



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

Summary

EudraCT number	2016-001224-63
Trial protocol	ES CZ EE PL LT LV BG PT GR
Global end of trial date	04 December 2020

Results information

Result version number	v1 (current)
This version publication date	26 November 2021
First version publication date	26 November 2021

Trial information

Trial identification

Sponsor protocol code	CR108219
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03158285
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	04 December 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 December 2020
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 PsA 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	13 July 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	Bulgaria: 29
Country: Number of subjects enrolled	Czechia: 33
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	Estonia: 18
Country: Number of subjects enrolled	Lithuania: 20
Country: Number of subjects enrolled	Latvia: 6
Country: Number of subjects enrolled	Malaysia: 12
Country: Number of subjects enrolled	Poland: 85
Country: Number of subjects enrolled	Russian Federation: 273
Country: Number of subjects enrolled	Turkey: 16
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	Ukraine: 221
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	739
EEA total number of subjects	210

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)	706
From 65 to 84 years	33
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 741 subjects were randomized and 739 subjects received at least one dose of study drug: 246 in placebo group, 248 in guselkumab 100 mg q8w group, and 245 in guselkumab 100 mg q4w group. Two subjects were randomized in error and were never treated. Disposition is presented till active treatment period (Week100).

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 to Guselkumab 100 mg q4w

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 100 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), then to receive guselkumab 100 milligrams (mg) subcutaneous injection from Week 24 every 4 weeks through Week 100 in the active treatment period.

Arm title	Guselkumab 100 mg q8w
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Arm description:

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

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.

Arm title	Guselkumab 100 mg q4w
Arm description: Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 100.	
Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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 100.

Number of subjects in period 1	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	246	248	245
Completed	240	240	236
Not completed	6	8	9
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	-	2	4
Serious adverse event, non-fatal	4	-	2
Unspecified	1	1	-
Lost to follow-up	-	1	-
Lack of efficacy	-	3	3

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

Blinding implementation details:

Sponsor was also blinded.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo to Guselkumab 100 mg q4w
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 100 in the active treatment period.	
Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects 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 100 in the active treatment period.

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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.

Arm title	Guselkumab 100 mg q4w
Arm description: Subjects were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 100.	
Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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 100.

Number of subjects in period 2 ^[1]	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	238	240	234
Completed	228	234	227
Not completed	10	6	7
Consent withdrawn by subject	1	2	1
Adverse event, non-fatal	2	-	1
Serious adverse event, non-fatal	1	-	-
Pregnancy	-	-	1
Unspecified	1	1	-
Lack of efficacy	5	3	4

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: 2 subjects did not enter the active treatment.

Period 3

Period 3 title	Active Treatment Period: Week 52-100
Is this the baseline period?	No
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 to Guselkumab 100 mg q4w

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 100 in the active treatment period.

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

Dosage and administration details:

Subjects 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 100 in the active treatment period.

Arm title	Guselkumab 100 mg q8w
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Arm description:

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

Arm type	Experimental
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Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.

Arm title	Guselkumab 100 mg q4w
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Arm description:

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

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
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 100.

Number of subjects in period 3^[2]	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Started	228	232	227
Completed	210	223	219
Not completed	18	9	8
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	5	2	1
Adverse event, non-fatal	4	3	-
Serious adverse event, non-fatal	3	2	3
Pregnancy	-	-	1
Unspecified	4	1	-
Lack of efficacy	1	1	3

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: 2 subjects did not enter the active treatment.

Baseline characteristics

Reporting groups

Reporting group title	Placebo to Guselkumab 100 mg q4w
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 100 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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
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 100.	

Reporting group values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w
Number of subjects	246	248	245
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	235	237	234
From 65 to 84 years	11	11	11
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	46.3	44.9	45.9
standard deviation	± 11.68	± 11.89	± 11.47
Title for Gender Units: subjects			
Female	129	119	103
Male	117	129	142

Reporting group values	Total		
Number of subjects	739		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	706		
From 65 to 84 years	33		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			

standard deviation	-		
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Title for Gender			
Units: subjects			
Female	351		
Male	388		

End points

End points reporting groups

Reporting group title	Placebo to Guselkumab 100 mg q4w
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 100 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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
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 100.	
Reporting group title	Placebo to Guselkumab 100 mg q4w
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 100 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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
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 100.	
Reporting group title	Placebo to Guselkumab 100 mg q4w
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 100 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) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
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 100.	
Subject analysis set title	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis)
Subject analysis set type	Full analysis
Subject analysis set description: Participants 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 100 in the active treatment period.	
Subject analysis set title	Guselkumab 100 mg q8w(Pooled Population: Enthesitis)

Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
Subject analysis set title	Guselkumab 100 mg q4w(Pooled Population: Enthesitis)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 100.	
Subject analysis set title	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants 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 100 in the active treatment period.	
Subject analysis set title	Guselkumab 100 mg q8w(Pooled Population: Dactylitis)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were randomized to receive guselkumab 100 mg subcutaneous injections at Weeks 0 and 4, then every 8 weeks (q8w) through Week 100 and placebo matched to guselkumab injections at Week 8 then q8w through Week 100.	
Subject analysis set title	Guselkumab 100 mg q4w(Pooled Population: Dactylitis)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants were randomized to receive guselkumab 100 mg subcutaneous injections every 4 weeks (q4w) through Week 100.	

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:	
ACR20 response: $\geq 20\%$ improvement from baseline in both swollen(66 joints) and tender joint count(68 joints), and $\geq 20\%$ 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, 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis, 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. FAS1 with subjects who achieved ACR20 response at Week24 and did not meet any TF criteria before Week24 were considered as responders. Subjects who met 1 or more TF criteria or with missing data were considered as non-responders.	
End point type	Primary
End point timeframe:	
Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of participants				
number (not applicable)	32.9	64.1	63.7	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg q8w v Placebo to Guselkumab 100 mg q4w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	31.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.9
upper limit	39.5

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	30.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.4
upper limit	39.1

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
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End point description:

HAQ-DI score assess functional status of subjects. 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. Data after meeting one or more 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
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.1300 (-0.1912 to -0.0687)	-0.3672 (-0.4282 to -0.3062)	-0.4004 (-0.4617 to -0.3390)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Square (LS) Mean difference
Point estimate	-0.2372
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.321
upper limit	-0.1534

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

Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.2704
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3544
upper limit	-0.1864

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

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

ACR50 response defined as $\geq 50\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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; 0-100mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis 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 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 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
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End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of Subjects				
number (not applicable)	14.2	31.5	33.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w

Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	17.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	10
upper limit	24.4

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	18.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.5
upper limit	26.1

Secondary: Percentage of Subjects who Achieved Psoriasis Response with IGA score of 0 (Cleared) or 1 (Minimal) and ≥ 2 Grade Reduction From Baseline at Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and IGA Score of ≥ 2 (Mild) at Baseline

End point title	Percentage of Subjects who Achieved Psoriasis Response with IGA score of 0 (Cleared) or 1 (Minimal) and ≥ 2 Grade Reduction From Baseline at Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and IGA Score of ≥ 2 (Mild) at Baseline
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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 participant's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). FAS1 among participants with $\geq 3\%$ BSA psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Participants 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
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End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)	19.1	70.5	68.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	367
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	49.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.2
upper limit	58.4

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	359
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	50.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.2
upper limit	59.7

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
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End point description:

ACR 20 response was defined as $\geq 20\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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 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. Participants 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 before Week 16 or with missing data were considered as non-responders.

End point type	Secondary
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End point timeframe:

Week 16

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	33.7	55.2	55.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	22.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.7
upper limit	30.7

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	21.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.1
upper limit	30

Secondary: Change From Baseline in Modified Van Der Heijde-Sharp (vdH-S) Score at Week 24

End point title	Change From Baseline in Modified Van Der Heijde-Sharp (vdH-S) Score at Week 24
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD included all subjects with at least 1 dose (complete/partial) of study agent as per randomized treatment group regardless of treatment actually received. Observed data used regardless if 1 or more TF criteria met. Missing data assumed to be MAR and imputed using MI.

End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	0.95 (0.61 to 1.29)	0.52 (0.18 to 0.86)	0.29 (-0.05 to 0.63)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.03

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	-0.19

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:	<p>Enthesitis assessed using LEI, a tool developed to assess enthesitis in subjects with PsA and evaluates presence (1) or absence (0) of pain by applying local pressure to following entheses: left and right lateral epicondyle humerus, medial femoral condyle, and achilles tendon insertion. Enthesitis index score is a total score of 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. Outcome measure was planned to be reported for pooled population from CNT01959PSA3001 and CNT01959PSA3002 studies. FAS1 among participants with enthesitis at baseline pooled from CNT01959PSA3001 (NCT03162796) and CNT01959PSA3002 (NCT03158285) studies. Subjects with enthesitis resolution 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.</p>
End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis)	Guselkumab 100 mg q8w(Pooled Population: Enthesitis)	Guselkumab 100 mg q4w(Pooled Population: Enthesitis)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	255	230	243	
Units: percentage of subjects				
number (not applicable)	29.4	49.6	44.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis) v Guselkumab 100 mg q8w(Pooled Population: Enthesitis)
Number of subjects included in analysis	485
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	20.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.8
upper limit	28.5

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis) v Guselkumab 100 mg q4w(Pooled Population: Enthesitis)
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	14.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	6.4
upper limit	22.7

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:	
<p>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. The outcome measure was planned to be reported for pooled population from CNT01959PSA3001 and CNT01959PSA3002 studies. FAS1 among participants with dactylitis at baseline pooled from CNT01959PSA3001 (NCT03162796) and CNT01959PSA3002 (NCT03158285) studies. Subjects with dactylitis resolution 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.</p>	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis)	Guselkumab 100 mg q8w(Pooled Population: Dactylitis)	Guselkumab 100 mg q4w(Pooled Population: Dactylitis)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	154	160	159	
Units: percentage of subjects				
number (not applicable)	42.2	59.4	63.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis) v Guselkumab 100 mg q8w(Pooled Population: Dactylitis)
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	18

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.4
upper limit	28.6

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis) v Guselkumab 100 mg q4w(Pooled Population: Dactylitis)
Number of subjects included in analysis	313
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.5
upper limit	32

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:	
<p>Enthesitis was assessed using LEI, a tool developed to assess enthesitis in participants with PsA and evaluates presence (score of 1) or absence (score of 0) of pain by applying local pressure to following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. Tnthesitis 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. Outcome measure was planned to be reported for pooled population from CNTO1959PSA3001 and CNTO1959PSA3002 studies. Analysis population is FAS1 among participants with enthesitis at baseline pooled from both CNTO1959PSA3001 (NCT03162796) and CNTO1959PSA3002 (NCT03158285) studies. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random and imputed using MI.</p>	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis)	Guselkumab 100 mg q8w(Pooled Population: Enthesitis)	Guselkumab 100 mg q4w(Pooled Population: Enthesitis)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	255	230	243	
Units: units on a scale				
least squares mean (confidence interval 95%)	-1.02 (-1.22 to -0.82)	-1.52 (-1.73 to -1.31)	-1.59 (-1.79 to -1.38)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis) v Guselkumab 100 mg q4w(Pooled Population: Enthesitis)
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[1]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	-0.31

Notes:

[1] - Nominal

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Enthesitis) v Guselkumab 100 mg q8w(Pooled Population: Enthesitis)
Number of subjects included in analysis	485
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[2]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	-0.23

Notes:

[2] - Nominal

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

End point title	Change From Baseline in Dactylitis Scores at Week 24 Among the Participants with Dactylitis at Baseline
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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. Negative changes from baseline indicate improvement of dactylitis. The outcome measure was planned to be reported for pooled population from CNTO1959PSA3001 and CNTO1959PSA3002 studies. Analysis population is FAS1 among participants with dactylitis at baseline pooled from both from CNTO1959PSA3001 (NCT03162796) and CNTO1959PSA3002 (NCT03158285) studies. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis)	Guselkumab 100 mg q8w(Pooled Population: Dactylitis)	Guselkumab 100 mg q4w(Pooled Population: Dactylitis)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	154	160	159	
Units: units on a scale				
least squares mean (confidence interval 95%)	-4.21 (-5.05 to -3.36)	-6.10 (-6.92 to -5.27)	-5.97 (-6.84 to -5.11)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis) v Guselkumab 100 mg q8w(Pooled Population: Dactylitis)
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001 ^[3]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.99
upper limit	-0.79

Notes:

[3] - Nominal

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100mg q4w(Pooled Population: Dactylitis) v Guselkumab 100 mg q4w(Pooled Population: Dactylitis)
Number of subjects included in analysis	313
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002 ^[4]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.87
upper limit	-0.66

Notes:

[4] - 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
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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 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	3.42 (2.53 to 4.32)	7.39 (6.50 to 8.29)	7.04 (6.14 to 7.94)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	3.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.75
upper limit	5.2

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	3.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.39
upper limit	4.85

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
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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 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.97 (-1.11 to -0.84)	-1.59 (-1.72 to -1.45)	-1.62 (-1.76 to -1.49)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.43

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	-0.47

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

End point title	Change From Baseline in 36-Item Short Form Health Survey (SF-36) Mental Component Summary (MCS) at Week 24
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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 missing at random (MAR) and imputed using multiple imputation (MI).

End point type	Secondary
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	2.14 (1.07 to 3.22)	4.17 (3.10 to 5.23)	4.22 (3.14 to 5.29)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	2.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	3.49

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	3.54

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:	
ACR50 response defined as $\geq 50\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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; 0-100mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis 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 C-Reactive Protein (CRP). FAS1 with subjects who achieved ACR 50 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 non-responders.	
End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	9.3	28.6	20.8	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	19.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.6
upper limit	25.9

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	11.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.2
upper limit	17.7

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

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

ACR 70 response defined as $\geq 70\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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 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. 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	4.1	18.5	13.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q8w
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.068
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	14.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.1
upper limit	19.9

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo to Guselkumab 100 mg q4w v Guselkumab 100 mg q4w
Number of subjects included in analysis	491
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	9

Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	13.8

Secondary: Percentage of Subjects who Achieved ACR 20 Response Through Week 24

End point title	Percentage of Subjects who Achieved ACR 20 Response Through Week 24
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End point description:

ACR 20 response defined as $\geq 20\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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 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. FAS1 with 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	8.1	10.1	10.6	
Week 4	11.8	19.8	21.6	
Week 8	17.5	39.1	40.0	
Week 12	26.4	49.6	51.0	
Week 16	33.7	55.2	55.9	
Week 20	29.7	62.9	58.8	
Week 24	32.9	64.1	63.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 50 Response Through Week 24

End point title	Percentage of Subjects who Achieved ACR 50 Response Through Week 24
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End point description:

ACR50 response defined as $\geq 50\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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; 0-100mm, 0=excellent and 100=poor), PGA of disease activity (VAS; 0-100 mm, 0=no arthritis 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 C-Reactive Protein (CRP). Analysis population is FAS1. Subjects who achieved ACR 50 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	0.4	1.6	0.4	
Week 4	1.2	4.0	3.3	
Week 8	4.1	10.1	11.0	
Week 12	6.1	19.0	16.7	
Week 16	9.3	28.6	20.8	
Week 20	16.3	31.5	29.8	
Week 24	14.2	31.5	33.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ACR 70 Response Through Week 24

End point title	Percentage of Subjects who Achieved ACR 70 Response Through Week 24
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End point description:

ACR 70 response defined as $\geq 70\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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 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. FAS1 with 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	0	0	0	
Week 4	0.8	0.4	0.8	
Week 8	0.8	3.6	2.0	
Week 12	0.4	8.1	4.9	
Week 16	0.8	13.7	8.2	
Week 20	3.3	15.3	13.9	
Week 24	4.1	18.5	13.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in ACR Components at Weeks 2, 4, 8, 12, 16, 20 and 24

End point title	Percent Change From Baseline in ACR Components at Weeks 2, 4, 8, 12, 16, 20 and 24
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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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment (PtGA) of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10=poor), physician's global assessment (PGA) of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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(milligram per deciliter [mg/dL]). Analysis population is FAS1. Here 'n' (number analyzed) signifies number of subjects with observed data regardless meeting TF criteria at specified categories.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percent change				
arithmetic mean (standard deviation)				
Week 2: Swollen Joint Count (n=242, 245, 239)	-18.9 (± 32.16)	-18.8 (± 39.68)	-18.5 (± 38.38)	

Week 4: Swollen Joint Count (n=245, 246 240)	-27.1 (± 37.29)	-30.5 (± 36.92)	-33.6 (± 37.57)	
Week 8: Swollen Joint Count (n=246, 246, 243)	-37.4 (± 39.03)	-46.8 (± 40.68)	-46.7 (± 37.69)	
Week 12: Swollen Joint Count(n=246,246,242)	-46.1 (± 41.20)	-57.6 (± 39.22)	-58.3 (± 35.42)	
Week 16: Swollen Joint Count (n=245, 244, 240)	-48.6 (± 43.01)	-64.1 (± 35.46)	-63.7 (± 34.42)	
Week 20: Swollen Joint Count (n=243, 243, 236)	-54.2 (± 41.70)	-69.3 (± 33.63)	-71.4 (± 30.42)	
Week 24: Swollen Joint Count (n=243, 243, 240)	-53.9 (± 45.54)	-71.3 (± 34.06)	-73.1 (± 30.67)	
Week 2: Tender Joint Count (n=242, 245, 239)	-9.4 (± 25.99)	-10.4 (± 40.31)	-14.8 (± 28.31)	
Week 4: Tender Joint Count (n=245, 246, 240)	-14.1 (± 36.04)	-15.0 (± 41.57)	-22.6 (± 32.91)	
Week 8: Tender Joint Count (n=246, 246, 243)	-21.9 (± 37.83)	-31.0 (± 42.36)	-33.8 (± 37.58)	
Week 12: Tender Joint Count (n=246, 246, 242)	-30.4 (± 37.57)	-40.9 (± 42.73)	-43.0 (± 35.90)	
Week 16: Tender Joint Count (n=245, 244, 240)	-30.6 (± 41.87)	-47.0 (± 40.96)	-48.1 (± 37.01)	
Week 20: Tender Joint Count (n=243, 243, 236)	-33.9 (± 44.22)	-53.9 (± 37.83)	-54.2 (± 35.43)	
Week 24: Tender Joint Count (n=243, 243, 240)	-33.3 (± 44.87)	-54.2 (± 37.15)	-57.3 (± 34.98)	
Week 2: Patient's Assessment of Pain(n=244,246,240)	0.05 (± 35.794)	-8.92 (± 32.374)	-4.66 (± 32.229)	
Week 4: Patient's Assessment of Pain(n=246,247,240)	-0.64 (± 35.849)	-12.58 (± 33.065)	-7.96 (± 37.958)	
Week8: Patient's Assessment of Pain(n=246,245,243)	-6.76 (± 34.213)	-21.61 (± 36.705)	-17.05 (± 44.783)	
Week12: Patient's Assessment of Pain(n=246,246,242)	-9.01 (± 36.061)	-26.26 (± 40.223)	-25.91 (± 37.862)	
Week16: Patient's Assessment of Pain(n=245,244,240)	-9.70 (± 41.673)	-31.94 (± 42.882)	-27.85 (± 38.913)	
Week20: Patient's Assessment of Pain(n=244,243,237)	-10.85 (± 46.497)	-35.16 (± 39.471)	-35.35 (± 39.016)	
Week24: Patient's Assessment of Pain(n=243,243,240)	-11.84 (± 48.324)	-38.06 (± 40.565)	-36.52 (± 38.423)	
Week2: PtGA of Disease Activity (n=244,246,240)	-1.12 (± 35.882)	-10.15 (± 31.060)	-5.25 (± 32.658)	
Week4: PtGA of Disease Activity (n=246,247,240)	-2.27 (± 34.291)	-12.71 (± 34.440)	-11.02 (± 33.605)	
Week8: PtGA of Disease Activity (n=246,245, 243)	-6.51 (± 35.908)	-21.58 (± 33.697)	-19.13 (± 40.545)	
Week12: PtGA of Disease Activity(n=246,246,242)	-9.30 (± 37.185)	-27.86 (± 38.900)	-28.33 (± 34.058)	
Week16: PtGA of Disease Activity(n=245,244,240)	-12.34 (± 39.207)	-32.25 (± 40.056)	-28.60 (± 39.759)	
Week20: PtGA of Disease Activity(n=244,243,237)	-12.52 (± 42.498)	-35.31 (± 36.205)	-35.11 (± 37.791)	
Week24: PtGA of Disease Activity(n=243,243,240)	-13.87 (± 45.650)	-37.05 (± 38.372)	-34.13 (± 51.445)	
Week2: PGA of Disease Activity (n=240,231,241)	-9.79 (± 25.687)	-15.06 (± 27.150)	-13.85 (± 23.307)	
Week4: PGA of Disease Activity(n=243,245,239)	-16.63 (± 27.573)	-23.72 (± 27.658)	-22.32 (± 28.183)	
Week 8: PGA of Disease Activity (n=244, 244, 240)	-23.29 (± 28.416)	-36.54 (± 31.224)	-37.99 (± 29.970)	
Week 12: PGA of Disease Activity (n=245, 243, 242)	-27.63 (± 32.379)	-46.54 (± 30.489)	-42.84 (± 31.305)	

Week 16: PGA of Disease Activity (n=245, 244, 240)	-31.11 (± 32.023)	-52.02 (± 31.915)	-49.18 (± 31.383)
Week 20: PGA of Disease Activity (n=240, 243, 234)	-34.13 (± 36.576)	-54.32 (± 30.941)	-54.59 (± 29.336)
Week 24: PGA of Disease Activity (n=243, 242, 238)	-36.59 (± 33.740)	-57.22 (± 32.480)	-58.70 (± 28.255)
Week 2: HAQ-DI Score (n=240, 236, 237)	-0.3191 (± 36.62364)	-6.3577 (± 50.81980)	-0.2385 (± 57.44896)
Week 4: HAQ-DI Score (n=242, 237, 237)	-2.8744 (± 46.90795)	-9.1272 (± 53.41051)	-5.1209 (± 85.16625)
Week 8: HAQ-DI Score (n=242, 235, 240)	-5.0965 (± 39.89566)	-12.7684 (± 67.23239)	-9.8081 (± 86.78973)
Week 12: HAQ-DI Score (n=242, 236, 239)	-8.0811 (± 46.90093)	-18.0336 (± 66.96524)	-17.7758 (± 17.7758)
Week 16: HAQ-DI Score (n=241, 235, 237)	-7.1776 (± 48.33253)	-19.3627 (± 70.83578)	-26.6732 (± 53.14973)
Week 20: HAQ-DI Score (n=240, 234, 234)	-10.4296 (± 50.87958)	-24.9496 (± 64.86820)	-28.9317 (± 60.67279)
Week 24: HAQ-DI Score (n=249, 233, 237)	-6.7995 (± 54.78602)	-25.2578 (± 63.15450)	-33.8837 (± 51.59441)
Week 2: CRP (n=246, 247, 242)	86.677 (± 645.0281)	0.935 (± 91.3783)	10.664 (± 132.5947)
Week 4: CRP (n=242, 244, 236)	28.042 (± 208.6385)	-16.885 (± 79.3501)	1.128 (± 168.9301)
Week 8: CRP (n=240, 240, 241)	45.451 (± 322.4433)	-11.214 (± 150.1689)	-17.474 (± 112.3803)
Week 12: CRP (n=241, 242, 236)	47.034 (± 313.9875)	-25.620 (± 97.1384)	-22.277 (± 122.3489)
Week 16: CRP (n=241, 239, 238)	28.595 (± 237.6660)	-19.874 (± 134.5210)	-26.592 (± 86.8465)
Week 20: CRP (n=241, 239, 236)	42.282 (± 284.1330)	-13.551 (± 193.3814)	-28.701 (± 83.0912)
Week 24: CRP (n=240, 243, 239)	19.263 (± 149.5120)	-27.470 (± 109.5239)	-28.125 (± 87.7229)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HAQ-DI Score at Weeks 2, 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in HAQ-DI Score at Weeks 2, 4, 8, 12, 16, 20 and 24
End point description:	
HAQ-DI score assess functional status of participant. It is a 20 question instrument that assess the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0=indicating no difficulty, to 3=indicating inability to perform a task in that area. 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 changes from baseline indicate improvement of physical function. 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 missing at random (MAR) and imputed using multiple imputation (MI).	
End point type	Secondary
End point timeframe:	
Baseline and Weeks 2, 4, 8, 12, 16, 20 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-0.0594 (- 0.1023 to - 0.0165)	-0.1423 (- 0.1850 to - 0.0997)	-0.0795 (- 0.1226 to - 0.0364)	
Week 4	-0.0722 (- 0.1196 to - 0.0247)	-0.1472 (- 0.1944 to - 0.1000)	-0.1605 (- 0.2081 to - 0.1128)	
Week 8	-0.0942 (- 0.1464 to - 0.0420)	-0.2294 (- 0.2815 to - 0.1773)	-0.2336 (- 0.2859 to - 0.1813)	
Week 12	-0.1332 (- 0.1875 to - 0.0790)	-0.2870 (- 0.3411 to - 0.2330)	-0.3010 (- 0.3554 to - 0.2466)	
Week 16	-0.1167 (- 0.1753 to - 0.0582)	-0.3177 (- 0.3760 to - 0.2595)	-0.3442 (- 0.4029 to - 0.2855)	
Week 20	-0.1565 (- 0.2163 to - 0.0968)	-0.3536 (- 0.4131 to - 0.2941)	-0.4019 (- 0.4618 to - 0.3420)	
Week 24	-0.1300 (- 0.1912 to - 0.0687)	-0.3672 (- 0.4282 to - 0.3062)	-0.4004 (- 0.4617 to - 0.3390)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ≥ 0.35 improvement from Baseline in HAQ-DI Score Through Week 24 Among Subjects With HAQ-DI Score ≥ 0.35 at Baseline

End point title	Percentage of Subjects who Achieved ≥ 0.35 improvement from Baseline in HAQ-DI Score Through Week 24 Among Subjects With HAQ-DI Score ≥ 0.35 at Baseline
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End point description:

HAQ-DI score assess functional status of participant. 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 scored from 0=indicating no difficulty, to 3=indicating inability to perform a task. Total HAQ score: average of the computed categories scores ranging from 0-3, 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. FAS1 among participants with HAQ-DI ≥ 0.35 at baseline. Subjects with HAQ-DI ≥ 0.35 improvement from baseline at specific timepoint 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	236	228	228	
Units: percentage of subjects				
number (not applicable)				
Week 2	19.9	30.7	23.2	
Week 4	23.7	32.0	35.1	
Week 8	28.0	43.4	42.5	
Week 12	31.8	47.4	46.9	
Week 16	30.9	50.0	51.8	
Week 20	38.6	48.7	53.1	
Week 24	31.4	50.0	56.1	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Response Through Week 24
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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. FAS1 with subjects who achieved a DAS28 (CRP) 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, considered as non-responders.

End point type	Secondary
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	21.5	23.8	24.5	

Week 4	32.9	38.7	40.8	
Week 8	38.6	56.9	54.7	
Week 12	51.2	67.3	65.7	
Week 16	51.2	69.8	72.7	
Week 20	50.4	75.0	76.3	
Week 24	52.4	75.4	80.0	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects Who Achieved a DAS28 (CRP) Remission Through Week 24
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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 a DAS28 (CRP) remission 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	0.8	2.4	2.4	
Week 4	2.0	5.2	4.9	
Week 8	0.8	10.5	9.0	
Week 12	6.1	14.1	11.8	
Week 16	6.5	18.5	16.3	
Week 20	9.8	23.0	21.2	
Week 24	8.5	24.6	23.3	

Statistical analyses

Secondary: Change From Baseline in DAS28 (CRP) at Weeks 2, 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in DAS28 (CRP) at Weeks 2, 4, 8, 12, 16, 20 and 24
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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 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
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End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-0.29 (-0.37 to -0.21)	-0.42 (-0.50 to -0.33)	-0.43 (-0.51 to -0.35)	
Week 4	-0.44 (-0.53 to -0.35)	-0.62 (-0.71 to -0.53)	-0.65 (-0.74 to -0.55)	
Week 8	-0.59 (-0.71 to -0.48)	-0.99 (-1.11 to -0.88)	-0.98 (-1.09 to -0.86)	
Week 12	-0.85 (-0.97 to -0.73)	-1.27 (-1.39 to -1.15)	-1.22 (-1.35 to -1.10)	
Week 16	-0.88 (-1.01 to -0.75)	-1.39 (-1.52 to -1.26)	-1.37 (-1.50 to -1.24)	
Week 20	-1.00 (-1.13 to -0.87)	-1.52 (-1.65 to -1.38)	-1.56 (-1.70 to -1.43)	
Week 24	-0.97 (-1.11 to -0.84)	-1.59 (-1.72 to -1.45)	-1.62 (-1.76 to -1.49)	

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) Through Week 24

End point title	Percentage of Subjects Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) Through Week 24
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End point description:

The modified PsARC response was defined as improvement in at least 2 of the four criteria: $\geq 30\%$ decrease in swollen joint count, $\geq 30\%$ decrease in tender joint count, $\geq 20\%$ improvement in patient's Global Assessment of Disease Activity (arthritis) on a VAS (0-100 mm, 0=excellent and 100=poor), $\geq 20\%$ 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
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End point timeframe:

Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 2	13.0	22.2	18.0	
Week 4	27.2	32.7	29.8	
Week 8	35.8	48.8	50.2	
Week 12	40.7	60.9	60.8	
Week 16	44.7	66.5	66.5	
Week 20	46.7	72.2	69.0	
Week 24	44.7	72.6	68.6	

Statistical analyses

No statistical analyses for this end point

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

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

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in participants 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 participants with enthesitis at baseline. Subjects with enthesitis resolution at 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
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End point timeframe:

Weeks 2, 4, 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	178	158	170	
Units: percentage of subjects				
number (not applicable)				
Week 2	16.3	17.7	17.1	
Week 4	18.0	21.5	25.3	
Week 8	24.7	31.0	27.6	
Week 16	30.9	47.5	40.6	
Week 24	30.3	53.8	43.5	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects With Resolution of Dactylitis Through Week 24 Among the Subjects With Dactylitis at Baseline
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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 subjects with dactylitis at baseline. Subjects who achieved dactylitis resolution at specific time point and did not meet any TF criteria before, were considered as responders at that time point. Participants 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
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End point timeframe:

Weeks 2, 4, 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99	111	121	
Units: percentage of subjects				
number (not applicable)				
Week 2	12.1	13.5	13.2	
Week 4	18.2	19.8	20.7	
Week 8	29.3	30.6	31.4	
Week 16	36.4	45.0	52.1	
Week 24	38.4	56.8	63.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 2, 4, 8, 16, and 24 Among the Subjects with Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 2, 4, 8, 16, and 24 Among the Subjects with Enthesitis at Baseline
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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 subjects with enthesitis at baseline. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 2, 4, 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	178	158	170	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-0.33 (-0.53 to -0.12)	-0.37 (-0.59 to -0.16)	-0.49 (-0.70 to -0.29)	
Week 4	-0.46 (-0.68 to -0.24)	-0.56 (-0.79 to -0.33)	-0.69 (-0.92 to -0.47)	
Week 8	-0.67 (-0.90 to -0.45)	-0.92 (-1.16 to -0.67)	-0.88 (-1.11 to -0.64)	
Week 16	-0.94 (-1.18 to -0.71)	-1.37 (-1.62 to -1.12)	-1.42 (-1.66 to -1.18)	
Week 24	-1.03 (-1.25 to -0.81)	-1.60 (-1.84 to -1.37)	-1.52 (-1.75 to -1.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Scores at Weeks 2, 4, 8, 16 and 24 Among the Subjects with Dactylitis at Baseline

End point title	Change From Baseline in Dactylitis Scores at Weeks 2, 4, 8, 16 and 24 Among the Subjects with Dactylitis at Baseline
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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. Negative changes from baseline indicate improvement of dactylitis. Analysis population is FAS1 among subjects with dactylitis at baseline. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 2, 4, 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99	111	121	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-0.21 (-1.11 to 0.69)	-1.11 (-1.95 to -0.26)	-0.78 (-1.61 to 0.05)	
Week 4	-1.10 (-2.07 to -0.13)	-2.11 (-3.02 to -1.20)	-1.56 (-2.47 to -0.66)	
Week 8	-2.17 (-3.19 to -1.16)	-3.17 (-4.12 to -2.22)	-3.11 (-4.05 to -2.17)	
Week 16	-3.40 (-4.42 to -2.38)	-4.88 (-5.84 to -3.92)	-4.80 (-5.75 to -3.85)	
Week 24	-4.03 (-4.96 to -3.10)	-5.95 (-6.83 to -5.08)	-5.88 (-6.74 to -5.01)	

Statistical analyses

No statistical analyses for this end point

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

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

PASDAS (score range of 0 to 10, where higher score=more severe disease) is composite 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 (VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen (66 joints), tender joint count (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 FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	-0.863 (-1.007 to -0.719)	-1.452 (-1.595 to -1.309)	-1.413 (-1.557 to -1.270)	
Week 16	-1.158 (-1.327 to -0.988)	-2.110 (-2.278 to -1.942)	-1.994 (-2.164 to -1.825)	
Week 24	-1.336 (-1.516 to -1.156)	-2.403 (-2.582 to -2.225)	-2.399 (-2.579 to -2.219)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Change From Baseline in Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Composite Score (GRACE) at Weeks 16 and 24
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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. Analysis population is FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	-1.029 (-1.212 to -0.847)	-2.326 (-2.507 to -2.145)	-2.214 (-2.397 to -2.032)	
Week 24	-1.198 (-1.395 to -1.001)	-2.593 (-2.789 to -2.397)	-2.589 (-2.786 to -2.392)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Work Time Missed) at Weeks 16 and 24

End point title	Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Work Time Missed) at Weeks 16 and 24
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. FAS1. Data after meeting 1/more TF criteria, imputed as no change from baseline. Missing data assumed MAR. LS mean is based on MMRM model that included data from all visits for all subjects. Here, N(number of subjects analyzed) signifies number of subjects evaluable for this OM.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	155	145	145	
Units: percentage of work time missed				
least squares mean (confidence interval 95%)				
Week 16	-4.553 (-7.199 to -1.906)	-3.451 (-6.199 to -0.703)	-4.717 (-7.449 to -1.985)	
Week 24	-3.491 (-6.403 to -0.578)	-3.103 (-6.062 to -0.144)	-3.827 (-6.826 to -0.828)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Impairment while Working) at Weeks 16 and 24

End point title	Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Impairment while Working) at Weeks 16 and 24
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. FAS1. Data after meeting 1/more TF criteria, imputed as no change from baseline. Missing data assumed MAR. LS mean is based on MMRM model that included data from all visits for all subjects. Here, N(number of subjects analyzed) signifies number of subjects evaluable for this OM.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	129	133	
Units: percentage of impairment				
least squares mean (confidence interval 95%)				
Week 16	-10.281 (- 13.887 to - 6.675)	-16.054 (- 19.699 to - 12.409)	-15.083 (- 18.655 to - 11.511)	
Week 24	-10.157 (- 13.663 to - 6.650)	-19.366 (- 22.857 to - 15.875)	-19.492 (- 22.982 to - 16.003)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment

Scores (Percent Overall Work Impairment) at Weeks 16 and 24

End point title	Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Overall Work Impairment) at Weeks 16 and 24
End point description: WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. FAS1. Data after meeting 1/more TF criteria, imputed as no change from baseline. Missing data assumed MAR. LS mean is based on MMRM model that included data from all visits for all subjects. Here, N(number of subjects analyzed) signifies number of subjects evaluable for this OM.	
End point type	Secondary
End point timeframe: Baseline, Weeks 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	129	133	
Units: percentage of overall work impairment				
least squares mean (confidence interval 95%)				
Week 16	-11.232 (-14.962 to -7.501)	-15.926 (-19.694 to -12.159)	-15.808 (-19.501 to -12.115)	
Week 24	-10.869 (-14.591 to -7.147)	-19.711 (-23.416 to -16.006)	-20.023 (-23.726 to -16.320)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Activity Impairment Outside of Work) at Weeks 16 and 24

End point title	Change From Baseline in Work Productivity and Activity Impairment Scores (Percent Activity Impairment Outside of Work) at Weeks 16 and 24
End point description: WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. FAS1. Data after meeting 1/more TF criteria, imputed as no change from baseline. Missing data assumed MAR. LS mean is based on MMRM model that included data from all	

visits for all subjects. Here, N(number of subjects analyzed) signifies number of subjects evaluable for this OM.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	244	247	245	
Units: percentage of activity impairment				
least squares mean (confidence interval 95%)				
Week 16	-10.569 (- 13.262 to - 7.877)	-17.107 (- 19.787 to - 14.428)	-17.029 (- 19.727 to - 14.331)	
Week 24	-10.320 (- 13.071 to - 7.570)	-21.467 (- 24.204 to - 18.729)	-20.480 (- 23.226 to - 17.734)	

Statistical analyses

No statistical analyses for this end point

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

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

The mCPDAI assessed 4 domains (joints, skin, entheses, and dactylitis). The mCPDAI scores were calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ-DI score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0–3) was assigned, where 0= Not involved, 1= Mild, 2= Moderate and 3= Severe. The scores for each domain were then added together to give a final score range of 0 to 12. A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. Analysis population is FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	-1.18 (-1.43 to -0.93)	-2.39 (-2.64 to -2.14)	-2.57 (-2.82 to -2.31)	
Week 24	-1.30 (-1.57 to -1.04)	-2.94 (-3.20 to -2.68)	-3.09 (-3.35 to -2.83)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Index for Psoriatic Arthritis (DAPSA) at Weeks 2, 4, 8, 12, 16, 20 and 24

End point title	Change From Baseline in Disease Activity Index for Psoriatic Arthritis (DAPSA) at Weeks 2, 4, 8, 12, 16, 20 and 24
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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, value <lower limit of quantification [LLOQ] is considered equal to half of the value of LLOQ for numerical calculations), 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 FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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
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End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 2	-4.6447 (-5.9287 to -3.3607)	-6.7838 (-8.0642 to -5.5034)	-6.3783 (-7.6664 to -5.0902)	
Week 4	-7.6695 (-9.2194 to -6.1197)	-9.9687 (-11.5128 to -8.4246)	-10.2484 (-11.8049 to -8.6919)	
Week 8	-10.4480 (-12.1877 to -8.7084)	-15.3303 (-17.0682 to -13.5924)	-15.8657 (-17.6038 to -14.1277)	

Week 12	-14.2915 (-16.1107 to -12.4724)	-18.9772 (-20.7912 to -17.1632)	-19.9687 (-21.7915 to -18.1459)	
Week 16	-14.8556 (-16.8664 to -12.8448)	-21.6939 (-23.6979 to -19.6899)	-21.4722 (-23.4873 to -19.4571)	
Week 20	-16.1375 (-18.1165 to -14.1586)	-23.3163 (-25.2890 to -21.3436)	-24.6844 (-26.6691 to -22.6997)	
Week 24	-15.8489 (-17.9229 to -13.7750)	-24.0359 (-26.1019 to -21.9699)	-25.1583 (-27.2341 to -23.0824)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Minimal Disease Activity (MDA) Criteria Through Week 24

End point title	Percentage of Subjects who Achieved Minimal Disease Activity (MDA) Criteria Through Week 24
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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 (\leq) 1; swollen joint count \leq 1; psoriasis activity and severity index \leq 1; patient's assessment of pain VAS score of \leq 15; patient's global assessment of disease activity VAS (arthritis and psoriasis) score of \leq 20; HAQ-DI \leq 0.5; and tender enthesal points \leq 1. Analysis population is FAS1. Participants who achieved MDA 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
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End point timeframe:

Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 16	3.3	16.9	13.1	
Week 24	6.1	25.0	18.8	

Statistical analyses

No statistical analyses for this end point

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

Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	92	67	83	
Units: percentage of subjects				
number (not applicable)				
Week 8: Participants with $\geq 20\%$ Improvement	38.0	46.3	53.0	
Week 16: Participants with $\geq 20\%$ Improvement	39.1	58.2	69.9	
Week 24: Participants with $\geq 20\%$ Improvement	42.4	59.7	68.7	
Week 8: Participants with $\geq 50\%$ Improvement	6.5	17.9	18.1	
Week 16: Participants with $\geq 50\%$ Improvement	17.4	37.3	26.5	
Week 24: Participants with $\geq 50\%$ Improvement	21.7	38.8	37.3	
Week 8: Participants with $\geq 70\%$ Improvement	3.3	11.9	4.8	
Week 16: Participants with $\geq 70\%$ Improvement	5.4	23.9	9.6	
Week 24: Participants with $\geq 70\%$ Improvement	8.7	20.9	15.7	
Week 8: Participants with $\geq 90\%$ Improvement	0	1.5	0	
Week 16: Participants with $\geq 90\%$ Improvement	1.1	0	2.4	
Week 24: Participants with $\geq 90\%$ Improvement	2.2	1.5	3.6	

Statistical analyses

Secondary: Percentage of Subjects Who Achieved PASI 75 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (Mild) at Baseline

End point title	Percentage of Subjects Who Achieved PASI 75 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (Mild) at Baseline
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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. A PASI 75 response: $\geq 75\%$ improvement in PASI score from baseline. PASI among subjects with $\geq 3\%$ 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
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End point timeframe:

Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	18.6	73.3	73.9	
Week 24	23.0	79.0	78.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 90 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (Mild) at Baseline

End point title	Percentage of Subjects Who Achieved PASI 90 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (Mild) at Baseline
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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. A PASI 90 response: $\geq 90\%$ improvement in PASI score from baseline. PASI among subjects with $\geq 3\%$ 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	8.2	55.1	53.8	
Week 24	9.8	68.8	60.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 100 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 at Baseline

End point title	Percentage of Subjects Who Achieved PASI 100 Response Through Week 24 Among Subjects With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 at Baseline
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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. A PASI 100 response: 100% improvement in PASI score from baseline. PASI 100 among subjects with $\geq 3\%$ 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	3.8	27.3	33.2	

Week 24	2.7	45.5	44.6	
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Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with an IGA Score of 0 (Cleared) Through Week 24 Among the Subjects with $\geq 3\%$ 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) Through Week 24 Among the Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA score of ≥ 2 (mild) 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). FAS1 among subjects with $\geq 3\%$ BSA of psoriasis and IGA score ≥ 2 at baseline. Subjects with IGA score of 0 (cleared) at specific time point and did not meet 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	6.0	38.6	40.8	
Week 24	7.7	50.0	51.5	

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 $\geq 3\%$ 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 $\geq 3\%$ BSA Psoriatic Involvement and
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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 change from baseline indicates improvement of psoriasis. PASI among subjects who had $\geq 3\%$ BSA of psoriatic involvement and IGA score ≥ 2 (mild) at baseline. 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
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End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	-3.482 (-4.346 to -2.618)	-11.151 (-12.028 to -10.274)	-11.278 (-12.153 to -10.404)	
Week 24	-3.904 (-4.748 to -3.059)	-11.407 (-12.265 to -10.549)	-11.471 (-12.325 to -10.617)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a DLQI Score of 0 or 1 Through Week 24 Among the Subjects with DLQI Score >1 , with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Subjects who Achieved a DLQI Score of 0 or 1 Through Week 24 Among the Subjects with DLQI Score >1 , with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. A DLQI score of 0 or 1 indicates psoriasis had no effect at all on patient's life. PASI among participants with DLQI >1 , $\geq 3\%$ BSA of psoriasis and IGA score ≥ 2 (mild) at baseline. Subjects with DLQI score of 0/1 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
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End point timeframe:

Weeks 8, 16, 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	158	173	
Units: percentage of subjects				
number (not applicable)				
Week 8	7.6	33.5	26.6	
Week 16	10.0	51.3	45.1	
Week 24	11.8	63.9	59.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ≥ 5 -point Improvement From Baseline in DLQI Score Through Week 24 Among the Subjects with DLQI score ≥ 5 , $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Subjects who Achieved ≥ 5 -point Improvement From Baseline in DLQI Score Through Week 24 Among the Subjects with DLQI score ≥ 5 , $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. An improvement of 5 points was considered clinically meaningful. FAS1 with DLQI ≥ 5 , $\geq 3\%$ BSA of psoriasis and IGA score ≥ 2 (mild) at baseline. Subjects with ≥ 5 -point improvement from baseline in DLQI score 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 considered non-responders.

End point type	Secondary
End point timeframe:	
Weeks 8, 16, 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143	132	152	
Units: percentage of subjects				
number (not applicable)				
Week 8	30.1	71.2	69.7	
Week 16	36.4	79.5	79.6	
Week 24	37.8	83.3	86.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DLQI Score at Weeks 8, 16 and 24 among the Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Change from Baseline in DLQI Score at Weeks 8, 16 and 24 among the Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. Negative changes from baseline indicate improvement of life quality impacted by psoriasis. Analysis population is FAS1 among subjects with $\geq 3\%$ BSA of psoriasis and an IGA score ≥ 2 (mild) at baseline. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. LS mean is based on MMRM model that included data from all visits for all subjects included in

End point type	Secondary
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End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	-1.653 (-2.373 to -0.933)	-6.818 (-7.549 to -6.086)	-6.396 (-7.121 to -5.671)	
Week 16	-2.410 (-3.109 to -1.710)	-8.545 (-9.255 to -7.835)	-8.147 (-8.853 to -7.441)	
Week 24	-2.129 (-2.854 to -1.404)	-8.954 (-9.691 to -8.218)	-8.853 (-9.581 to -8.124)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved both PASI 75 and ACR 20 Responses Through Week 24 Among the Subjects with $\geq 3\%$ 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 Through Week 24 Among the Subjects with $\geq 3\%$ 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 severity. PASI produces numeric score from 0-72. Higher scores=more severe disease. PASI 75: $\geq 75\%$ improvement in PASI score from baseline. PASI subjects with $\geq 3\%$ 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	10.4	48.9	48.4	
Week 24	11.5	56.8	57.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved both PASI 75 and Modified PsARC Response Through Week 24 Among the Subjects with $\geq 3\%$ 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 Through Week 24 Among the Subjects with $\geq 3\%$ 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 severity. PASI produces numeric score range 0-72. Higher scores=more severe disease. PASI 75 response: $\geq 75\%$ improvement in PASI score from baseline. PASI subjects with $\geq 3\%$ 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	184	
Units: percentage of subjects				
number (not applicable)				
Week 16	13.1	56.8	54.3	
Week 24	15.3	65.3	60.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Modified vdH-S Erosion Score at Week 24

End point title	Change from Baseline in Modified vdH-S Erosion Score at Week 24
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. Analysis population is FAS1-SD. Observed data were used regardless if 1 or more TF criteria were met. Missing data were assumed to be missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	0.58 (0.33 to 0.83)	0.36 (0.11 to 0.61)	0.13 (-0.12 to 0.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in modified vdH-S Joint Space Narrowing (JSN) Score at Week 24

End point title	Change from Baseline in modified vdH-S Joint Space Narrowing (JSN) Score at Week 24
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End point description:

The modified vdH-S score is the sum of the erosion score (hand, feet) and joint space narrowing (JSN) score (hand, feet). The JSN score is the total JSN score in 40 joints of the two hands and 12 joints of the 2 feet. Each joint is scored from 0 to 4 with 0 indicating no JSN, and 4 indicating a complete loss of joint space, bony ankylosis, or complete luxation, for a maximum JSN score of 208. Higher score indicates more severe joint space narrowing. A positive change from baseline in the modified vdH-S JSN score indicates progression of joint space narrowing. Analysis population is FAS1-SD. Observed data were used regardless if 1 or more TF criteria were met. Missing data were assumed to be missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)	0.37 (0.23 to 0.51)	0.16 (0.02 to 0.30)	0.16 (0.02 to 0.30)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores) at Week 24

End point title	Change from Baseline in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores) at Week 24
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD. Observed data used regardless if 1 or more TF criteria met. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary
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End point timeframe:

Baseline and Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
arithmetic mean (standard deviation)				
Hand Erosion Score n=245,247,240)	0.40 (± 1.555)	0.18 (± 1.280)	-0.03 (± 1.514)	
Hand JSN Score n=245,247,240)	0.26 (± 1.106)	0.10 (± 0.637)	0.08 (± 0.607)	
Hand Score n=245,247,240)	0.66 (± 2.441)	0.28 (± 1.649)	0.05 (± 1.881)	
Foot Erosion Score n=245,247,240)	0.14 (± 0.801)	0.15 (± 0.982)	0.14 (± 0.894)	
Foot JSN Score n=245,247,240)	0.10 (± 0.516)	0.02 (± 0.516)	0.07 (± 0.632)	
Foot Score n=245,247,240)	0.24 (± 1.116)	0.17 (± 1.180)	0.21 (± 1.210)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with a Change of ≤0 or ≤0.5 from Baseline in modified vdH-S Score at Week 24

End point title	Percentage of Subjects with a Change of ≤0 or ≤0.5 from Baseline in modified vdH-S Score at Week 24
End point description:	
Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD. Observed data used regardless if 1 or more TF criteria met. Missing data were assumed to be MAR and imputed using MI.	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subject				
number (not applicable)				
Change of ≤0 from Baseline	64.7	63.5	67.3	
Change of ≤0.5 from Baseline	72.1	74.4	78.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with a Change of ≤ 0 from Baseline and ≤ 0.5 from Baseline in modified vdH-S Erosion Score at Week 24

End point title	Percentage of Subjects with a Change of ≤ 0 from Baseline and ≤ 0.5 from Baseline in modified vdH-S Erosion Score at Week 24
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD. Observed data used regardless if 1 or more TF criteria met. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Change of ≤ 0 from Baseline	66.8	66.3	71.4	
Change of ≤ 0.5 from Baseline	72.9	76.8	80.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with a Change of ≤ 0 From Baseline and ≤ 0.5 From Baseline in modified vdH-S JSN Score at Week 24

End point title	Percentage of Subjects with a Change of ≤ 0 From Baseline and ≤ 0.5 From Baseline in modified vdH-S JSN Score at Week 24
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End point description:

The modified vdH-S score is the sum of the erosion score (hand, feet) and joint space narrowing (JSN) score (hand, feet). The JSN score is the sum of JSN score in 40 joints of the two hands and 12 joints of the 2 feet. Each joint is scored from 0 – 4 with 0 indicating no JSN, and 4 indicating a complete loss of joint space, bony ankylosis, or complete luxation, for a maximum JSN score of 208. Higher score indicates more severe joint space narrowing. Change from baseline in the modified vdH-S JSN score ≤ 0 (assessed by both readers) or ≤ 0.5 (assessed by at least one reader) was considered as no progression of JSN. Analysis population is FAS1-SD. Observed data were used regardless if 1 or more TF criteria were met. Missing data were assumed to be missing at random and imputed using multiple imputation.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Change of ≤ 0 from Baseline	78.6	78.8	80.1	
Change of ≤ 0.5 from Baseline	85.5	88.1	88.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects without Radiographic Progression (Based on the Smallest Detectable Change [SDC]) from Baseline at Week 24

End point title	Percentage of Subjects without Radiographic Progression (Based on the Smallest Detectable Change [SDC]) from Baseline at Week 24
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD. Observed data used regardless if 1 or more TF criteria met. Missing data were assumed to be MAR and imputed using MI.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	86.4	87.8	89.3	

Statistical analyses

Secondary: Percentage of Subjects without Radiographic Joint Erosion Progression (Based on SDC) From Baseline at Week 24

End point title	Percentage of Subjects without Radiographic Joint Erosion Progression (Based on SDC) From Baseline at Week 24
End point description:	
Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS1-SD. Observed data used regardless if 1 or more TF criteria met. Missing data were assumed to be MAR and imputed using MI.	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	84.0	89.0	89.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects without Radiographic JSN Progression (Based on the SDC) From Baseline at Week 24

End point title	Percentage of Subjects without Radiographic JSN Progression (Based on the SDC) From Baseline at Week 24
End point description:	
The modified vdH-S score is the sum of the erosion score (hand, feet) and joint space narrowing (JSN) score (hand, feet). The JSN score is the sum of JSN score in 40 joints of the two hands and 12 joints of the 2 feet. Each joint is scored from 0 – 4 with 0 indicating no JSN, and 4 indicating a complete loss of joint space, bony ankylosis, or complete luxation, for a maximum JSN score of 208. Higher score indicates more severe joint space narrowing. The smallest detectable change (SDC) was defined as the cut-off above which the changes can be detected beyond measurement error. Without radiographic JSN progression was defined as change from baseline in the modified vdH-S JSN score \leq SDC of 1.11. Analysis population is FAS1-SD. Observed data were used regardless if 1 or more TF criteria were met. Missing data were assumed to be missing at random and imputed using multiple imputation.	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)	91.3	93.5	91.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Pencil in cup or Gross Osteolysis Deformities at Baseline and Week 24

End point title	Percentage of Subjects with Pencil in cup or Gross Osteolysis Deformities at Baseline and Week 24
End point description: Pencil in Cup or Gross Osteolysis Deformities are radiographic features specific for psoriatic arthritis. Analysis population is FAS1-SD. Observed data were summarized regardless if 1 or more TF criteria were met.	
End point type	Secondary
End point timeframe: Baseline and Week 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Baseline(n=246,248,245)	4.5	3.6	3.7	
Week 24(n=245,247,240)	4.9	3.6	3.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 PCS Score at Weeks 8, 16 and 24

End point title	Change from Baseline in SF-36 PCS Score at Weeks 8, 16 and 24
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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
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End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	2.75 (1.98 to 3.52)	4.83 (4.06 to 5.59)	4.34 (3.56 to 5.1)	
Week 16	3.03 (2.18 to 3.88)	6.65 (5.80 to 7.49)	5.93 (5.07 to 6.78)	
Week 24	3.42 (2.53 to 4.32)	7.39 (6.50 to 8.29)	7.04 (6.14 to 7.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 MCS Score at Weeks 8, 16 and 24

End point title	Change from Baseline in SF-36 MCS Score at Weeks 8, 16 and 24
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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
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End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	1.11 (0.12 to 2.09)	2.28 (1.30 to 3.27)	2.87 (1.89 to 3.86)	
Week 16	1.96 (0.91 to 3.01)	4.28 (3.24 to 5.33)	3.41 (2.36 to 4.47)	
Week 24	2.14 (1.07 to 3.22)	4.17 (3.10 to 5.23)	4.22 (3.14 to 5.29)	

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
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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 participants included in the model.

End point type	Secondary
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End point timeframe:

Baseline and Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8: Physical Function Score	2.095 (1.251 to 2.940)	3.879 (3.038 to 4.720)	3.936 (3.090 to 4.782)	
Week 16: Physical Function Score	2.581 (1.669 to 3.492)	6.124 (5.218 to 7.030)	5.618 (4.704 to 6.532)	
Week 24: Physical Function Score	3.254 (2.310 to 4.197)	6.703 (5.764 to 7.642)	6.624 (5.680 to 7.567)	

Week 8: Role-physical Score	2.619 (1.828 to 3.410)	3.599 (2.812 to 4.387)	3.107 (2.315 to 3.899)
Week 16: Role-physical Score	2.965 (2.120 to 3.810)	5.616 (4.776 to 6.455)	4.942 (4.095 to 5.789)
Week 24: Role-physical Score	3.365 (2.477 to 4.253)	6.549 (5.666 to 7.433)	6.241 (5.354 to 7.129)
Week 8: Bodily Pain Score	2.760 (1.974 to 3.546)	5.456 (4.674 to 6.239)	4.901 (4.115 to 5.688)
Week 16: Bodily Pain Score	3.086 (2.196 to 3.977)	7.485 (6.601 to 8.369)	6.613 (5.721 to 7.505)
Week 24: Bodily Pain Score	3.482 (2.556 to 4.408)	7.811 (6.890 to 8.733)	7.739 (6.813 to 8.664)
Week 8: General Health Score	1.662 (0.906 to 2.418)	4.111 (3.358 to 4.863)	4.174 (3.418 to 4.931)
Week 16: General Health Score	2.520 (1.681 to 3.358)	5.719 (4.886 to 6.552)	4.808 (3.967 to 5.648)
Week 24: General Health Score	2.290 (1.415 to 3.165)	5.794 (4.924 to 6.665)	5.269 (4.394 to 6.144)
Week 8: Vitality Score	2.505 (1.574 to 3.436)	4.286 (3.358 to 5.213)	4.669 (3.736 to 5.601)
Week 16: Vitality Score	3.554 (2.559 to 4.548)	6.967 (5.980 to 7.955)	5.901 (4.904 to 6.898)
Week 24: Vitality Score	3.835 (2.755 to 4.914)	7.373 (6.299 to 8.447)	7.009 (5.929 to 8.088)
Week 8: Social Function Score	1.929 (0.976 to 2.882)	3.337 (2.387 to 4.286)	4.306 (3.352 to 5.260)
Week 16: Social Function Score	2.884 (1.853 to 3.915)	5.584 (4.560 to 6.609)	5.022 (3.989 to 6.055)
Week 24: Social Function Score	2.978 (1.964 to 3.992)	5.806 (4.796 to 6.816)	5.922 (4.909 to 6.936)
Week 8: Role-emotional Score	1.108 (0.095 to 2.121)	2.121 (1.451 to 3.468)	2.294 (1.280 to 3.307)
Week 16: Role-emotional Score	1.530 (0.499 to 2.562)	4.497 (3.472 to 5.522)	3.596 (2.563 to 4.630)
Week 24: Role-emotional Score	1.813 (0.793 to 2.834)	4.382 (3.367 to 5.398)	4.255 (3.235 to 5.275)
Week 8: Mental Health Score	1.081 (0.137 to 2.025)	2.380 (1.440 to 3.320)	3.048 (2.104 to 3.992)
Week 16: Mental Health Score	2.195 (1.204 to 3.185)	4.529 (3.546 to 5.513)	3.896 (2.905 to 4.888)
Week 24: Mental Health Score	2.335 (1.314 to 3.356)	4.490 (3.474 to 5.506)	4.767 (3.747 to 5.788)

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 Through Week 24

End point title	Percentage of Subjects who Achieved ≥ 5 -point Improvement from Baseline in SF-36 MCS Score Through Week 24
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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:	
Week 8, 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 8	26.4	33.1	27.3	
Week 16	31.7	42.3	31.8	
Week 24	30.9	37.5	34.3	

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
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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 score-better 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:	
Week 8, 16 and 24	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 8	37.8	45.2	41.2	
Week 16	35.8	59.3	51.0	
Week 24	40.2	60.1	55.9	

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
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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 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed 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
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End point timeframe:

Baseline, Weeks 8, 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 8	2.451 (1.508 to 3.395)	5.031 (4.092 to 5.970)	4.850 (3.905 to 5.795)	
Week 16	3.696 (2.675 to 4.717)	6.977 (5.963 to 7.992)	6.598 (5.574 to 7.622)	
Week 24	3.559 (2.500 to 4.619)	7.550 (6.496 to 8.603)	7.111 (6.051 to 8.171)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score Improvement Through Week 24

End point title	Percentage of Subjects who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score Improvement Through Week 24
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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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: percentage of subjects				
number (not applicable)				
Week 8	45.9	56.0	51.8	
Week 16	50.4	60.9	56.7	
Week 24	45.5	60.5	59.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EuroQol-5 Dimension-5 Level (EQ-5D-5L) at Weeks 16 and 24: EQ-VAS

End point title	Change From Baseline in EuroQol-5 Dimension-5 Level (EQ-5D-5L) at Weeks 16 and 24: EQ-VAS
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End point description:

EQ-5D-5L is a 2-part instrument for use as a measure of health outcome, designed for self-completion by respondents. It consists of EQ-5D-5L descriptive system and EQ VAS. The EQ VAS self-rating records the respondent's own assessment of his or her overall health status at the time of completion, on a vertical line VAS with scale of 0 (the worst health you can imagine) to 100 (the best health you can imagine). A higher score indicates better health and positive changes from baseline indicate improvement of health status. Analysis population is FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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
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End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	6.477 (4.013 to 8.941)	17.496 (15.049 to 19.943)	14.646 (12.179 to 17.112)	
Week 24	6.796 (4.298 to 9.294)	18.371 (15.890 to 20.852)	18.089 (15.596 to 20.581)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L at Weeks 16 and 24: EQ-5D Index

End point title	Change From Baseline in EQ-5D-5L at Weeks 16 and 24: EQ-5D Index
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End point description:

EQ-5D-5L: 2-part instrument to measure health outcome. EQ-5D-5L descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). Participant selects answer for each of 5 dimensions considering response that best matches his/her health "today". Responses were used to generate a weighted summary index (EQ-5D index), which ranges from 0 (dead) to 1.00 (full health). A higher score indicates better health and positive changes from baseline indicate improvement of health. Analysis population is FAS1. Data after meeting 1 or more TF criteria were imputed as no change from baseline. Missing data were assumed missing at random. 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
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End point timeframe:

Baseline, Weeks 16 and 24

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	246	248	245	
Units: units on a scale				
least squares mean (confidence interval 95%)				
Week 16	0.058 (0.043 to 0.074)	0.112 (0.097 to 0.127)	0.101 (0.086 to 0.116)	

Week 24	0.053 (0.037 to 0.069)	0.115 (0.099 to 0.131)	0.116 (0.100 to 0.132)	
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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 $\geq 20\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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. 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,238,234)	34.0	66.8	66.2	
Week 28 (n=238,236,232)	48.3	71.2	72.0	
Week 36 (n=231,238,230)	68.8	77.7	78.7	
Week 44 (n=234,232,223)	69.7	79.7	76.7	
Week 52 (n=230,234,228)	68.7	79.1	75.9	

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
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End point description:

ACR 50 response was defined as $\geq 50\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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
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End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=237,238,233)	15.2	32.8	34.3	
Week 28 (n=238,237,232)	22.7	41.4	40.5	
Week 36 (n=234,238,230)	39.3	44.1	45.7	
Week 44 (n=235,234,224)	43.8	48.3	48.7	
Week 52 (n=231,234,228)	43.7	51.3	49.1	

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
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End point description:

ACR 70 response was defined as $\geq 70\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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
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End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,238,233)	4.6	19.3	13.7	
Week 28 (n=237,237,232)	7.6	21.1	21.1	
Week 36 (n=234,238,231)	15.4	27.3	24.7	
Week 44 (n=235,234,225)	20.9	29.9	24.4	
Week 52 (n=229,234,228)	19.2	29.5	28.1	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Components at Weeks 24, 28, 36, 44 and 52

End point title	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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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(mg/dL). 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week24: Swollen Joint Count(n=238,238,234)	5.8 (± 6.99)	3.4 (± 5.19)	4.1 (± 5.77)	
Week28: Swollen Joint Count(n=238,238,232)	4.1 (± 5.17)	2.9 (± 4.95)	3.2 (± 5.53)	
Week36: Swollen Joint Count(n=233,238,230)	2.5 (± 3.77)	2.4 (± 4.58)	2.7 (± 4.67)	
Week44: Swollen Joint Count(n=234,234,228)	2.1 (± 3.19)	2.3 (± 4.42)	2.8 (± 5.65)	
Week52: Swollen Joint Count(n=231,234,228)	2.1 (± 3.59)	2.1 (± 4.16)	2.5 (± 4.83)	
Week24: Tender Joint Count(n=238,238,234)	14.4 (± 13.16)	9.1 (± 9.94)	10.5 (± 11.82)	

Week 28: Tender Joint Count(n=238,238,232)	11.7 (± 11.87)	7.9 (± 9.02)	8.6 (± 10.03)
Week 36: Tender Joint Count(n=233,238,230)	8.5 (± 10.00)	7.0 (± 8.72)	7.5 (± 9.25)
Week44: Tender Joint Count(n=234,234,224)	7.5 (± 9.42)	6.3 (± 8.45)	7.0 (± 9.42)
Week52: Tender Joint Count(n=231,234,228)	7.4 (± 10.24)	6.2 (± 8.18)	7.3 (± 9.46)
Week24: Patient's Assessment of Pain(n=238,238,234)	5.21 (± 2.368)	3.77 (± 2.457)	3.70 (± 2.193)
Week28: Patient's Assessment of Pain(n=238,237,232)	4.66 (± 2.341)	3.50 (± 2.311)	3.45 (± 2.259)
Week36: Patient's Assessment of Pain(n=234,239,231)	3.78 (± 2.297)	3.28 (± 2.336)	3.20 (± 2.242)
Week44: Patient's Assessment of Pain(n=235,233,225)	3.67 (± 2.312)	3.22 (± 2.370)	3.24 (± 2.277)
Week52: Patient's Assessment of Pain(n=231,234,229)	3.53 (± 2.253)	3.10 (± 2.333)	3.21 (± 2.371)
Week24: PtGA of Disease Activity(n=238,238,234)	5.29 (± 2.367)	4.01 (± 2.516)	3.93 (± 2.276)
Week28: PtGA of Disease Activity(n=238,237,232)	4.75 (± 2.338)	3.76 (± 2.348)	3.62 (± 2.275)
Week36: PtGA of Disease Activity(n=234,239,231)	3.84 (± 2.295)	3.52 (± 2.390)	3.30 (± 2.318)
Week44: PtGA of Disease Activity(n=235,233,226)	3.78 (± 2.378)	3.36 (± 2.447)	3.50 (± 2.323)
Week52: PtGA of Disease Activity(n=231,234,229)	3.68 (± 2.318)	3.23 (± 2.383)	3.28 (± 2.354)
Week24: PGA of Disease Activity(n=238,237,232)	4.22 (± 2.342)	2.74 (± 2.113)	2.66 (± 1.906)
Week28: PGA of Disease Activity(n=236,236,231)	3.27 (± 1.930)	2.44 (± 1.941)	2.33 (± 1.668)
Week36: PGA of Disease Activity(n=230,235,229)	2.28 (± 1.594)	2.10 (± 1.777)	2.06 (± 1.716)
Week44: PGA of Disease Activity(n=232,231,224)	2.06 (± 1.649)	1.97 (± 1.842)	1.93 (± 1.631)
Week52: PGA of Disease Activity(n=229,234,228)	1.90 (± 1.654)	1.77 (± 1.645)	1.77 (± 1.616)
Week24: HAQ-DI score(n=238,238,234)	1.1350 (± 0.61984)	0.8766 (± 0.59893)	0.8194 (± 0.57287)
Week28: HAQ-DI score(n=238,237,232)	1.0457 (± 0.59051)	0.8497 (± 0.61863)	0.7985 (± 0.56677)
Week36: HAQ-DI score(n=234,239,231)	0.9621 (± 0.60695)	0.8091 (± 0.61588)	0.7376 (± 0.56257)
Week44: HAQ-DI score(n=235,234,226)	0.9117 (± 0.63353)	0.7927 (± 0.59979)	0.7804 (± 0.57721)
Week52: HAQ-DI score(n=231,234,229)	0.9069 (± 0.63695)	0.7917 (± 0.59527)	0.7364 (± 0.58655)
Week24: CRP(n=236,238,234)	1.543 (± 2.1572)	0.961 (± 1.2868)	0.790 (± 0.8390)
Week28: CRP(n=235,236,229)	1.120 (± 1.5140)	0.956 (± 1.3749)	0.885 (± 1.0299)
Week36: CRP(n=231,237,231)	0.920 (± 1.4674)	0.892 (± 1.3109)	0.837 (± 1.0730)
Week 44: CRP(n=234,234,228)	0.858 (± 1.0558)	0.812 (± 1.0139)	0.992 (± 1.9875)
Week52: CRP(n=228,234,229)	0.907 (± 1.5985)	0.937 (± 1.2422)	0.910 (± 1.2756)

Statistical analyses

No statistical analyses for this end point

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

End point title	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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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 (mg/dL). 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week24: Swollen Joint Count(n=238,238,234)	-6.4 (± 7.25)	-8.2 (± 6.09)	-8.8 (± 5.50)	
Week28: Swollen Joint Count(n=238,238,232)	-8.1 (± 6.99)	-8.8 (± 5.98)	-9.6 (± 6.65)	
Week36: Swollen Joint Count(n=233,238,230)	-9.9 (± 6.47)	-9.2 (± 5.81)	-10.2 (± 6.76)	
Week44: Swollen Joint Count(n=234,234,224)	-10.1 (± 6.77)	-9.3 (± 6.24)	-10.2 (± 6.28)	
Week52: Swollen Joint Count(n=231,234,228)	-10.2 (± 6.79)	-9.6 (± 6.28)	-10.4 (± 6.17)	
Week24: Tender Joint Count(n=238,238,234)	-7.0 (± 10.91)	-10.4 (± 9.51)	-11.9 (± 9.98)	
Week28: Tender Joint Count(n=238,238,232)	-9.7 (± 10.78)	-11.7 (± 9.24)	-13.7 (± 10.53)	
Week36: Tender Joint Count(n=233,238,230)	-13.2 (± 10.78)	-12.5 (± 9.68)	-14.6 (± 10.31)	
Week44: Tender Joint Count(n=234,234,224)	-14.0 (± 11.02)	-13.3 (± 9.56)	-15.2 (± 10.25)	
Week52: Tender Joint Count(n=231,234,228)	-14.1 (± 11.39)	-13.4 (± 10.03)	-15.0 (± 10.51)	
Week24:Patient's Assessment of Pain(n=238,238,234)	-1.08 (± 2.441)	-2.55 (± 2.477)	-2.41 (± 2.335)	
Week28:Patient's Assessment of Pain(n=238,237,232)	-1.63 (± 2.420)	-2.83 (± 2.519)	-2.66 (± 2.416)	
Week36:Patient's Assessment of Pain(n=234,239,231)	-2.51 (± 2.588)	-3.02 (± 2.534)	-2.89 (± 2.540)	
Week44:Patient's Assessment of Pain(n=235,233,225)	-2.62 (± 2.640)	-3.07 (± 2.644)	-2.87 (± 2.601)	

Week52: Patient's Assessment of Pain(n=231,234,229)	-2.75 (± 2.659)	-3.20 (± 2.555)	-2.89 (± 2.681)	
Week24: PtGA of Disease Activity(n=238,238,234)	-1.25 (± 2.601)	-2.52 (± 2.490)	-2.40 (± 2.383)	
Week28: PtGA of Disease Activity(n=238,237,232)	-1.79 (± 2.543)	-2.79 (± 2.560)	-2.70 (± 2.382)	
Week36: PtGA of Disease Activity(n=234,239,231)	-2.70 (± 2.555)	-2.99 (± 2.569)	-3.01 (± 2.445)	
Week44: PtGA of Disease Activity(n=235,233,226)	-2.76 (± 2.741)	-3.15 (± 2.650)	-2.86 (± 2.559)	
Week52: PtGA of Disease Activity(n=231,234,229)	-2.85 (± 2.757)	-3.29 (± 2.558)	-3.06 (± 2.527)	
Week24: PGA of Disease Activity(n=238,237,232)	-2.45 (± 2.248)	-3.84 (± 2.316)	-3.93 (± 2.227)	
Week28: PGA of Disease Activity(n=236,236,231)	-3.42 (± 2.189)	-4.16 (± 2.175)	-4.28 (± 2.054)	
Week36: PGA of Disease Activity(n=230,235,229)	-4.39 (± 2.052)	-4.49 (± 2.116)	-4.53 (± 2.173)	
Week44: PGA of Disease Activity(n=232,231,224)	-4.61 (± 2.043)	-4.55 (± 2.139)	-4.70 (± 2.084)	
Week52: PGA of Disease Activity(n=229,234,228)	-4.77 (± 2.007)	-4.78 (± 1.996)	-4.81 (± 2.120)	
Week24: HAQ-DI score(n=237,238,234)	-0.1646 (± 0.53253)	-0.4044 (± 0.54194)	-0.4257 (± 0.50337)	
Week28: HAQ-DI score(n=237,237,232)	-0.2547 (± 0.50426)	-0.4383 (± 0.55648)	-0.4429 (± 0.51556)	
Week36: HAQ-DI score(n=233,239,231)	-0.3423 (± 0.52951)	-0.4702 (± 0.55698)	-0.5000 (± 0.55438)	
Week44: HAQ-DI score(n=234,234,226)	-0.3868 (± 0.57065)	-0.4824 (± 0.57091)	-0.4652 (± 0.56121)	
Week52: HAQ-DI score(n=230,234,239)	-0.3848 (± 0.58049)	-0.4824 (± 0.56167)	-0.5082 (± 0.58255)	
Week24: CRP(n=236,238,234)	-0.547 (± 2.5657)	-1.038 (± 2.0932)	-1.052 (± 2.1295)	
Week28: CRP(n=235,236,229)	-0.993 (± 2.3669)	-1.028 (± 2.0476)	-0.976 (± 2.1663)	
Week36: CRP(n=231,237,231)	-1.202 (± 2.3234)	-1.098 (± 2.1102)	-1.020 (± 2.1985)	
Week44: CRP(n=234,234,228)	-1.262 (± 2.5377)	-1.145 (± 2.1378)	-0.861 (± 2.8133)	
Week52: CRP(n=228,234,229)	-1.237 (± 2.8242)	-1.021 (± 2.2289)	-0.937 (± 2.4116)	

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
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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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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(mg/dL). 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percent change				
arithmetic mean (standard deviation)				
Week24: Swollen Joint Count(n=238,238,234)	-53.44 (± 45.655)	-72.06 (± 33.971)	-73.17 (± 30.614)	
Week28: Swollen Joint Count(n=238,238,232)	-66.15 (± 37.305)	-78.02 (± 30.197)	-78.85 (± 28.109)	
Week36: Swollen Joint Count(n=233,238,230)	-80.38 (± 28.144)	-82.82 (± 26.054)	-81.49 (± 27.338)	
Week44: Swollen Joint Count(n=234,234,224)	-81.85 (± 26.328)	-82.10 (± 27.742)	-83.32 (± 24.289)	
Week52: Swollen Joint Count(n=231,234,228)	-82.34 (± 30.494)	-83.18 (± 30.121)	-84.07 (± 24.070)	
Week24: Tender Joint Count(n=238,238,234)	-32.53 (± 44.850)	-54.81 (± 37.134)	-57.11 (± 35.073)	
Week28: Tender Joint Count(n=238,238,232)	-45.52 (± 41.132)	-62.48 (± 32.820)	-64.31 (± 31.767)	
Week36: Tender Joint Count(n=233,238,230)	-62.21 (± 34.292)	-66.12 (± 32.829)	-68.50 (± 30.000)	
Week44: Tender Joint Count(n=234,234,224)	-65.88 (± 33.344)	-70.90 (± 29.688)	-72.10 (± 27.670)	
Week52: Tender Joint Count(n=231,234,228)	-67.29 (± 35.583)	-70.29 (± 31.985)	-69.82 (± 32.122)	
Week24: Patient's Assessment of Pain(n=238,238,234)	-11.52 (± 48.647)	-38.44 (± 40.734)	-36.64 (± 38.086)	
Week28: Patient's Assessment of Pain(n=238,237,232)	-22.20 (± 42.404)	-42.17 (± 41.660)	-41.02 (± 39.624)	
Week36: Patient's Assessment of Pain(n=234,239,231)	-35.65 (± 43.207)	-45.89 (± 40.125)	-43.29 (± 44.442)	
Week44: Patient's Assessment of Pain(n=235,233,225)	-37.45 (± 43.534)	-46.48 (± 41.725)	-43.60 (± 42.560)	
Week52: Patient's Assessment of Pain(n=231,234,229)	-38.23 (± 47.430)	-49.00 (± 39.082)	-43.51 (± 45.742)	
Week24: PtGA of Disease Activity(n=238,238,234)	-13.78 (± 45.943)	-37.18 (± 38.628)	-33.90 (± 51.672)	
Week28: PtGA of Disease Activity(n=238,237,232)	-23.78 (± 40.895)	-39.92 (± 40.228)	-40.70 (± 36.587)	
Week36: PtGA of Disease Activity(n=234,239,231)	-38.82 (± 37.114)	-44.21 (± 36.982)	-45.52 (± 38.659)	
Week44: PtGA of Disease Activity(n=235,233,226)	-38.45 (± 43.993)	-46.64 (± 38.228)	-42.45 (± 39.243)	
Week52: PtGA of Disease Activity(n=231,234,229)	-39.34 (± 44.933)	-48.73 (± 38.925)	-45.50 (± 40.653)	
Week24: PGA of Disease Activity(n=238,237,232)	-36.13 (± 33.383)	-57.60 (± 32.634)	-59.06 (± 28.137)	

Week28: PGA of Disease Activity(n=236,236,231)	-49.72 (± 30.129)	-62.89 (± 28.027)	-64.14 (± 25.784)	
Week36: PGA of Disease Activity(n=230,235,229)	-64.57 (± 25.695)	-67.98 (± 25.989)	-67.74 (± 28.029)	
Week44: PGA of Disease Activity(n=232,231,224)	-68.32 (± 25.560)	-69.79 (± 26.949)	-70.27 (± 24.516)	
Week52: PGA of Disease Activity(n=229,234,228)	-71.05 (± 25.056)	-73.09 (± 24.133)	-72.46 (± 24.485)	
Week24: HAQ-DI score(n=234,229,231)	-6.86 (± 54.753)	-25.47 (± 63.639)	-33.72 (± 51.766)	
Week28: HAQ-DI score(n=234,229,229)	-15.66 (± 49.522)	-28.82 (± 73.930)	-33.91 (± 59.310)	
Week36: HAQ-DI score(n=230,230,228)	-23.34 (± 46.393)	-31.95 (± 78.348)	-37.74 (± 56.329)	
Week44: HAQ-DI score(n=231,225,223)	-27.01 (± 49.683)	-33.84 (± 60.164)	-32.45 (± 72.337)	
Week52: HAQ-DI score(n=227,225,226)	-26.83 (± 54.380)	-33.49 (± 63.823)	-35.02 (± 65.765)	
Week24: CRP(n=236,238,234)	19.81 (± 150.274)	-26.90 (± 110.466)	-28.35 (± 88.038)	
Week28: CRP(n=235,236,229)	-0.80 (± 155.637)	-21.09 (± 144.287)	15.69 (± 468.613)	
Week36: CRP(n=231,237,231)	-6.70 (± 183.299)	-25.47 (± 157.839)	-23.97 (± 104.641)	
Week44: CRP(n=234,234,228)	-8.33 (± 143.843)	-37.54 (± 76.302)	-17.44 (± 127.594)	
Week52: CRP(n=228,234,229)	-0.25 (± 208.267)	-23.15 (± 104.461)	-0.99 (± 193.429)	

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
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End point description:

ACR 20 response defined as $\geq 20\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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 a task in that area), and CRP. FAS2 among subject 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	

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	151		
Units: percentage of subjects				
number (not applicable)	91.7	86.8		

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
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End point description:

ACR 50 response defined as $\geq 50\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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 a task in that area), and CRP. FAS2 among subject achieved ACR50 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	

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: percentage of subjects				
number (not applicable)	87.2	79.2		

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
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End point description:

ACR 70 response defined as $\geq 70\%$ improvement from baseline in both swollen (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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 a task in that area), and CRP. FAS2 among subject achieved ACR70 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
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End point timeframe:

Week 52

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	32		
Units: percentage of subjects				
number (not applicable)	82.6	75.0		

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
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End point description:

HAQ-DI score assess functional status of participant. 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
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End point timeframe:

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

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,238,234)	-0.1646 (± 0.53253)	-0.4044 (± 0.54194)	-0.4257 (± 0.50337)	
Week 28 (n=237,237,232)	-0.2547 (± 0.50426)	-0.4383 (± 0.55648)	-0.4429 (± 0.51556)	
Week 36 (n=233,239,231)	-0.3423 (± 0.52951)	-0.4702 (± 0.55698)	-0.5000 (± 0.55438)	
-Week 44 (n=234,234,226)	-0.3868 (± 0.57065)	-0.4824 (± 0.57091)	-0.4652 (± 0.56121)	
Week 52 (n=230,234,229)	-0.3848 (± 0.58049)	-0.4824 (± 0.56167)	-0.5082 (± 0.58255)	

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
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End point description:

HAQ-DI score assess functional status of participant. 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
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End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	229	221	218	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=229,219,218)	34.1	52.5	58.3	
Week 28 (n=229,219,216)	42.4	58.4	63.4	
Week 36 (n=225,220,215)	48.4	58.2	61.9	

Week 44 (n=226,215,210)	50.9	60.0	61.4	
Week 52 (n=222,215,213)	50.5	60.9	62.9	

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
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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 scored from 0=indicating no difficulty, to 3=indicating inability to perform a task. Total HAQ score: average of the computed categories scores ranging from 0-3, 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. FAS2 among subjects who achieved HAQ-DI 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 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
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End point timeframe:

Week 52

End point values	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	123		
Units: percentage of subjects				
number (not applicable)	92.0	88.6		

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
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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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=236,238,234)	55.5	79.0	83.8	
Week 28 (n=235,238,227)	72.3	85.0	85.9	
Week 36 (n=230,236,228)	86.5	86.9	92.5	
Week 44 (n=233,232,221)	91.0	91.8	91.9	
Week 52 (n=228,234,227)	89.0	89.7	89.4	

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
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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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=236,238,234)	9.3	25.6	24.4	
Week 28 (n=235,233,227)	13.2	27.5	30.4	
Week 36 (n=230,236,228)	25.7	36.0	39.5	
Week 44 (n=233,232,221)	30.0	38.4	38.0	
Week 52 (n=228,234,227)	34.2	39.7	39.6	

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
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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
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End point timeframe:

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

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=236,238,234)	-1.02 (± 1.101)	-1.63 (± 1.051)	-1.68 (± 0.976)	
Week 28 (n=235,233,227)	-1.38 (± 1.099)	-1.78 (± 1.038)	-1.86 (± 1.066)	
Week 36 (n=230,236,228)	-1.92 (± 1.086)	-1.97 (± 1.114)	-2.08 (± 1.088)	
Week 44 (n=233,232,221)	-2.04 (± 1.098)	-2.09 (± 1.107)	-2.08 (± 1.063)	
Week 52 (n=228,234,227)	-2.14 (± 1.142)	-2.08 (± 1.121)	-2.11 (± 1.128)	

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
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End point description:

The modified PsARC response was defined as improvement in at least 2 of the four criteria: $\geq 30\%$ decrease in swollen joint count, $\geq 30\%$ decrease in tender joint count, $\geq 20\%$ improvement in patient's Global Assessment of Disease Activity (arthritis) on a VAS (0-100 mm, 0=excellent and 100=poor), $\geq 20\%$ 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
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End point timeframe:

Weeks 24, 28, 36, 44 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,237,232)	46.6	76.4	72.8	
Week 28 (n=237,237,231)	64.6	79.3	83.1	
Week 36 (n=230,237,230)	78.7	82.3	84.3	
Week 44 (n=232,233,225)	77.6	83.7	82.2	
Week 52 (n=229,234,228)	81.2	86.3	82.9	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects With Resolution of Enthesitis at Weeks 24 and 52 Among the Subjects with Enthesitis at Baseline
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End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in participants 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 participants with enthesitis (LEI) at baseline. Here, n (number analyzed) signifies the number of participants evaluable for enthesitis resolution at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	165	172	152	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=172,151,165)	45.5	32.6	57.6	
Week 52 (n=168,148,160)	60.0	67.3	65.5	

Statistical analyses

No statistical analyses for this end point

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

End point title	Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 24 and 52 Among the Subjects With Enthesitis at Baseline
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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 participants with enthesitis (LEI) at baseline. Here n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	152	165	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=170,150,161)	-1.1 (± 1.66)	-1.6 (± 1.75)	-1.6 (± 1.63)	
Week 52 (n=166,147,156)	-2.1 (± 1.61)	-1.9 (± 1.65)	-2.0 (± 1.78)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Subjects With Resolution of Dactylitis at Weeks 24 and 52 Among Subjects with Dactylitis at Baseline
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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 participants with dactylitis at baseline. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95	108	116	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=95,107,116)	41.1	60.7	68.1	
Week 52 (n=93,105,111)	78.5	81.9	81.1	

Statistical analyses

No statistical analyses for this end point

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

End point title	Change From Baseline in Dactylitis Score at Weeks 24 and 52 Among the Subjects With Dactylitis at Baseline
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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
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95	108	116	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=95,107,116)	-4.6 (± 7.88)	-6.1 (± 7.83)	-6.6 (± 7.84)	
Week 52 (n=93,105,111)	-7.4 (± 9.18)	-7.3 (± 9.74)	-7.4 (± 8.59)	

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
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End point description:

PASDAS (score range of 0 to 10, where higher score=more severe disease) is composite 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 (VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen (66 joints), tender joint count (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. 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
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=232,235,228)	-1.399 (± 1.3169)	-2.496 (± 1.5024)	-2.506 (± 1.2578)	
Week 52 (n=223,232,223)	-3.041 (± 1.4979)	-3.197 (± 1.5212)	-3.161 (± 1.4646)	

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) at Weeks 24 and 52

End point title	Percentage of Subjects with low or very low Disease Activity Based on Psoriatic Arthritis Disease Activity Score (PASDAS) at Weeks 24 and 52
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End point description:

PASDAS (score range of 0 to 10, where higher score=more severe disease) is composite 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 (VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen (66 joints), tender joint count (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
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=236,237,232)	8.1	31.6	24.6	
Week 52 (n=226,234,227)	38.5	45.3	46.3	

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
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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. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,237,232)	-1.260 (± 1.4909)	-2.658 (± 1.6770)	-2.672 (± 1.4589)	
Week 52 (n=228,234,228)	-3.085 (± 1.6277)	-3.271 (± 1.6453)	-3.267 (± 1.5646)	

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 at Weeks 24 and 52

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 at Weeks 24 and 52
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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. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,237,232)	7.6	29.5	27.6	
Week 52 (n=229,234,228)	34.9	43.2	43.0	

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
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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
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End point timeframe:

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

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=236,238,234)	-16.377 (± 19.1814)	-24.718 (± 16.7967)	-26.578 (± 15.3393)	
Week 28 (n=235,233,227)	-22.199 (± 17.9394)	-26.573 (± 15.5254)	-29.613 (± 17.6129)	
Week 36 (n=230,236,228)	-29.251 (± 18.1137)	-28.889 (± 16.4372)	-31.782 (± 16.7698)	

Week 44 (n=233,232,221)	-30.754 (± 18.5016)	-30.108 (± 16.6013)	-32.126 (± 15.7605)	
Week 52 (n=228,234,227)	-31.209 (± 18.9981)	-30.512 (± 17.5074)	-32.282 (± 16.6320)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Weeks 24 and 52

End point title	Change From Baseline in Modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Weeks 24 and 52
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End point description:

The mCPDAI assessed 4 domains (joints, skin, entheses, and dactylitis). The mCPDAI scores were calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ-DI score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0–3) was assigned, where 0= Not involved, 1= Mild, 2= Moderate and 3= Severe. The scores for each domain were then added together to give a final score range of 0 to 12. A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. Analysis population is FAS2. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=234,235,228)	-1.34 (± 2.144)	-2.97 (± 2.382)	-3.32 (± 2.098)	
Week 52 (n=226,232,224)	-3.75 (± 2.391)	-3.84 (± 2.449)	-4.10 (± 2.387)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Low Disease Activity Based on Modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Weeks 24 and 52

End point title	Percentage of Subjects with Low Disease Activity Based on Modified Composite Psoriatic Disease Activity Index (mCPDAI) Score at Weeks 24 and 52
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End point description:

The mCPDAI assessed 4 domains (joints, skin, entheses, and dactylitis). The mCPDAI scores were calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ-DI

score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0-3) was assigned, where 0= Not involved, 1= Mild, 2= Moderate and 3= Severe. The scores for each domain were then added together to give a final score range of 0 to 12. A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. mCPDAI low disease activity is defined as mCPDAI score ≤ 3.2 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 and 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,237,232)	15.1	48.9	43.5	
Week 52 (n=229,234,228)	56.3	61.1	60.1	

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
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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 entheses 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,238,234)	6.3	26.5	19.7	
Week 52 (n=231,234,228)	31.6	32.9	36.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Very low Disease Activity (VLDA) at Weeks 24 and 52

End point title	Percentage of Subjects with Very low Disease Activity (VLDA) at Weeks 24 and 52
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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 participant was considered as having achieved VLDA at a visit if the participant 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 entheses points ≤ 1) at that visit. number of subjects analyzed at specified timepoints. Analysis population is FAS2. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of subjects				
number (not applicable)				
Week 24 (n=238,237,234)	1.3	4.6	5.1	
Week 52 (n=231,234,229)	6.9	17.1	12.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score at Weeks 24 and 52 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 Weeks 24 and 52 Among Subjects with Spondylitis and Peripheral Arthritis 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. FAS2 among the subjects with spondylitis and peripheral arthritis and BASDAI score >0 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	66	79	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=91,64,78)	-1.374 (± 2.4269)	-2.652 (± 2.3825)	-2.674 (± 1.9941)	
Week 52 (n=88,64,79)	-2.986 (± 2.4945)	-2.883 (± 2.5193)	-3.084 (± 2.1843)	

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 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 at Weeks 24 and 52 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. FAS2 among the subjects with spondylitis and peripheral arthritis and BASDAI score >0 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	66	79	
Units: percentage of Subjects				
number (not applicable)				
Week24:Subjects with $\geq 20\%$ Improvement(n=91,64,78)	44.0	62.5	73.1	
Week52:Subjects with $\geq 20\%$ Improvement(n=88,64,79)	71.6	70.3	79.7	
Week24:Subjects with $\geq 50\%$ Improvement(n=91,64,78)	22.0	40.6	39.7	
Week52:Subjects with $\geq 50\%$ Improvement(n=88,64,79)	50.0	42.2	50.6	
Week24:Subjects with $\geq 70\%$ Improvement(n=91,64,78)	8.8	21.9	16.7	
Week52:Subjects with $\geq 70\%$ Improvement(n=88,64,79)	23.9	26.6	30.4	
Week24:Subjects with $\geq 90\%$ Improvement(n=91,64,78)	2.2	1.6	3.8	
Week52:Subjects with $\geq 90\%$ Improvement(n=88,64,79)	6.8	10.9	8.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Score at Weeks 24 and 52 Among the Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Change From Baseline in PASI Score at Weeks 24 and 52 Among the Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 change from baseline indicates improvement of psoriasis. Analysis population is FAS2 among the subjects who had $\geq 3\%$ 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 to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=176,172,176)	-2.989 (± 6.1515)	-11.685 (± 12.3496)	-12.574 (± 11.8391)	
Week 52 (n=172,170,173)	-11.016 (± 9.9801)	-11.977 (± 12.0847)	-12.857 (± 11.3052)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 50 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 50 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 50 response: $\geq 50\%$ improvement in PASI score from baseline. Analysis population is FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	39.8	94.8	93.8	
Week 52 (n=172,170,173)	95.9	97.1	98.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 75 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 75 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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: $\geq 75\%$ improvement in PASI score from baseline. Analysis population is FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 24 and 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	23.3	80.8	81.8	
Week 52 (n=172,170,173)	88.4	88.8	91.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 90 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 90 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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: $\geq 90\%$ improvement in PASI score from baseline. Analysis population is FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	10.2	70.3	63.6	
Week 52 (n=172,170,173)	76.7	77.1	81.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 100 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 100 Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	2.8	46.5	46.6	
Week 52 (n=172,170,173)	55.2	54.7	61.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Both PASI 75 and ACR 20 Responses at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved Both PASI 75 and ACR 20 Responses at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 severity. PASI produces numeric score from 0-72. Higher scores=more severe disease. PASI 75: $\geq 75\%$ improvement in PASI score from baseline. PASI 20 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	11.4	58.1	59.7	
Week 52 (n=171,170,173)	59.6	73.5	69.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Both PASI 75 and Modified

PsARC Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved Both PASI 75 and Modified PsARC Response at Weeks 24 and 52 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 severity. PASI produces numeric score range 0-72. Higher scores = more severe disease. PASI 75 response: $\geq 75\%$ improvement in PASI score from baseline. FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	15.3	66.9	63.6	
Week 52 (n=172,170,173)	70.9	79.4	76.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved an IGA Response at Weeks 24 and 52 Among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved an IGA Response at Weeks 24 and 52 Among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA score of ≥ 2 (mild) at Baseline
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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 participant's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Analysis population is FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177	176	173	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	71.0	19.9	72.1	
Week 52 (n=172,170,173)	84.4	84.3	77.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved an IGA Score of 0 (Cleared) at Weeks 24 and 52 Among the Participants with $\geq 3\%$ BSA of Psoriatic Involvement and an IGA score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved an IGA Score of 0 (Cleared) at Weeks 24 and 52 Among the Participants with $\geq 3\%$ BSA of Psoriatic Involvement and an IGA score of ≥ 2 (mild) at Baseline
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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 participant's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Analysis population is FAS2 among the participants who had $\geq 3\%$ BSA of psoriatic involvement and an IGA score ≥ 2 (mild) at baseline.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	177	176	173	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=176,172,176)	52.8	8.0	51.2	
Week 52 (n=172,170,173)	66.5	66.9	60.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved a DLQI Score of 0 or 1 at Weeks 24 and 52 Among the Participants with DLQI Score >1, with ≥3% BSA Psoriatic Involvement and an IGA Score of ≥2 (mild) at Baseline

End point title	Percentage of Participants who Achieved a DLQI Score of 0 or 1 at Weeks 24 and 52 Among the Participants with DLQI Score >1, with ≥3% BSA Psoriatic Involvement and an IGA Score of ≥2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. A DLQI score of 0 or 1 indicates psoriasis had no effect at all on patient's life. Analysis population is FAS2 among the participants with DLQI Score >1, with ≥3% BSA psoriatic involvement and an IGA score of ≥2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	165	155	166	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=165,154,166)	12.1	65.6	61.4	
Week 52 (n=162,153,163)	56.8	68.6	68.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ≥5-point Improvement From Baseline in DLQI Score at Weeks 24 and 52 Among the Participants with DLQI score ≥5, ≥3% BSA Psoriatic Involvement and an IGA Score of ≥2 (mild) at Baseline

End point title	Percentage of Participants who Achieved ≥5-point Improvement From Baseline in DLQI Score at Weeks 24 and 52 Among the Participants with DLQI score ≥5, ≥3% BSA Psoriatic Involvement and an IGA Score of ≥2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. An improvement of 5 points was considered clinically meaningful. Analysis population is FAS2 among the participants with DLQI score ≥5, ≥3% BSA psoriatic involvement and an IGA score of ≥2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 24 and 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	140	131	145	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=140,130,145)	40.7	85.4	90.3	
Week 52 (n=138,129,142)	84.8	92.2	89.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DLQI Score at Weeks 24 and 52 among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Change from Baseline in DLQI Score at Weeks 24 and 52 among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. Negative changes from baseline indicate improvement of life quality impacted by psoriasis. Analysis population is FAS2 among the participants with $\geq 3\%$ BSA psoriatic involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

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

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	173	177	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=176,172,177)	-2.142 (\pm 6.4593)	-8.901 (\pm 7.3657)	-9.249 (\pm 7.0988)	
Week 52 (n=173,170,174)	-8.815 (\pm 7.2714)	-9.235 (\pm 7.3840)	-9.839 (\pm 6.8777)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Modified vdH-S Score at Week 52

End point title	Change From Baseline in Modified vdH-S Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline and Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	1.25 (± 3.508)	0.97 (± 3.623)	1.07 (± 3.843)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Total Modified vdH-S Score from Week 24 to Week 52

End point title	Change in Total Modified vdH-S Score from Week 24 to Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week

24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
End point timeframe:	
From Week 24 to Week 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	0.25 (± 1.635)	0.23 (± 1.808)	0.62 (± 2.530)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Modified vdH-S Erosion Score at Week 52

End point title	Change from Baseline in Modified vdH-S Erosion Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
End point timeframe:	
Baseline and Week 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	0.92 (± 2.497)	0.67 (± 2.707)	0.70 (± 2.631)	

Statistical analyses

Secondary: Change in Modified vdH-S Erosion Score From Week 24 to Week 52

End point title	Change in Modified vdH-S Erosion Score From Week 24 to Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

From Week 24 to Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	0.17 (± 1.277)	0.10 (± 1.422)	0.39 (± 1.725)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Modified vdH-S JSN Score at Week 52

End point title	Change From Baseline in Modified vdH-S JSN Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline and Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	0.33 (± 1.356)	0.29 (± 1.272)	0.38 (± 1.633)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-S JSN Score From Week 24 to Week 52

End point title	Change in Modified vdH-S JSN Score From Week 24 to Week 52
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: From Week 24 to Week 52	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: units on a scale				
arithmetic mean (standard deviation)	0.07 (± 0.635)	0.13 (± 0.705)	0.23 (± 1.088)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores) at Week 52

End point title	Change from Baseline in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores) at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2-SD among all randomized participants who were continuing study treatment at Week 24. Here, 'n' (number analyzed) signifies the number of participants analyzed for a specified score.

End point type	Secondary
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End point timeframe:

Baseline and Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Hand Erosion Score (n=230,235,229)	0.66 (± 1.815)	0.37 (± 1.969)	0.35 (± 1.830)	
Hand JSN Score (n=230,235,229)	0.29 (± 1.181)	0.19 (± 0.913)	0.22 (± 1.235)	
Hand Score (n=230,235,229)	0.95 (± 2.706)	0.56 (± 2.589)	0.57 (± 2.759)	
Foot Erosion Score (n=230,235,229)	0.26 (± 1.014)	0.30 (± 1.339)	0.34 (± 1.413)	
Foot JSN Score (n=230,235,229)	0.04 (± 0.353)	0.10 (± 0.660)	0.16 (± 0.864)	
Foot Score (n=230,235,229)	0.30 (± 1.220)	0.40 (± 1.687)	0.50 (± 1.939)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S Score at Week 52

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=230,235,229)	57.4	55.7	56.8	
Change of ≤ 0.5 from Baseline(n=230,235,229)	67.4	67.2	72.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S Erosion Score at Week 52

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S Erosion Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=230,235,229)	58.3	59.6	60.3	
Change of ≤ 0.5 from Baseline(n=230,235,229)	70.4	71.1	72.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S JSN Score at Week 52

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline in modified vdH-S JSN Score at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=230,235,229)	78.7	75.3	79.5	
Change of ≤ 0.5 from Baseline(n=230,235,229)	88.3	86.0	86.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic Progression (Based on the SDC) from Baseline at Week 52

End point title	Percentage of Participants without Radiographic Progression (Based on the SDC) from Baseline at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: percentage of participants				
number (not applicable)	80.4	82.6	85.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic Joint Erosion Progression (Based on the SDC) from Baseline at Week 52

End point title	Percentage of Participants without Radiographic Joint Erosion Progression (Based on the SDC) from Baseline at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: percentage of participants				
number (not applicable)	82.2	84.3	87.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic JSN Progression (Based on the SDC) from Baseline at Week 52

End point title	Percentage of Participants without Radiographic JSN Progression (Based on the SDC) from Baseline at Week 52
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS2 for structural damage (FAS2-SD) included all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	230	235	229	
Units: percentage of participants				
number (not applicable)	91.3	91.5	90.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Pencil in cup or Gross Osteolysis Deformities at Baseline and Week 52

End point title	Percentage of Participants with Pencil in cup or Gross Osteolysis Deformities at Baseline and Week 52
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End point description:

Percentage of Participants with Pencil in cup or Gross Osteolysis Deformities were reported. Pencil in Cup or Gross Osteolysis Deformities are radiographic features specific for psoriatic arthritis. FAS2 for structural damage (FAS2-SD) among all randomized participants who were continuing study treatment at Week 24. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline and Week 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Baseline (n=231, 238,232)	6.9	4.6	6.9	
Week 52 (n=230, 235,229)	7.8	5.1	7.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 PCS Score at Weeks 24 and 52

End point title	Change from Baseline in SF-36 PCS Score at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				

Week 24 (n=237, 238,234)	3.782 (± 7.1776)	7.838 (± 8.0335)	7.183 (± 6.9793)	
Week 52 (n=230, 234,229)	8.124 (± 8.2192)	9.511 (± 8.3176)	8.960 (± 8.5891)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 MCS Score at Weeks 24 and 52

End point title	Change from Baseline in SF-36 MCS Score at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237, 238,234)	2.211 (± 10.1368)	4.452 (± 9.9560)	4.128 (± 9.1814)	
Week 52 (n=230, 234,229)	4.297 (± 10.8960)	4.465 (± 9.7780)	4.076 (± 9.1101)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 24 and 52

End point title	Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

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

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24: Physical Function Score (n=237,238,234)	3.602 (± 7.7388)	7.052 (± 8.5020)	6.772 (± 7.5920)	
Week 52: Physical Function Score(n=230,234,229)	7.722 (± 8.9480)	8.489 (± 8.8599)	8.374 (± 8.7884)	
Week 24: Role-physical Score(n=237,238,234)	3.695 (± 7.5950)	6.897 (± 7.7240)	6.381 (± 7.2203)	
Week 52: Role-physical Score(n=230,234,229)	6.560 (± 8.5399)	7.677 (± 8.2995)	7.344 (± 7.7145)	
Week 24: Bodily Pain Score(n=237,238,234)	3.882 (± 8.3009)	8.333 (± 8.3852)	7.833 (± 7.3390)	
Week 52: Bodily Pain Score(n=230,234,229)	8.460 (± 8.4659)	10.238 (± 8.7185)	9.457 (± 9.7977)	
Week 24: General Health Score(n=237,238,234)	2.255 (± 7.2176)	5.963 (± 7.8794)	5.067 (± 7.4182)	
Week 52: General Health Score(n=230,234,229)	6.396 (± 8.5589)	7.173 (± 7.2703)	6.366 (± 8.4199)	
Week 24: Vitality Score(n=237,238,234)	4.224 (± 9.0878)	7.914 (± 9.4638)	6.970 (± 9.4889)	
Week 52: Vitality Score(n=230,234,229)	7.879 (± 9.4160)	8.646 (± 9.5131)	7.654 (± 9.3905)	
Week 24: Social Function Score(n=237,238,234)	3.088 (± 10.4330)	6.551 (± 9.7076)	5.892 (± 8.5510)	
Week 52: Social Function Score(n=230,234,229)	6.278 (± 10.9444)	7.199 (± 10.1315)	6.787 (± 9.5326)	
Week 24: Role-emotional Score(n=237,238,234)	1.910 (± 10.0772)	4.535 (± 10.1304)	4.107 (± 8.9473)	
Week 52: Role-emotional Score(n=230,234,229)	4.057 (± 10.8795)	4.970 (± 10.1685)	4.607 (± 8.7627)	
Week 24: Mental Health Score(n=237,238,234)	2.583 (± 9.2222)	4.605 (± 9.7905)	4.752 (± