	
Week 24	16.7	40.9	49.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Very low Disease Activity (VLDA) by Visit Over Time Through Week 24

End point title	Percentage of Subjects with Very low Disease Activity (VLDA) by Visit Over Time Through Week 24

End point description:

A measurement that defines a satisfactory state of disease activity that includes the 5 domains of PsA (joint symptoms, skin psoriasis, patient's perspective of pain and disease activity, physical function, and enthesitis). A subject was considered as having achieved VLDA at a visit if the subject fulfilled all 7 criteria (tender joint count <=1; swollen joint count <=1; PASI <=1; patient pain VAS score of <=15; patient global disease activity VAS [arthritis and psoriasis] score of <=20; Health Assessment Questionnaire (HAQ) score <=0.5; and tender entheseal points <=1) at that visit. Analysis population is FAS1. Subjects who achieved VLDA response at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 16	2.4	3.1	3.1	

Week 24	1.6	3.9	9.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 75 Response at Weeks 16 and 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 75 Response at Weeks 16 and 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severtiy. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. A PASI 75 response: >=75% improvement in PASI score from baseline. FAS1 among subjects with >=3% BSA of psoriasis and IGA score >=2 at baseline. Subjects with PASI 75 response at specific time point and did not meet any TF criteria before, were considered responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point were considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	20.5	63.4	73.0	
Week 24	14.1	75.6	86.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 90 Response at Weeks 16 and 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 90 Response at Weeks 16 and 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severtiy. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. A PASI 90 response: >=90% improvement in PASI score from baseline. FAS1 among subjects with >=3% BSA of psoriasis and IGA score >=2 at baseline. Subjects with PASI 90 response at specific time point and did not meet any TF criteria before, were considered responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	10.3	45.1	52.8	
Week 24	11.5	50.0	62.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 100 Response by Visit Over Time Through Week 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 100 Response by Visit Over Time Through Week 24 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severtiy. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. A PASI 100 response: 100% improvement in PASI score from baseline. FAS1 among subjects with >=3% BSA of psoriasis and IGA score >=2 at baseline. Subjects with PASI 100 response at specific time point and did not meet any TF criteria before, were considered responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point were considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	7.7	23.2	32.6	
Week 24	6.4	25.6	44.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved both PASI 75 and ACR 20 Responses at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point title	Percentage of Subjects who Achieved both PASI 75 and ACR 20 Responses at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point description:

In PASI, each area (head, trunk, upper/lower extremities) assessed for % of area involved and translated to numeric score from 0(no involvement) to 6(90-100% involvement) and for erythema, induration, and scaling, each rated on scale of 0-4 that is none to maximum severtiy. PASI produces numeric score from 0-72. Higher scores=more severe disease. PASI 75: >=75% improvement in PASI score from baseline. FAS1 subjects with >=3% BSA psoriatic involvement and IGA score >=2 at baseline. Subjects with both PASI75 and ACR20 responses at specific timepoint and did not meet TF criteria before, considered responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	6.4	35.4	48.3	
Week 24	6.4	40.2	52.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved both PASI 75 and Modified PsARC Response by visit over time Through Week 24 Among Subjects with >=3% BSA

Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point title	Percentage of Subjects who Achieved both PASI 75 and Modified PsARC Response by visit over time Through Week 24 Among Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point description:

In PASI, each area (head, trunk, upper and lower extremities) was assessed separately for % of area involved and translated to numeric score ranging from 0(no involvement) to 6(90-100% involvement), and for erythema, induration, and scaling, each rated on scale of 0-4 that is none to maximum severtiy. PASI produces numeric score range 0-72. Higher scores=more severe disease. PASI 75 response: >=75% improvement in PASI score from baseline. FAS1 with >=3% BSA psoriatic involvement and IGA score >=2 at baseline. Subjects with both PASI 75 and modified PsARC responses at specific timepoint and did not meet TF criteria before, considered responders at that time point. Subjects who met 1/more TF criteria before or with missing data at that time point considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	9.0	48.8	55.1	
Week 24	5.1	50.0	62.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with an IGA Score of 0 (Cleared) at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA score of >=2 (mild) at Baseline

End point title	Percentage of Subjects with an IGA Score of 0 (Cleared) at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA score of >=2 (mild) at Baseline

End point description:

The IGA documents the investigator’s assessment of the patient’s psoriasis and lesions are graded for induration, erythema and scaling, each using a 5 point scale: 0 (no evidence), 1 (minimal), 2 (mild), 3 (moderate), and 4 (severe). The IGA score of psoriasis was based upon the average of induration, erythema and scaling scores. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Subjects who achieved IGA Score of 0 (cleared) at a specific timepoint and did not meet any TF criteria before, were considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point were considered as non-responders. Analysis population is FAS1 among subjects with >=3% BSA psoriatic involvement and an IGA score of >=2 at baseline.

End point type	Secondary

End point timeframe:

Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: percentage of subjects				
number (not applicable)				
Week 16	9.0	32.9	40.4	
Week 24	7.7	37.8	53.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Score at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point title	Change From Baseline in PASI Score at Weeks 16 and 24 Among the Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severtiy. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. Negative change from baseline indicates improvement of psoriasis. Analysis population is FAS1 among subjects who had >=3% BSA of psoriatic involvement and IGA score >=2 (mild) at baseline. Data after meeting one/more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR. LS mean is based on MMRM model that included data from all visits for all subjects included in model.

End point type	Secondary

End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	82	89	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	-2.910 (-4.207 to -1.612)	-9.631 (-10.881 to -8.381)	-10.096 (-11.318 to -8.874)	
Week 24	-2.317 (-3.709 to -0.926)	-9.974 (-11.323 to -8.624)	-10.915 (-12.224 to -9.605)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) at Weeks 8, 16 and 24

End point title	Change From Baseline in 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) at Weeks 8, 16 and 24

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The PCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	2.15 (1.06 to 3.23)	2.87 (1.80 to 3.95)	4.46 (3.39 to 5.54)	
Week 16	2.50 (1.31 to 3.69)	5.26 (4.08 to 6.43)	6.72 (5.54 to 7.89)	
Week 24	1.96 (0.69 to 3.24)	6.10 (4.83 to 7.37)	6.87 (5.60 to 8.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in 36-Item Short Form Health Survey (SF-36) Mental Component Summary (MCS) at Weeks 8, 16 and 24

End point title	Change From Baseline in 36-Item Short Form Health Survey

	(SF-36) Mental Component Summary (MCS) at Weeks 8, 16 and 24

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The MCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	1.99 (0.73 to 3.24)	2.72 (1.47 to 3.97)	2.46 (1.22 to 3.71)	
Week 16	2.25 (0.87 to 3.63)	2.61 (1.25 to 3.98)	3.04 (1.68 to 4.41)	
Week 24	2.37 (0.93 to 3.81)	3.20 (1.78 to 4.63)	3.60 (2.17 to 5.02)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 8, 16 and 24

End point title	Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 8, 16 and 24

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales: physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. The scores 0-100 (where higher scores indicated a better quality of life) from each subscale of SF-36 were normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better health status. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR. The LS mean is based on MMRM model that included data from all visits for all subjects included in the model.

End point type	Secondary

End point timeframe:

Baseline, Week 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8: Physical Function Score	1.362 (0.201 to 2.524)	2.616 (1.456 to 3.777)	4.082 (2.927 to 5.237)	
Week 16: Physical Function Score	1.901 (0.603 to 3.199)	5.143 (3.851 to 6.434)	6.190 (4.902 to 7.478)	
Week 24: Physical Function Score	1.636 (0.249 to 3.023)	5.776 (4.394 to 7.158)	6.952 (5.571 to 8.333)	
Week 8: Role-physical Score	2.212 (1.104 to 3.321)	2.084 (0.978 to 3.190)	3.834 (2.730 to 4.938)	
Week 16: Role-physical Score	2.242 (1.037 to 3.447)	4.224 (3.027 to 5.422)	5.447 (4.250 to 6.644)	
Week 24: Role-physical Score	2.319 (1.063 to 3.576)	4.878 (3.627 to 6.130)	5.442 (4.189 to 6.694)	
Week 8: Bodily Pain Score	3.081 (1.876 to 4.286)	3.886 (2.682 to 5.089)	5.140 (3.941 to 6.338)	
Week 16: Bodily Pain Score	3.125 (1.859 to 4.391)	5.059 (3.800 to 6.318)	6.778 (5.521 to 8.035)	
Week 24: Bodily Pain Score	2.854 (1.468 to 4.240)	6.840 (5.459 to 8.221)	7.490 (6.110 to 8.871)	
Week 8: General Health Score	1.989 (0.806 to 3.172)	3.071 (1.890 to 4.252)	3.486 (2.309 to 4.663)	
Week 16: General Health Score	1.683 (0.492 to 2.874)	3.769 (2.585 to 4.953)	5.225 (4.042 to 6.408)	
Week 24: General Health Score	1.690 (0.510 to 2.869)	4.349 (3.175 to 5.524)	5.174 (3.998 to 6.349)	
Week 8: Vitality Score	2.312 (1.081 to 3.542)	3.917 (2.689 to 5.144)	4.614 (3.389 to 5.838)	
Week 16: Vitality Score	3.084 (1.720 to 4.449)	4.777 (3.422 to 6.133)	5.589 (4.234 to 6.943)	
Week 24: Vitality Score	2.311 (0.881 to 3.742)	5.596 (4.172 to 7.020)	6.426 (5.000 to 7.852)	
Week 8: Social Function Score	2.025 (0.643 to 3.407)	3.287 (1.907 to 4.667)	3.798 (2.423 to 5.173)	
Week 16: Social Function Score	2.455 (1.020 to 3.890)	3.531 (2.105 to 4.957)	4.817 (3.392 to 6.241)	
Week 24: Social Function Score	2.582 (1.240 to 3.924)	5.426 (4.089 to 6.762)	5.227 (3.889 to 6.564)	
Week 8: Role-emotional Score	1.980 (0.615 to 3.345)	2.237 (0.877 to 3.598)	1.987 (0.631 to 3.343)	
Week 16: Role-emotional Score	1.784 (0.316 to 3.253)	2.496 (1.040 to 3.953)	3.265 (1.810 to 4.720)	
Week 24: Role-emotional Score	2.201 (0.753 to 3.649)	2.415 (0.976 to 3.853)	3.531 (2.090 to 4.972)	
Week 8: Mental Health Score	2.124 (0.901 to 3.348)	2.574 (1.358 to 3.790)	3.126 (1.914 to 4.339)	
Week 16: Mental Health Score	2.360 (1.058 to 3.662)	3.489 (2.200 to 4.777)	3.984 (2.696 to 5.272)	
Week 24: Mental Health Score	2.062 (0.658 to 3.466)	3.818 (2.425 to 5.211)	4.356 (2.961 to 5.751)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved >=5-point Improvement from Baseline in SF-36 MCS Score by Visit Over Time Through Week 24

End point title	Percentage of Subjects who Achieved >=5-point Improvement from Baseline in SF-36 MCS Score by Visit Over Time Through Week 24

End point description:

SF-36 is multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded PCS with score range 0-100 (higher score-better quality of life) and MCS with score range 0-100 (higher score-better quality of life) in addition to subscale scores. MCS scores normalized to mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better outcome, with an increase of 5 points considered to be clinically meaningful. FAS1 with subjects who achieved >=5-point improvement from baseline in SF-36 MCS score at specific time point and did not meet any TF criteria before, considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8	27.0	33.9	35.2	
Week 16	31.0	32.3	39.8	
Week 24	25.4	37.8	43.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 PCS Score Through Week 24

End point title	Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 PCS Score Through Week 24

End point description:

SF-36 is multi-domain instrument with 36 items to evaluate health status and quality of life. It included

8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a PCS with score range 0-100 (higher score-better quality of life) and a MCS with score range 0-100 (higher scorebetter quality of life) in addition to subscale scores. The PCS scores normalized to mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better outcome, with increase of 5 points considered to be clinically meaningful. FAS1 with subjects who achieved >=5-point improvement from baseline in SF-36 PCS score at specific time point and did not meet any TF criteria before, considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8	31.0	33.9	46.1	
Week 16	29.4	48.0	50.0	
Week 24	28.6	51.2	53.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 8, 16, and 24

End point title	Change from Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 8, 16, and 24

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. The subscale consists 13-item instrument to measure fatigue. Each of the 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as the sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with a higher score indicating less fatigue. Positive changes from baseline indicate improvement of fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR. The LS mean is based on MMRM model that included data from all visits for all subjects included in the model.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	2.356 (1.081 to 3.632)	3.643 (2.369 to 4.917)	3.576 (2.306 to 4.845)	
Week 16	2.164 (0.782 to 3.547)	4.853 (3.478 to 6.228)	4.544 (3.171 to 5.918)	
Week 24	2.206 (0.773 to 3.638)	5.609 (4.181 to 7.036)	5.841 (4.416 to 7.267)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=4-point Improvement from Baseline in FACIT-Fatigue Score at Weeks 8, 16, and 24

End point title	Percentage of Subjects Who Achieved >=4-point Improvement from Baseline in FACIT-Fatigue Score at Weeks 8, 16, and 24

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. Subscale consists 13-item instrument to measure fatigue. Each of 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as the sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with higher score indicating less fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS1. Subjects who achieved >=4-point improvement from baseline in FACIT-fatigue score at specific time point and did not meet any TF criteria before, considered responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point considered non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16, and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8 (n=126, 127, 125)	35.7	44.1	43.8	
Week 16 (n=107, 119, 121)	34.1	50.4	52.3	
Week 24 (n=104, 114, 124)	34.9	53.5	63.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS)-29 Scores at Weeks 8, 16 and 24

End point title	Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS)-29 Scores at Weeks 8, 16 and 24

End point description:

PROMIS-29 contains 4 items for each of seven PROMIS domains (Anxiety, Depression, Fatigue, Pain Interference, Physical Function, Sleep Disturbance, and Satisfaction-Social Role and Activity. PROMIS-29 also includes an additional pain intensity 0-10 numeric rating scale (NRS). The raw score of each domain is converted into a standardized score with a mean of 50 and a standard deviation (SD) of 10 for the general population in the US (T-Score). Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Missing data were assumed to be MAR. The LS mean is based on MMRM model that included data from all visits for all subjects included in the model.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: T-score				
least squares mean (confidence interval 95%)				
Week 8: Anxiety	-1.98 (-3.29 to -0.66)	-2.19 (-3.50 to -0.88)	-1.83 (-3.14 to -0.53)	
Week 16: Anxiety	-2.30 (-3.63 to -0.97)	-3.08 (-4.40 to -1.75)	-2.23 (-3.54 to -0.91)	
Week 24: Anxiety	-1.37 (-2.71 to -0.03)	-3.23 (-4.57 to -1.89)	-2.92 (-4.25 to -1.59)	
Week 8: Depression	-0.86 (-2.07 to 0.35)	-2.42 (-3.63 to -1.21)	-1.54 (-2.74 to -0.34)	
Week 16: Depression	-0.85 (-2.02 to 0.31)	-2.70 (-3.87 to -1.54)	-2.69 (-3.85 to -1.54)	
Week 24: Depression	-0.85 (-2.12 to 0.42)	-3.40 (-4.66 to -2.14)	-2.67 (-3.92 to -1.41)	
Week 8: Fatigue	-1.87 (-3.13 to -0.62)	-3.25 (-4.50 to -1.99)	-2.90 (-4.14 to -1.65)	
Week 16: Fatigue	-2.29 (-3.57 to -1.02)	-4.26 (-5.53 to -2.99)	-4.14 (-5.40 to -2.88)	
Week 24: Fatigue	-1.86 (-3.24 to -0.48)	-4.79 (-6.16 to -3.42)	-5.08 (-6.45 to -3.71)	
Week 8: Pain Interference	-2.42 (-3.40 to -1.43)	-2.99 (-3.97 to -2.00)	-3.32 (-4.30 to -2.33)	
Week 16: Pain Interference	-2.62 (-3.69 to -1.55)	-3.99 (-5.06 to -2.93)	-5.02 (-6.08 to -3.96)	
Week 24: Pain Interference	-2.30 (-3.46 to -1.13)	-5.49 (-6.65 to -4.34)	-5.69 (-6.85 to -4.53)	
Week 8: Physical Function	1.34 (0.44 to 2.23)	1.31 (0.42 to 2.20)	2.37 (1.48 to 3.26)	
Week 16: Physical Function	1.53 (0.49 to 2.57)	3.21 (2.17 to 4.24)	4.12 (3.09 to 5.15)	
Week 24: Physical Function	1.34 (0.25 to 2.43)	3.89 (2.81 to 4.98)	5.05 (3.96 to 6.13)	

Week 8: Sleep Disturbance	-1.22 (-2.23 to -0.21)	-1.91 (-2.92 to -0.91)	-2.09 (-3.09 to -1.09)	
Week 16: Sleep Disturbance	-1.54 (-2.53 to -0.54)	-3.82 (-4.82 to -2.83)	-3.09 (-4.08 to -2.10)	
Week 24: Sleep Disturbance	-1.17 (-2.25 to -0.09)	-3.48 (-4.56 to -2.40)	-2.46 (-3.53 to -1.38)	
Week 8: Satisfaction-Social Role and Activity	1.52 (0.39 to 2.64)	3.13 (2.01 to 4.25)	3.18 (2.06 to 4.29)	
Week 16: Satisfaction-Social Role and Activity	1.86 (0.65 to 3.08)	3.93 (2.72 to 5.14)	3.97 (2.76 to 5.17)	
Week 24: Satisfaction-Social Role and Activity	1.45 (0.22 to 2.69)	4.90 (3.66 to 6.13)	4.52 (3.29 to 5.75)	
Week 8: Pain Intensity	-0.74 (-1.06 to -0.41)	-1.34 (-1.66 to -1.01)	-1.28 (-1.61 to -0.96)	
Week 16: Pain Intensity	-0.73 (-1.09 to -0.37)	-1.63 (-1.98 to -1.27)	-2.03 (-2.38 to -1.67)	
Week 24: Pain Intensity	-0.56 (-0.94 to -0.19)	-1.98 (-2.36 to -1.61)	-2.32 (-2.69 to -1.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in FACIT-Fatigue Score at Week 24 by ACR 20 response at Week 24

End point title	Change from Baseline in FACIT-Fatigue Score at Week 24 by ACR 20 response at Week 24

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. The subscale consists 13-item instrument to measure fatigue. Each of the 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as the sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with a higher score indicating less fatigue. Positive changes from baseline indicate improvement of fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS1. Data after meeting one or more TF criteria were imputed as no change from baseline. Here, n (number analyzed) signifies the number of subjects who were ACR 20 responders or non-responders at Week 24.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: units on a scale				
arithmetic mean (standard deviation)				
Among ACR 20 responders (n=28, 66, 76)	8.571 (± 7.8995)	9.242 (± 10.8473)	6.684 (± 8.0948)	
Among ACR 20 non-responders (n=98, 61, 52)	0.316 (± 6.8181)	1.984 (± 7.8877)	3.635 (± 6.8170)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=4-point Improvement From Baseline in FACIT-Fatigue Score at Week 24 by ACR 20 Response at Week 24

End point title	Percentage of Subjects Who Achieved >=4-point Improvement From Baseline in FACIT-Fatigue Score at Week 24 by ACR 20 Response at Week 24

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. Subscale consists 13-item instrument to measure fatigue. Each of 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with higher score indicating less fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. FAS1. Subjects who achieved >=4-point improvement from baseline at Week 24 and did not meet any TF criteria before Week 24: responders. Subjects who met 1 or more TF criteria or with missing data: non-responders. Here, n (number analyzed) signifies the number of subjects who were ACR 20 responders or non-responders at Week 24.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Among ACR 20 responders (n=28, 66, 76)	67.9	68.2	73.7	
Among ACR 20 non-responders (n=98, 61, 52)	25.5	37.7	48.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved an Improvement of >=3 Points from Baseline in PROMIS-29 Domain Scores at Weeks 8, 16, and 24

End point title	Percentage of Subjects who Achieved an Improvement of >=3 Points from Baseline in PROMIS-29 Domain Scores at Weeks 8, 16, and 24

End point description:

PROMIS-29 contains 4 items for each of seven PROMIS domains (Anxiety, Depression, Fatigue, Pain Interference, Physical Function, Sleep Disturbance, and Satisfaction-Social Role and Activity. PROMIS-29 also includes an additional pain intensity 0-10 NRS. The raw score of each domain is converted into a standardized score with a mean of 50 and a SD of 10 for the general population in the US (T-Score). Analysis population is FAS1. Subjects who achieved >=3-point improvement from baseline in PROMIS-29 domain scores at a specific timepoint and did not meet any TF criteria before, considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point, considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16, and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8: Anxiety	41.3	41.7	39.1	
Week 16: Anxiety	-34.9	42.5	41.4	
Week 24: Anxiety	34.9	45.7	42.2	
Week 8: Depression	24.6	30.7	34.4	
Week 16: Depression	25.4	35.4	33.6	
Week 24: Depression	26.2	39.4	38.3	
Week 8: Fatigue	34.1	39.4	42.2	
Week 16: Fatigue	38.9	49.6	49.2	
Week 24: Fatigue	32.5	48.8	55.5	
Week 8: Pain Interference	34.9	41.7	43.8	
Week 16: Pain Interference	39.7	47.2	56.3	
Week 24: Pain Interference	33.3	54.3	57.0	
Week 8: Physical Function	28.6	30.7	40.6	
Week 16: Physical Function	28.6	44.1	45.3	
Week 24: Physical Function	22.2	48.0	53.9	
Week 8: Sleep Disturbance	35.7	38.6	39.1	
Week 16: Sleep Disturbance	36.5	48.8	38.3	
Week 24: Sleep Disturbance	31.0	48.8	40.6	
Week 8: Satisfaction-Social Role and Activity	35.7	44.9	49.2	
Week 16: Satisfaction-Social Role and Activity	37.3	46.5	46.1	
Week 24: Satisfaction-Social Role and Activity	32.5	52.0	50.0	
Week 8: Pain Intensity	15.1	22.8	26.6	
Week 16: Pain Intensity	18.3	33.1	42.2	
Week 24: Pain Intensity	15.1	37.0	45.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved an Improvement of >=5 points from Baseline in PROMIS-29 Domain Scores at Weeks 8, 16, and 24

End point title	Percentage of Subjects who Achieved an Improvement of >=5 points from Baseline in PROMIS-29 Domain Scores at Weeks 8, 16, and 24

End point description:

PROMIS-29 contains 4 items for each of seven PROMIS domains (Anxiety, Depression, Fatigue, Pain Interference, Physical Function, Sleep Disturbance, and Satisfaction-Social Role and Activity. PROMIS-29 also includes an additional pain intensity 0-10 NRS. The raw score of each domain is converted into a standardized score with a mean of 50 and a SD of 10 for the general population in the US (T-Score). Analysis population is FAS1. Subjects who achieved >=5-point improvement from baseline in PROMIS-29 domain scores at a specific timepoint and did not meet any TF criteria before, considered as responders at that time point. Subjects who met 1 or more TF criteria before or with missing data at that time point, considered as non-responders.

End point type	Secondary

End point timeframe:

Weeks 8, 16, and 24

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	127	128	
Units: percentage of subjects				
number (not applicable)				
Week 8: Anxiety	33.3	37.0	29.7	
Week 16: Anxiety	29.4	34.6	33.6	
Week 24: Anxiety	28.6	41.7	38.3	
Week 8: Depression	17.5	27.6	26.6	
Week 16: Depression	19.0	32.3	28.9	
Week 24: Depression	19.8	36.2	30.5	
Week 8: Fatigue	27.8	29.1	33.6	
Week 16: Fatigue	33.3	40.9	43.0	
Week 24: Fatigue	31.0	45.7	47.7	
Week 8: Pain Interference	22.2	29.9	35.9	
Week 16: Pain Interference	29.4	38.6	43.8	
Week 24: Pain Interference	23.8	46.5	51.6	
Week 8: Physical Function	15.1	18.9	22.7	
Week 16: Physical Function	18.3	26.8	32.8	
Week 24: Physical Function	15.9	36.2	39.8	
Week 8: Sleep Disturbance	24.6	24.4	27.3	
Week 16: Sleep Disturbance	24.6	40.2	30.5	
Week 24: Sleep Disturbance	21.4	37.0	32.8	
Week 8: Satisfaction-Social Role and Activity	25.4	40.2	38.3	
Week 16: Satisfaction-Social Role and Activity	30.2	42.5	39.8	
Week 24: Satisfaction-Social Role and Activity	22.2	45.7	43.0	
Week 8: Pain Intensity	5.6	6.3	6.3	
Week 16: Pain Intensity	6.3	8.7	14.8	

Week 24: Pain Intensity	4.0	18.1	18.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 20 Response at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects who Achieved ACR 20 Response at Weeks 24, 28, 36, 44 and 52

End point description:

ACR 20 response was defined as >=20% improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and >=20% improvement from baseline in 3 of the 5 assessments: patient's assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician's global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is full analysis set 2 (FAS2) included all randomized subjects who were still on study treatment at Week 24. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 123, 125)	27.2	54.5	60.8	
Week 28 (n=112, 122, 125)	50.0	68.9	74.4	
Week 36 (n=109, 118, 121)	56.9	70.3	71.1	
Week 44 (n=107, 117, 125)	61.7	73.5	72.0	
Week 52 (n=104, 112, 124)	68.3	67.9	75.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 50 Response at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects who Achieved ACR 50 Response at Weeks 24, 28, 36, 44 and 52

End point description:

ACR 50 response was defined as >=50% improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and >=50% improvement from baseline in 3 of the 5 assessments: patient’s assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), patient’s global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician’s global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 123, 125)	9.6	30.9	36.8	
Week 28 (n=112, 122, 125)	21.4	42.6	39.2	
Week 36 (n=110, 119, 121)	32.7	47.1	44.6	
Week 44 (n=107, 117, 124)	30.8	51.3	46.0	
Week 52 (n=104, 113, 124)	36.5	43.4	55.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 70 Response at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects who Achieved ACR 70 Response at Weeks 24, 28, 36, 44 and 52

End point description:

ACR 70 response was defined as >=70% improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and >=70% improvement from baseline in 3 of the 5 assessments: patient’s assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), patient’s global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician’s global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 123, 125)	6.1	12.2	20.8	
Week 28 (n=112, 122, 125)	9.8	20.5	24.8	
Week 36 (n=111, 119, 121)	18.0	25.2	26.4	
Week 44 (n=107, 116, 125)	16.8	28.4	26.4	
Week 52 (n=104, 114, 124)	19.2	28.9	29.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in ACR Components at Weeks 24, 28, 36, 44 and 52

End point title	Percent Change From Baseline in ACR Components at Weeks 24, 28, 36, 44 and 52

End point description:

ACR components include swollen joint count (66 joints), tender joint count (68 joints), patient's assessment of pain using visual analog scale (VAS; 0-100 mm, 0=no pain and 100=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), physician's global assessment of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by Disability Index of the Health Assessment Questionnaire (HAQ-DI; a 20-question instrument assessing 8 functional areas; range: 0-3, 0=no difficulty, 3=inability to perform a task in that area), and CRP. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percent change				
arithmetic mean (standard deviation)				
Week 24: Swollen Joint Count (n=114, 123, 125)	-48.33 (± 45.987)	-66.62 (± 47.086)	-73.23 (± 38.120)	
Week 28: Swollen Joint Count (n=112, 123, 125)	-59.95 (± 47.826)	-75.42 (± 33.774)	-80.93 (± 27.197)	
Week 36: Swollen Joint Count (n=111, 119, 122)	-70.50 (± 37.359)	-79.16 (± 35.141)	-80.19 (± 29.160)	
Week 44: Swollen Joint Count (n=108, 117, 125)	-72.63 (± 38.625)	-80.35 (± 34.653)	-82.46 (± 31.652)	
Week 52: Swollen Joint Count (n=103, 112, 124)	-78.23 (± 37.345)	-79.63 (± 36.471)	-86.73 (± 26.776)	
Week 24: Tender Joint Count (n=114, 123, 125)	-27.58 (± 53.737)	-53.73 (± 45.118)	-56.56 (± 41.774)	

Week 28: Tender Joint Count (n=112, 123, 125)	-42.99 (± 62.128)	-64.03 (± 40.678)	-66.68 (± 31.528)	
Week 36: Tender Joint Count (n=111, 119, 122)	-57.06 (± 43.351)	-68.44 (± 39.771)	-64.67 (± 41.606)	
Week 44: Tender Joint Count (n=108, 117, 125)	-60.08 (± 42.811)	-69.23 (± 51.229)	-71.90 (± 31.422)	
Week 52: Tender Joint Count (n=103, 112, 124)	-65.65 (± 37.682)	-72.39 (± 35.102)	-72.70 (± 37.487)	
Week24:Patient's Assessment of Pain(n=113,123,124)	-6.05 (± 52.682)	-32.65 (± 45.343)	-38.90 (± 43.955)	
Week28:Patient's Assessment of Pain(n=110,122,124)	-21.93 (± 52.597)	-38.86 (± 45.149)	-43.59 (± 39.524)	
Week36:Patient's Assessment of Pain(n=109,120,120)	-27.61 (± 56.373)	-42.85 (± 43.952)	-47.23 (± 41.167)	
Week44:Patient's Assessment of Pain(n=107,117,124)	-27.98 (± 64.080)	-45.27 (± 47.794)	-48.97 (± 36.509)	
Week52:Patient's Assessment of Pain(n=103,114,123)	-35.64 (± 66.672)	-42.67 (± 47.250)	-50.03 (± 50.203)	
Week 24: PtGA of Disease Activity(n=114, 123, 125)	-7.63 (± 58.147)	-37.16 (± 39.760)	-40.27 (± 42.250)	
Week 28: PtGA of Disease Activity(n=111, 122, 125)	-21.74 (± 57.662)	-45.35 (± 41.564)	-37.62 (± 60.121)	
Week 36: PtGA of Disease Activity(n=110, 120, 121)	-26.51 (± 60.926)	-46.03 (± 39.547)	-45.17 (± 39.277)	
Week 44: PtGA of Disease Activity(n=108, 117, 125)	-21.76 (± 81.481)	-46.11 (± 40.973)	-45.84 (± 43.368)	
Week 52: PtGA of Disease Activity(n=103, 114, 124)	-35.17 (± 56.398)	-45.84 (± 42.176)	-47.85 (± 55.429)	
Week 24: PGA of Disease Activity(n=113, 122, 125)	-33.22 (± 34.014)	-53.43 (± 37.305)	-61.59 (± 31.445)	
Week 28: PGA of Disease Activity(n=111, 122, 123)	-53.88 (± 31.619)	-57.70 (± 33.724)	-65.96 (± 29.400)	
Week 36: PGA of Disease Activity(n=109, 117, 120)	-62.40 (± 29.215)	-64.51 (± 34.389)	-68.37 (± 27.206)	
Week 44: PGA of Disease Activity(n=107, 117, 124)	-64.93 (± 28.895)	-69.08 (± 30.743)	-72.65 (± 25.842)	
Week 52: PGA of Disease Activity(n=103, 111, 124)	-68.67 (± 32.861)	-68.83 (± 32.776)	-74.71 (± 25.456)	
Week 24: HAQ-DI score(n=108, 121, 118)	-7.65 (± 62.206)	-8.80 (± 148.199)	-31.18 (± 72.701)	
Week 28: HAQ-DI score (n=105, 121, 118)	-15.62 (± 51.720)	-29.10 (± 60.044)	-33.41 (± 72.942)	
Week 36: HAQ-DI score (n=104, 118, 114)	-15.37 (± 53.391)	-29.43 (± 73.712)	-32.74 (± 86.404)	
Week 44: HAQ-DI score (n=102, 116, 118)	-29.61 (± 45.603)	-34.54 (± 73.685)	-35.91 (± 80.885)	
Week 52: HAQ-DI score (n=100, 112, 117)	-28.42 (± 45.473)	-31.09 (± 60.232)	-46.13 (± 56.354)	
Week 24: CRP (n=114, 122, 125)	-13.58 (± 150.494)	-7.83 (± 101.789)	-6.48 (± 149.288)	
Week 28: CRP (n=111, 121, 124)	-8.67 (± 122.851)	-5.58 (± 99.590)	-10.30 (± 97.703)	
Week 36: CRP (n=112, 119, 124)	-17.33 (± 102.168)	-31.55 (± 50.560)	-14.65 (± 113.746)	
Week 44: CRP (n=107, 116, 124)	-29.10 (± 70.460)	-17.81 (± 76.247)	-4.39 (± 190.368)	
Week 52: CRP (n=106, 117, 123)	-1.68 (± 167.086)	-19.28 (± 69.875)	-15.76 (± 129.101)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HAQ-DI Score at Weeks 24, 28, 36, 44 and 52

End point title	Change From Baseline in HAQ-DI Score at Weeks 24, 28, 36, 44 and 52

End point description:

HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score is average of the computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning. Negative change from baseline indicates improvement of physical function. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 123, 125)	-0.1217 (± 0.52442)	-0.3374 (± 0.56967)	-0.3740 (± 0.45914)	
Week 28 (n=111, 123, 125)	-0.2241 (± 0.50876)	-0.4004 (± 0.52303)	-0.3850 (± 0.46381)	
Week 36 (n=110, 120, 121)	-0.2602 (± 0.51278)	-0.4396 (± 0.54426)	-0.4132 (± 0.47155)	
Week 44 (n=108, 118, 125)	-0.3634 (± 0.53486)	-0.4672 (± 0.57140)	-0.4180 (± 0.51394)	
Week 52 (n=104, 114, 124)	-0.3642 (± 0.51084)	-0.4364 (± 0.56400)	-0.4970 (± 0.47990)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a Clinically Meaningful Improvement (>=0.35 improvement from baseline) in HAQ-DI Score at Weeks 24, 28, 36, 44 and 52 Among Subjects With HAQ-DI score >=0.35 at Baseline

End point title	Percentage of Subjects who Achieved a Clinically Meaningful Improvement (>=0.35 improvement from baseline) in HAQ-DI Score at Weeks 24, 28, 36, 44 and 52 Among Subjects With HAQ-DI score >=0.35 at Baseline

End point description:

HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score

is average of the computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning and a decrease of 0.35 from baseline in HAQ-DI score indicates a meaningful improvement. Analysis population is FAS2 among subjects with HAQ-DI score >=0.35 at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	100	109	109	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=100, 109, 109)	36.0	53.2	57.8	
Week 28 (n=97, 109, 109)	40.2	61.5	61.5	
Week 36 (n=96, 106, 105)	41.7	60.4	61.9	
Week 44 (n=94, 104, 109)	50.0	58.7	62.4	
Week 52 (n=92, 101, 108)	54.3	57.4	68.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (CRP) Score at Weeks 24, 28, 36, 44 and 52

End point title	Change From Baseline in DAS28 (CRP) Score at Weeks 24, 28, 36, 44 and 52

End point description:

DAS28 based on CRP is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. The values are 0=best to 10=worst. Negative changes from baseline indicate improvement of arthritis. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 122, 125)	-0.84 (± 1.043)	-1.49 (± 1.140)	-1.57 (± 1.045)	
Week 28 (n=110, 120, 124)	-1.33 (± 1.121)	-1.71 (± 1.126)	-1.67 (± 1.020)	
Week 36 (n=110, 118, 121)	-1.60 (± 1.123)	-1.96 (± 1.145)	-1.78 (± 1.054)	
Week 44 (n=105, 114, 124)	-1.69 (± 1.224)	-1.96 (± 1.226)	-1.92 (± 1.116)	
Week 52 (n=103, 112, 123)	-1.84 (± 1.087)	-2.03 (± 1.250)	-1.99 (± 1.062)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a DAS28 (CRP) Response at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Response at Weeks 24, 28, 36, 44 and 52

End point description:

DAS28 based on CRP is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. DAS28 (CRP) response criteria was defined as follows: Good response: <=3.2 at visit and >1.2 improvement; Moderate response: >3.2 at visit and >1.2 improvement or <=5.1 at visit and >0.6-1.2 improvement; No response: <=0.6 improvement, or >5.1 at visit and <=1.2 improvement. The values are 0=best to 10=worst. A DAS28 (CRP) responder was defined as achieving a good or moderate DAS28 response at a specific visit. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 122, 125)	51.8	74.6	78.4	
Week 28 (n=110, 120, 124)	73.6	83.3	83.9	
Week 36 (n=110, 118, 121)	76.4	89.0	86.8	
Week 44 (n=105, 114, 124)	80.0	86.8	89.5	
Week 52 (n=103, 112, 121)	86.4	88.4	87.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a DAS28 (CRP) Remission at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Remission at Weeks 24, 28, 36, 44 and 52

End point description:

DAS28 based on CRP is an index combining tender joints (28 joints), swollen joints (28 joints), CRP and patient's global assessment of disease activity. The set of 28 joint count is based on evaluation of the shoulder, elbow, wrist, metacarpophalangeal (MCP) MCP1 to MCP5, proximal interphalangeal (PIP) PIP1 to PIP5 joints of both the upper right extremity and the upper left extremity as well as the knee joints of lower right and lower left extremities. The values are 0=best to 10=worst. DAS28 (CRP) remission was defined as DAS28 (CRP) value <2.6 at the analysis visit. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 122, 125)	14.9	24.6	36.8	
Week 28 (n=110, 120, 124)	26.4	37.5	38.7	
Week 36 (n=110, 118, 121)	39.1	40.7	40.5	
Week 44 (n=105, 114, 124)	38.1	45.6	51.6	
Week 52 (n=103, 112, 123)	37.9	43.8	56.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Maintained a HAQ-DI Response (>=0.35 Improvement From Baseline in HAQ-DI Score) at Week 52 Among Subjects Who Achieved a HAQ-DI response at Week 24

End point title	Percentage of Subjects Who Maintained a HAQ-DI Response (>=0.35 Improvement From Baseline in HAQ-DI Score) at Week 52 Among Subjects Who Achieved a HAQ-DI response at Week 24[19]

End point description:

HAQ-DI score assess functional status of subject. It is 20 question instrument that assess 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. Total HAQ score is average of computed categories scores ranging from 0-3 where 0=least difficulty and 3=extreme difficulty. Lower scores are indicative of better functioning and a decrease of 0.35 from baseline in HAQ-DI score indicates a meaningful improvement. Analysis population is FAS2 among subjects who achieved a HAQ-DI response at Week 24. Outcome measure (OM) was planned to assess the maintenance of guselkumab effect only through Week 52, hence the data in this outcome measure is reported for guselkumab 100 mg q8w and guselkumab 100 mg q4w arms only and not for placebo arm.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[19] - 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: Endpoint was planned to be analyzed for specified arm only.

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	63		
Units: percentage of subjects				
number (not applicable)	84.9	87.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) at Weeks 24, 28, 36, 44 and 52

End point title	Percentage of Subjects Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) at Weeks 24, 28, 36, 44 and 52

End point description:

The modified PsARC response was defined as improvement in at least 2 of the four criteria: >=30% decrease in swollen joint count, >=30% decrease in tender joint count, >=20% improvement in patient's Global Assessment of Disease Activity (arthritis) on a VAS (0-100 mm, 0=excellent and 100= poor), >=20% improvement in physician's Global Assessment of Disease Activity using VAS (VAS: 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), and at least one of the 2 joint criteria with no deterioration in the other criteria. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=113, 122, 125)	37.2	63.1	74.4	
Week 28 (n=111, 122, 124)	64.9	78.7	82.3	
Week 36 (n=109, 118, 120)	68.8	80.5	80.0	
Week 44 (n=107, 116, 125)	73.8	81.9	80.0	
Week 52 (n=103, 111, 124)	73.8	83.8	83.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Disease Activity Index for Psoriatic Arthritis (DAPSA) Score at Weeks 24, 28, 36, 44 and 52

End point title	Change From Baseline in the Disease Activity Index for Psoriatic Arthritis (DAPSA) Score at Weeks 24, 28, 36, 44 and 52

End point description:

DAPSA assessed the joint domain of PsA and was derived from the sum of the following components: tender joint count (0–68), swollen joint count (0–66), CRP level (mg/dL), patient assessment of pain (0–10cm VAS, 0=no pain, 10=worst possible pain), and patient's global assessment of disease activity on arthritis (0 to 10cm VAS, 0=excellent and 10=poor). A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. The assessment does not have a score range with an upper or lower bound. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 28, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 122, 125)	-12.962 (± 17.9137)	-23.373 (± 20.2784)	-20.530 (± 13.2678)	
Week 28 (n=110, 120, 124)	-18.632 (± 19.4997)	-26.790 (± 19.3655)	-22.766 (± 12.8366)	
Week 36 (n=110, 118, 121)	-22.360 (± 18.8976)	-30.070 (± 21.0899)	-24.067 (± 14.0976)	
Week 44 (n=105, 114, 124)	-23.602 (± 19.9198)	-30.312 (± 22.5854)	-26.010 (± 15.3230)	
Week 52 (n=103, 112, 123)	-26.058 (± 18.6507)	-30.906 (± 23.0188)	-26.562 (± 15.1985)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Both PASI 75 and Modified PsARC Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved Both PASI 75 and Modified PsARC Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

In PASI, each area (head, trunk, upper and lower extremities) was assessed separately for % of area involved and translated to numeric score ranging from 0(no involvement) to 6(90-100% involvement), and for erythema, induration, and scaling, each rated on scale of 0-4. PASI produces numeric score range from 0-72. Higher scores=more severe disease. PASI75 response: >=75% improvement in PASI score from baseline. Modified PsARC response: improvement in at least 2 of 4 criteria: >=30% decrease in SJC and TJC, >=20% improvement in PtGA of Disease Activity (arthritis) on VAS (0-100mm, 0=excellent and 100=poor), >=20% improvement in PGA of Disease Activity on VAS: 0-100mm, 0=no arthritis and 100=extremely active arthritis, and at least 1 of 2 joint criteria with no deterioration in other criteria. FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2(mild) at baseline. Here, n (number analyzed) signifies number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	8.8	50.6	63.6	
Week 52 (n=65, 75, 88)	69.2	70.7	79.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Both PASI 75 and ACR 20 Responses at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved Both PASI 75 and ACR 20 Responses at Weeks 24 and 52 Among Subjects With

	>=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

In PASI, each area (head, trunk, upper and lower extremities) was assessed for % of area involved and translated to numeric score from 0(no involvement) to 6(90-100% involvement) and for erythema, induration, and scaling, each rated on scale of 0-4. PASI produces numeric score from 0-72. Higher scores=more severe disease. PASI 75: >=75% improvement in PASI score from baseline. ACR 20: >=20% improvement in SJC (66 joints)+TJC (68 joints) and >=20% improvement in 3 of 5: patient's assessment of pain using VAS, PtGA of disease activity using VAS, PGA of disease activity using VAS, patient's assessment of physical function (HAQ-DI: 20-question instrument; range: 0=no difficulty to 3=inability to perform task) and CRP. FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	10.3	40.7	53.4	
Week 52 (n=65, 75, 88)	64.6	58.7	73.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Score at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Change From Baseline in PASI Score at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severity. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. Negative changes from baseline indicate improvement of psoriasis. Analysis population is FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=68, 81, 88)	-3.046 (± 9.3053)	-9.968 (± 10.0178)	-11.614 (± 10.3771)	
Week 52 (n=66, 75, 88)	-10.565 (± 8.8792)	-10.431 (± 11.0277)	-11.988 (± 10.3067)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 75 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 75 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severity. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. PASI 75 response: >=75% improvement in PASI score from baseline. Analysis population is FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	20.6	76.5	87.5	
Week 52 (n=66, 75, 88)	84.8	80.0	94.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 90 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 90 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severity. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. PASI 90 response: >=90% improvement in PASI score from baseline. Analysis population is FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	13.2	50.6	63.6	
Week 52 (n=66, 75, 88)	72.7	66.7	76.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 100 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 100 Response at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA Score of >=2 at Baseline

End point description:

PASI is a tool to assess and grade severity of psoriasis and response to therapy. In PASI, body is divided into 4 areas: head, trunk, upper extremities, lower extremities. Each area was assessed separately for percentage of area involved and translated to numeric score ranging from 0 (no involvement) to 6 (90 to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 to 4 that is none to maximum severity. PASI numeric score range from 0 (no psoriasis) to 72. Higher scores indicate more severe disease. PASI 100 response: 100% improvement in PASI score from baseline. Analysis population is FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	7.4	25.9	45.5	
Week 52 (n=66, 75, 88)	62.1	48.0	64.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 PCS Score at Weeks 24, 36 and 52

End point title	Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 PCS Score at Weeks 24, 36 and 52

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The PCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better outcome, with an increase of 5 points considered to be clinically meaningful. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n= 114, 123, 124)	35.1	53.7	55.6	
Week 36 (n=107, 119, 120)	44.9	53.8	55.0	
Week 52 (n=104, 114, 124)	52.9	53.5	62.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 MCS Score at Weeks 24, 36 and 52

End point title	Percentage of Subjects Who Achieved >=5 Point Improvement From Baseline in SF-36 MCS Score at Weeks 24, 36 and 52

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The MCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better outcome, with an increase of 5 points considered to be clinically meaningful. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n= 114, 123, 124)	29.8	39.0	44.4	
Week 36 (n=107, 119, 120)	39.3	39.5	49.2	
Week 52 (n=104, 114, 124)	37.5	46.5	47.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Minimal Disease Activity (MDA) at Weeks 24 and 52

End point title	Percentage of Subjects Who Achieved Minimal Disease Activity (MDA) at Weeks 24 and 52

End point description:

MDA is a measure that defines a satisfactory state of disease activity that includes the 5 domains of PsA (joint symptoms, skin psoriasis, patient's perspective of pain and disease activity, physical function, and enthesitis). A subject was considered as having achieved the PsA MDA at a visit if the subject has fulfilled at least 5 of the following 7 criteria at that visit: Tender joint count (68 joints)<=1, Swollen joint count (66 joints) <=1, Psoriasis activity and severity index <=1, Patient's Assessment of Pain <=15 on a 100-unit VAS, Patient's Global Assessment of Disease Activity (arthritis and psoriasis) <=20 on a 100-unit VAS, HAQ-DI score <=0.5, and Tender entheseal points <= 1 (LEI index score <= 1). Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n= 114, 123, 125)	12.3	23.6	31.2	
Week 52 (n=103, 112, 124)	31.1	33.9	40.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score Index at Weeks 24 and 52

End point title	Change From Baseline in Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score Index at Weeks 24 and 52

End point description:

GRACE index is composite PsA disease activity score converted from AMDF, which derived from TJC(0-68) and SJC(0-66), HAQ-DI(0-3), PtGA of disease activity on arthritis and psoriasis (0-100mm, 0=excellent and 100=poor), patient's assessment of skin disease activity (0-100mm, 0=excellent and 100=poor), PtGA of disease activity on arthritis (0-100 mm, 0=excellent and 100=poor), PASI (0-72), and PsA Quality of Life Index (derived as PsAQOL =25.355+[2.367*HAQ-DI]–[0.234*SF-PCS]–[0.244*SF-MCS]), where HAQ-DI score (0-3, 0=least difficulty and 3=extreme difficulty), SF-PCS (Score ranges from 0-100, higher scores= better quality of life) and SF-MCS (score ranges from 0-100, higher scores=better quality of life). Total score is from 0-10, where lower score=better response. Higher score=more active disease activity. Negative change from baseline indicates improvement of PsA disease activity. Analysis population is FAS2. Here, 'n' signifies number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=113, 121, 124)	-0.998 (± 1.4808)	-2.493 (± 1.5195)	-2.751 (± 1.5060)	
Week 52 (n=103, 110, 123)	-2.829 (± 1.5773)	-3.112 (± 1.7479)	-3.364 (± 1.4638)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriatic Arthritis Disease Activity (PASDAS) Score at Weeks 24 and 52

End point title	Change From Baseline in Psoriatic Arthritis Disease Activity (PASDAS) Score at Weeks 24 and 52

End point description:

PASDAS (score range of 0 to 10, where higher score indicated more severe disease) is a compositive score of overall disease activity combining Patient's Global Assessment of Disease Activity (arthritis and psoriasis, using VAS [0-100 mm, 0=excellent and 100=poor), Physician's Global Assessment of Disease Activity (using VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen joint count (0-66 joints), tender joint count (0-68 joints), CRP (mg/L), enthesitis based on LEI (0–6), tender dactylitis count (scoring each digit from 0–3 and recoding to 0–1, where any score > 0 equaled 1), and the PCS score of the SF-36 health survey. The cutoffs for disease activity were 3.2 (low) to 5.4 (high). Negative changes from baseline indicate improvement of overall disease activity. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=113, 121, 124)	-1.140 (± 1.4036)	-2.246 (± 1.4978)	-2.413 (± 1.3906)	
Week 52 (n=103, 110, 123)	-2.748 (± 1.4706)	-2.897 (± 1.6788)	-3.026 (± 1.4446)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Maintained an ACR 20 Response at Week 52 Among Subjects Who Achieved an ACR 20 Response at Week 24

End point title	Percentage of Subjects Who Maintained an ACR 20 Response at Week 52 Among Subjects Who Achieved an ACR 20 Response at Week 24[20]

End point description:

ACR 20 response: >=20% improvement from baseline in both SJC(66 joints) and TJC(68 joints), and >=20% improvement from baseline in 3 of the 5 assessments: patient's assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. FAS2 among subjects achieved ACR20 response at Week 24. Here, N (number of subjects analyzed) signifies number of subjects analyzed for this OM. OM was planned to assess maintenance of guselkumab effect only through Week 52, hence data is reported for guselkumab 100mg q8w and guselkumab 100mg q4w arms only and not for placebo

arm.

End point type	Secondary

End point timeframe:

Week 52

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: Endpoint was planned to be analyzed for specified arm only.

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	76		
Units: percentage of subjects				
number (not applicable)	88.5	90.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Maintained an ACR 50 Response at Week 52 Among Subjects Who Achieved an ACR 50 Response at Week 24

End point title	Percentage of Subjects Who Maintained an ACR 50 Response at Week 52 Among Subjects Who Achieved an ACR 50 Response at Week 24[21]

End point description:

ACR 50 response: >=50% improvement from baseline in both SJC(66 joints) and TJC(68 joints), and >=50% improvement from baseline in 3 of the 5 assessments: patient’s assessment of pain using VAS (0-100 mm, 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. FAS2 among subjects achieved ACR50 response at Week 24. Here, N (number of subjects analyzed) signifies number of subjects analyzed for this OM. The OM was planned to assess maintenance of guselkumab effect only through Week 52, hence data is reported for guselkumab 100 mg q8w and guselkumab 100 mg q4w arms only and not for placebo arm.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[21] - 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: Endpoint was planned to be analyzed for specified arm only.

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	46		
Units: percentage of subjects				
number (not applicable)	83.8	91.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Maintained an ACR 70 Response at Week 52 Among Subjects Who Achieved an ACR 70 Response at Week 24

End point title	Percentage of Subjects Who Maintained an ACR 70 Response at Week 52 Among Subjects Who Achieved an ACR 70 Response at Week 24[22]

End point description:

ACR 70 response: >=70% improvement from baseline in both SJC(66 joints) and TJC(68 joints), and >=70% improvement from baseline in 3 of the 5 assessments: patient's assessment of pain using VAS (0-100 millimeters [mm], 0=no pain and 100=worst possible pain), PtGA of disease activity (arthritis, VAS; 0-100 mm, 0=excellent and 100= poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis activity and 100=extremely active arthritis), patient's assessment of physical function measured by HAQ-DI (defined as a 20-question instrument assessing 8 functional areas; range: 0-3, 0=indicating no difficulty, 3=indicating inability to perform a task in that area), and CRP. Analysis population is FAS2 among subjects who achieved ACR 70 response at Week 24. The outcome measure was planned to assess the maintenance of guselkumab effect only through Week 52, hence the data in this outcome measure is reported for guselkumab 100 mg q8w and guselkumab 100 mg q4w arms only and not for placebo arm.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[22] - 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: Endpoint was planned to be analyzed for specified arm only.

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	26		
Units: percentage of subjects				
number (not applicable)	80.0	84.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement From Baseline in BASDAI Score at Weeks 24 and 52 Among Subjects with Spondylitis and Peripheral Arthritis as their Primary Arthritic

Presentation of PsA

End point title	Percentage of Subjects Who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement From Baseline in BASDAI Score at Weeks 24 and 52 Among Subjects with Spondylitis and Peripheral Arthritis as their Primary Arthritic Presentation of PsA

End point description:

BASDAI is selfassessment tool with 6 questions relating to 5 major symptoms of ankylosing spondylitis: fatigue, spinal pain, joint pain, enthesitis, qualitative and quantitative morning stiffness. First 5 items scored on 10cm VAS ranging from 0=none to 10=very severe. Quantitative morning stiffness was scored on 10cm VAS ranging from 0=0 hours to 10=2/more hours. The 2 scores for qualitative and quantitative morning stiffness were averaged, and total BASDAI score was average of 5 scores of each symptom, ranging from 0=none to 10=very severe. Higher scores indicate greater disease severity and an improvement of 50% from baseline is considered clinically meaningful. Analysis population is FAS2 among subjects with spondylitis and peripheral arthritis and BASDAI score >0 at baseline. Here, 'n' signifies number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	24	20	
Units: percentage of subjects				
number (not applicable)				
Week24:Subjects with >=20% Improvement(n=21,24,20)	38.1	70.8	65.0	
Week52:Subjects with >=20% Improvement(n=21,22,20)	66.7	72.7	85.0	
Week24:Subjects with >=50% Improvement(n=21,24,20)	19.0	41.7	35.0	
Week52:Subjects with >=50% Improvement(n=21,24,20)	52.4	59.1	50.0	
Week24:Subjects with >=70% Improvement(n=21,24,20)	14.3	29.2	5.0	
Week52:Subjects with >=70% Improvement(n=21,24,20)	28.6	40.9	20.0	
Week24:Subjects with >=90% Improvement(n=21,24,20)	0	16.7	0	
Week52:Subjects with >=90% Improvement(n=21,24,20)	9.5	13.6	15.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Resolution of Enthesitis at Weeks 24, 36, 44 and 52 Among the Subjects with Enthesitis at Baseline

End point title	Percentage of Subjects With Resolution of Enthesitis at Weeks 24, 36, 44 and 52 Among the Subjects with Enthesitis at Baseline

End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). A LEI score of 0 at a post baseline visit indicates resolution of enthesitis when baseline LEI>0. Analysis population is FAS2 among the subjects with enthesitis (LEI) at baseline who achieved resolution of enthesitis at Week 24. Here, N (number of subjects analyzed) signifies the number of subjects analyzed for this outcome measure and n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	71	71	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=71, 71, 71)	31.0	40.8	49.3	
Week 36 (n=69, 70, 69)	49.3	52.9	58.0	
Week 44 (n=67, 69, 71)	58.2	46.4	71.8	
Week 52 (n=63, 64, 70)	69.8	56.3	62.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Resolution of Dactylitis at Weeks 24, 36, 44 and 52 Among Subjects with Dactylitis at Baseline

End point title	Percentage of Subjects With Resolution of Dactylitis at Weeks 24, 36, 44 and 52 Among Subjects with Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. Higher score indicates more severe dactylitis. Resolution of dactylitis was defined as a dactylitis score of 0 with the baseline dactylitis score >0. Analysis population is FAS2 among the subjects with dactylitis at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	49	37	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=47, 49, 37)	61.7	67.3	64.9	
Week 36 (n=44, 46, 35)	79.5	67.4	82.9	
Week 44 (n=46, 46, 37)	84.8	76.1	83.8	
Week 52 (n=43, 44, 37)	81.4	79.5	78.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Enthesitis Score (Based on SPARCC) at Weeks 24, 36, 44 and 52 Among the Subjects With Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score (Based on SPARCC) at Weeks 24, 36, 44 and 52 Among the Subjects With Enthesitis at Baseline

End point description:

Enthesitis was assessed using Spondyloarthritis Research Consortium of Canada (SPARCC). SPARCC developed measure for enthesitis in general spondyloarthritis which evaluates presence or absence of pain by applying local pressure to following entheses: supraspinatus insertion (left and right), medial epicondyle humerus (left and right), lateral epicondyle humerus (left and right), greater trochanter (left and right), quadriceps-to-patella (left and right), patellar-tibia (left and right), achilles tendon insertion (left and right), plantar fascia (left and right). Tenderness on examination was recorded as either present (1) or absent (0) for each of 16 sites for an overall score range of 0-16. Higher scores indicate more severe enthesitis. Negative changes from baseline indicate improvement of enthesitis. Analysis population is FAS2 among subjects with enthesitis (SPARCC) at baseline. Here, 'n' signifies number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	85	82	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=77, 85, 82)	-1.9 (± 3.55)	-2.7 (± 3.68)	-3.0 (± 3.60)	
Week 36 (n=73, 83, 80)	-3.1 (± 3.61)	-3.4 (± 3.90)	-3.6 (± 3.52)	
Week 44 (n=71, 82, 82)	-3.6 (± 3.67)	-3.6 (± 3.82)	-4.1 (± 3.55)	
Week 52 (n=69, 76, 81)	-3.9 (± 3.57)	-4.1 (± 4.04)	-4.0 (± 3.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 24, 36, 44 and 52 Among the Subjects With Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 24, 36, 44 and 52 Among the Subjects With Enthesitis at Baseline

End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score is a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). Negative changes from baseline indicate improvement of enthesitis. Analysis population is FAS2 among the subjects with enthesitis (LEI) at baseline. Here, N (number of subjects analyzed) signifies the number of subjects analyzed for this outcome measure and n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	71	71	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=71, 71, 71)	-1.0 (± 1.68)	-1.2 (± 1.95)	-1.8 (± 1.93)	
Week 36 (n=69, 70, 69)	-1.4 (± 1.73)	-1.3 (± 2.04)	-2.0 (± 1.68)	
Week 44 (n=67, 69, 71)	-1.6 (± 1.90)	-1.6 (± 1.70)	-2.4 (± 1.68)	
Week 52 (n=63, 64, 70)	-1.9 (± 1.65)	-1.8 (± 1.66)	-2.0 (± 1.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Score at Weeks 24, 36, 44 and 52 Among the Subjects With Dactylitis at Baseline

End point title	Change From Baseline in Dactylitis Score at Weeks 24, 36, 44 and 52 Among the Subjects With Dactylitis at Baseline

End point description:

The presence and severity of dactylitis was 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) for each digit. The results were summed to produce a final score ranging from 0 to 60. A higher score indicates more severe dactylitis. Negative changes from baseline indicate improvement in dactylitis. Analysis population is FAS2 among the subjects with dactylitis at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36, 44 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	49	37	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=47, 49, 37)	-4.0 (± 6.08)	-6.2 (± 10.31)	-6.6 (± 11.08)	
Week 36 (n=44, 46, 35)	-6.0 (± 7.17)	-6.4 (± 10.91)	-7.7 (± 11.58)	
Week 44 (n=46, 46, 37)	-5.3 (± 5.61)	-7.2 (± 10.57)	-7.5 (± 11.41)	
Week 52 (n=43, 44, 37)	-5.7 (± 5.86)	-7.8 (± 10.55)	-7.6 (± 10.91)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an IGA Score of 0 (cleared) or 1 (Cleared) at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA score of >=2 at Baseline

End point title	Percentage of Subjects With an IGA Score of 0 (cleared) or 1 (Cleared) at Weeks 24 and 52 Among Subjects With >=3% BSA Psoriatic Involvement and an IGA score of >=2 at Baseline

End point description:

A psoriasis IGA response was defined as an IGA score of 0 (cleared) or 1 (minimal) and >= 2 grade reduction from baseline in the IGA psoriasis score. The IGA documents the investigator’s assessment of the patient’s psoriasis and lesions are graded for induration, erythema and scaling, each using a 5 point scale: 0 (no evidence), 1 (minimal), 2 (mild), 3 (moderate), and 4 (severe). The IGA score of psoriasis was based upon the average of induration, erythema and scaling scores. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Analysis population is FAS2 among the subjects who had >=3% BSA of psoriatic involvement and an IGA score >=2 (mild) at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	82	88	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=68, 81, 88)	8.8	38.3	54.5	
Week 52 (n=65, 75, 88)	66.2	53.3	67.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SF-36 Physical Component Summary (PCS) Score at Weeks 24, 36 and 52

End point title	Change From Baseline in SF-36 Physical Component Summary (PCS) Score at Weeks 24, 36 and 52

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The PCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 123, 124)	2.700 (± 7.1649)	6.505 (± 7.7137)	6.560 (± 7.7566)	
Week 36 (n=107, 119, 120)	5.456 (± 8.0353)	7.439 (± 8.5626)	7.162 (± 7.9890)	
Week 52 (n=104, 114, 124)	6.905 (± 7.9376)	7.278 (± 8.0648)	8.517 (± 8.2717)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SF-36 Mental Component Summary (MCS) Score at Weeks 24, 36 and 52

End point title	Change From Baseline in SF-36 Mental Component Summary (MCS) Score at Weeks 24, 36 and 52

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health), which yielded a Physical Component Summary (PCS) with score range 0-100 (higher score-better quality of life) and a Mental Component Summary (MCS) with score range 0-100 (higher score-better quality of life) in addition to subscale scores. The MCS scores are normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
End point timeframe: Baseline, Weeks 24, 36 and 52	

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 123, 124)	1.827 (± 8.1508)	3.027 (± 10.6157)	3.796 (± 8.7396)	
Week 36 (n=107, 119, 120)	3.612 (± 7.2322)	4.300 (± 10.2373)	4.326 (± 9.2709)	
Week 52 (n=104, 114, 124)	4.240 (± 8.1200)	5.139 (± 9.1719)	4.931 (± 8.9482)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Norm Based Scores of SF-36 Scales at Week 24, 36 and 52

End point title	Change From Baseline in Norm Based Scores of SF-36 Scales at Week 24, 36 and 52

End point description:

SF-36 is a multi-domain instrument with 36 items to evaluate the health status and quality of life. It included 8 subscales: physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health. The scores 0-100 (where higher scores indicated a better quality of life) from each subscale of SF-36 were normalized to a mean of 50 and standard deviations of 10, based upon general US population norms. Higher score indicates better health status. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints for specific categories.

End point type	Secondary
End point timeframe: Baseline, Weeks 24, 36 and 52	

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24: Physical Functioning (n=114, 123, 124)	1.914 (± 8.8644)	6.006 (± 7.9608)	6.652 (± 8.4730)	
Week 36: Physical Functioning (n=107, 119, 120)	5.008 (± 8.6461)	6.900 (± 8.5458)	7.114 (± 8.8941)	

Week 52: Physical Functioning (n=104, 114, 124)	6.257 (± 8.3753)	7.000 (± 8.0953)	8.720 (± 8.9738)	
Week 24: Role-physical (n=114, 123, 124)	3.053 (± 7.6460)	5.239 (± 8.2864)	5.215 (± 7.5241)	
Week 36: Role-physical (n=107, 119, 120)	4.701 (± 8.1572)	6.245 (± 7.8346)	6.250 (± 7.9040)	
Week 52: Role-physical (n=104, 114, 124)	5.873 (± 8.8847)	6.126 (± 8.1008)	7.063 (± 8.2579)	
Week 24: Bodily Pain (n=114, 123, 124)	3.388 (± 7.2056)	7.058 (± 8.8315)	7.215 (± 9.1129)	
Week 36: Bodily Pain (n=107, 119, 120)	6.477 (± 8.6363)	8.487 (± 8.8135)	7.348 (± 9.0965)	
Week 52: Bodily Pain (n=104, 114, 124)	8.331 (± 8.1585)	8.781 (± 8.5691)	8.958 (± 9.1783)	
Week 24: General Health (n=114, 123, 124)	1.819 (± 6.9497)	4.361 (± 7.5573)	5.066 (± 7.1334)	
Week 36: General Health (n=107, 119, 120)	3.742 (± 8.2079)	5.638 (± 8.4919)	5.540 (± 7.4840)	
Week 52: General Health (n=104, 123, 125)	4.677 (± 7.8944)	5.547 (± 7.8712)	6.442 (± 7.9374)	
Week 24: Vitality (n=114, 123, 124)	2.684 (± 9.0049)	5.652 (± 9.6943)	6.158 (± 7.8842)	
Week 36: Vitality (n=107, 119, 120)	6.303 (± 9.0307)	7.065 (± 8.6659)	7.353 (± 8.7656)	
Week 52: Vitality (n=104, 114, 124)	7.742 (± 8.7476)	7.558 (± 9.1600)	8.218 (± 8.5308)	
Week 24: Social Function (n=114, 123, 125)	2.419 (± 8.8289)	5.666 (± 9.3449)	4.932 (± 9.5887)	
Week 36: Social Function (n=107, 119, 120)	4.873 (± 9.1477)	5.899 (± 9.9762)	5.598 (± 10.5240)	
Week 52: Social Function (n=104, 114, 124)	5.351 (± 8.9264)	6.729 (± 8.4844)	6.428 (± 10.1397)	
Week 24: Role-emotional (n=114, 123, 124)	1.833 (± 9.0800)	2.265 (± 10.6155)	3.706 (± 9.3529)	
Week 36: Role-emotional (n=107, 119, 120)	3.580 (± 8.5353)	4.301 (± 10.1127)	3.685 (± 10.5307)	
Week 52: Role-emotional (n=104, 114, 124)	4.520 (± 8.8658)	4.979 (± 10.2956)	4.830 (± 9.9053)	
Week 24: Mental Health (n=114, 123, 124)	1.905 (± 8.1196)	4.062 (± 10.0610)	4.873 (± 8.6431)	
Week 36: Mental Health (n=107, 119, 120)	3.472 (± 7.0761)	5.056 (± 9.7930)	5.559 (± 8.9957)	
Week 52: Mental Health (n=104, 114, 124)	4.251 (± 8.3059)	5.553 (± 8.4255)	6.223 (± 8.8360)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 24, 36 and 52

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 24, 36 and 52

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. The subscale consists 13-item instrument to measure fatigue. Each of the 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as the

sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with a higher score indicating less fatigue. Positive changes from baseline indicate improvement of fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=114, 123, 125)	2.605 (± 8.3142)	5.862 (± 10.3941)	5.576 (± 7.7670)	
Week 36 (n=107, 119, 121)	5.981 (± 8.3846)	7.252 (± 9.7182)	5.917 (± 8.5123)	
Week 52 (n=104, 114, 124)	6.577 (± 9.4105)	7.482 (± 9.6342)	6.911 (± 8.3986)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved >=4-point Improvement From Baseline in FACIT-Fatigue Score at Weeks 24, 36 and 52

End point title	Percentage of Subjects Who Achieved >=4-point Improvement From Baseline in FACIT-Fatigue Score at Weeks 24, 36 and 52

End point description:

The FACIT-Fatigue is a questionnaire that assesses self-reported tiredness, weakness, and difficulty conducting usual activities due to fatigue. The subscale consists 13-item instrument to measure fatigue. Each of the 13 items has a set of five response categories: Not at all (=0), A little bit (=1), Somewhat (=2), Quite a bit (=3) and Very much (=4). A total FACIT-Fatigue subscale score was calculated as the sum of the 13 item scores (reserved scores [4 - score]) and ranges from 0 to 52, with a higher score indicating less fatigue. Positive changes from baseline indicate improvement of fatigue. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=114, 123, 125)	41.2	55.3	64.8	
Week 36 (n=107, 119, 121)	60.7	58.0	66.1	
Week 52 (n=104, 114, 124)	63.5	61.4	63.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS)-29 Scores at Weeks 24, 36 and 52

End point title	Change From Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS)-29 Scores at Weeks 24, 36 and 52

End point description:

PROMIS-29 contains 4 items for each of seven PROMIS domains (Anxiety, Depression, Fatigue, Pain Interference, Physical Function, Sleep Disturbance, and Satisfaction-Social Role (S-SR) and Activity. PROMIS-29 also includes an additional pain intensity 0-10 NRS. The raw score of each domain is converted into a standardized score with a mean of 50 and a SD of 10 for the general population in the US (T-Score). Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Weeks 24, 36 and 52

End point values	Placebo	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	123	125	
Units: T-score				
arithmetic mean (standard deviation)				
Week 24: Anxiety Score (n=114, 123, 125)	-1.482 (± 8.3526)	-3.680 (± 9.8122)	-3.115 (± 7.9491)	
Week 36: Anxiety Score (n=107, 119, 121)	-2.410 (± 7.6503)	-3.929 (± 8.9614)	-2.961 (± 8.4679)	
Week 52: Anxiety Score (n=104, 114, 124)	-3.640 (± 8.3601)	-4.279 (± 9.6488)	-3.075 (± 8.5784)	
Week 24: Depression Score (n=114, 123, 125)	-0.601 (± 8.3133)	-3.963 (± 8.5473)	-2.706 (± 8.1872)	
Week 36: Depression Score (n=107, 119, 121)	-0.933 (± 7.1629)	-3.916 (± 8.6211)	-2.987 (± 7.8786)	
Week 52: Depression Score (n=104, 114, 124)	-2.488 (± 7.8259)	-4.004 (± 7.5271)	-2.985 (± 8.0519)	
Week 24: Fatigue Score (n=114, 123, 125)	-2.104 (± 7.5625)	-4.780 (± 9.7044)	-4.757 (± 7.7779)	
Week 36: Fatigue Score (n=107, 119, 121)	-5.533 (± 8.3256)	-5.857 (± 8.8525)	-5.693 (± 9.3854)	

Week 52: Fatigue Score (n=104, 114, 124)	-5.720 (± 9.0165)	-6.773 (± 8.5608)	-5.583 (± 8.1099)	
Week 24: Pain Interference Score (n=114, 123, 125)	-2.811 (± 5.9890)	-5.810 (± 7.5201)	-5.423 (± 7.1593)	
Week 36: Pain Interference Score (n=107, 119, 121)	-5.344 (± 7.2500)	-6.754 (± 8.0520)	-5.882 (± 7.5121)	
Week 52: Pain Interference Score (n=104, 114, 124)	-6.334 (± 6.9940)	-6.972 (± 8.2440)	-6.242 (± 7.4767)	
Week 24: Physical Function Score (n=114, 123, 125)	1.682 (± 5.9909)	4.101 (± 7.1353)	5.030 (± 6.5259)	
Week 36: Physical Function Score (n=107, 119, 121)	3.093 (± 6.5712)	4.970 (± 7.0012)	5.264 (± 7.0643)	
Week 52: Physical Function Score (n=104, 114, 124)	4.245 (± 6.1363)	5.033 (± 7.0184)	5.920 (± 6.9852)	
Week 24: Sleep Disturbance Score (n=114, 123, 125)	-1.497 (± 5.7591)	-3.750 (± 6.8758)	-2.549 (± 6.7263)	
Week 36: Sleep Disturbance Score (n=107, 119, 121)	-2.767 (± 5.7630)	-3.853 (± 6.5505)	-4.096 (± 6.8724)	
Week 52: Sleep Disturbance Score (n=104, 114, 124)	-3.290 (± 5.8368)	-4.375 (± 6.5738)	-3.856 (± 6.1181)	
Week24:S-SR and Activity Score (n=114, 123, 125)	1.666 (± 7.2572)	5.308 (± 8.5808)	4.235 (± 7.4745)	
Week36:S-SR and Activity Score (n=107, 119, 121)	4.120 (± 8.1899)	6.270 (± 8.8798)	4.517 (± 7.9605)	
Week52:S-SR and Activity Score (n=104, 114, 124)	4.885 (± 8.7421)	6.607 (± 7.8438)	5.347 (± 8.1806)	
Week 24: Pain Intensity Score (n=114, 123, 125)	-0.737 (± 2.0911)	-2.098 (± 2.4104)	-2.320 (± 2.4449)	
Week 36: Pain Intensity Score (n=107, 119, 121)	-1.720 (± 2.3424)	-2.496 (± 2.4212)	-2.488 (± 2.4018)	
Week 52: Pain Intensity Score (n=104, 114, 124)	-2.462 (± 2.3480)	-2.711 (± 2.4844)	-2.847 (± 2.5377)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 60

Adverse event reporting additional description:

Safety analysis set included subjects who were randomized at Week 0 and received at least 1 (partial or complete) administration of study agent and were analyzed according to the actual treatment received after randomization. Data for Guselkumab 100 mg q8w and q4w arms was planned to be reported separately for Week 0 to 24 and Week 0 to 60.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Placebo (CP)

Reporting group description:

Subjects received placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (CP). Data prior to the first administration of guselkumab, or through the last follow-up visit if the subject did not receive any guselkumab, were included.

Reporting group title	Guselkumab 100 mg q8w (CP)

Reporting group description:

Subjects received guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks and placebo matched to guselkumab injections at other visits through Week 20 in the placebo controlled period (CP). Data through Week 24, or through the last follow-up visit if the subject did not receive any study drug at or after Week 24, were included.

Reporting group title	Guselkumab 100 mg q4w (CP)

Reporting group description:

Subjects received guselkumab 100 mg subcutaneous injections every 4 weeks from Week 0 through Week 20 in the placebo controlled period (CP). Data through Week 24, or through the last follow-up visit if the subject did not receive any study drug at or after Week 24, were included.

Reporting group title	Placebo to Guselkumab 100 mg q4w (ACP through Week 60)

Reporting group description:

Subjects who received placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (CP) received guselkumab 100 mg subcutaneous injections every 4 weeks from Week 24 through Week 48. Data from the first administration of guselkumab through Week 60 were included.

Reporting group title	Guselkumab 100 mg q8w (through Week 60)

Reporting group description:

Subjects received guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks and placebo matched to guselkumab injections at other visits through Week 48. Data from Week 0 through Week 60 were included.

Reporting group title	Guselkumab 100 mg q4w (through Week 60)

Reporting group description:

Subjects received guselkumab 100 mg subcutaneous injections every 4 weeks from Week 0 through Week 48. Data from Week 0 through Week 60 were included.

Serious adverse events	Placebo (CP)	Guselkumab 100 mg q8w (CP)	Guselkumab 100 mg q4w (CP)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 126 (3.97%)	4 / 127 (3.15%)	0 / 128 (0.00%)
number of deaths (all causes)	2	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma Cell Myeloma			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Head Injury			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Meniscus Injury			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Venous Thrombosis Limb			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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			
Arrhythmia Supraventricular			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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 Failure			

subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Mechanical Ileus			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Cervical Dysplasia			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pustular Psoriasis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Renal Colic			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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			
Foot Deformity			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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			
Abscess Limb			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Cellulitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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

Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 128 (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	Placebo to Guselkumab 100 mg q4w (ACP through Week 60)	Guselkumab 100 mg q8w (through Week 60)	Guselkumab 100 mg q4w (through Week 60)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 114 (3.51%)	8 / 127 (6.30%)	4 / 128 (3.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma Cell Myeloma			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	1 / 114 (0.88%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Venous Thrombosis Limb			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia Supraventricular			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	1 / 114 (0.88%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Mechanical Ileus			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast Enlargement			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Dysplasia			

subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Skin and subcutaneous tissue disorders			
Pustular Psoriasis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Renal and urinary disorders			
Renal Colic			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess Limb			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Bronchitis			

subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 114 (0.00%)	1 / 127 (0.79%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Pyelonephritis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 114 (0.00%)	0 / 127 (0.00%)	0 / 128 (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
Urosepsis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 127 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo (CP)	Guselkumab 100 mg q8w (CP)	Guselkumab 100 mg q4w (CP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 126 (19.84%)	38 / 127 (29.92%)	28 / 128 (21.88%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 126 (2.38%)	8 / 127 (6.30%)	5 / 128 (3.91%)
occurrences (all)	3	10	5
Aspartate Aminotransferase			

Increased			
subjects affected / exposed	3 / 126 (2.38%)	9 / 127 (7.09%)	3 / 128 (2.34%)
occurrences (all)	3	9	3
Musculoskeletal and connective tissue disorders			
Enthesopathy			
subjects affected / exposed	6 / 126 (4.76%)	6 / 127 (4.72%)	6 / 128 (4.69%)
occurrences (all)	6	6	7
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 126 (0.79%)	5 / 127 (3.94%)	1 / 128 (0.78%)
occurrences (all)	1	5	1
Nasopharyngitis			
subjects affected / exposed	8 / 126 (6.35%)	16 / 127 (12.60%)	7 / 128 (5.47%)
occurrences (all)	8	16	7
Upper Respiratory Tract Infection			
subjects affected / exposed	8 / 126 (6.35%)	7 / 127 (5.51%)	11 / 128 (8.59%)
occurrences (all)	9	7	14

Non-serious adverse events	Placebo to Guselkumab 100 mg q4w (ACP through Week 60)	Guselkumab 100 mg q8w (through Week 60)	Guselkumab 100 mg q4w (through Week 60)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 114 (21.93%)	48 / 127 (37.80%)	41 / 128 (32.03%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	4 / 114 (3.51%)	9 / 127 (7.09%)	9 / 128 (7.03%)
occurrences (all)	4	14	9
Aspartate Aminotransferase Increased			
subjects affected / exposed	4 / 114 (3.51%)	11 / 127 (8.66%)	6 / 128 (4.69%)
occurrences (all)	4	12	6
Musculoskeletal and connective tissue disorders			
Enthesopathy			
subjects affected / exposed	0 / 114 (0.00%)	7 / 127 (5.51%)	8 / 128 (6.25%)
occurrences (all)	0	7	9
Infections and infestations			
Bronchitis			

subjects affected / exposed	3 / 114 (2.63%)	9 / 127 (7.09%)	2 / 128 (1.56%)
occurrences (all)	3	9	2
Nasopharyngitis			
subjects affected / exposed	13 / 114 (11.40%)	21 / 127 (16.54%)	14 / 128 (10.94%)
occurrences (all)	16	24	17
Upper Respiratory Tract Infection			
subjects affected / exposed	8 / 114 (7.02%)	10 / 127 (7.87%)	16 / 128 (12.50%)
occurrences (all)	8	11	22

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 January 2018	Amendment included the following key changes: 1) All references to Dermatology Life Quality Index and Modified Composite Psoriatic Disease Activity Index (mCPDAI) were removed as these assessments were not completed in the study, 2) Treatment failure criteria were amended to include study termination for any reason, and to remove the criterion of "Met EE criteria at Week 16 and initiated or increased the dose of one of the permitted concomitant medications", 3) To update the version names of the eC-SSRS and to clarify when the eC-SSRS should be performed during the screening visit, 4) Minor errors were corrected, and clarifications were provided throughout the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported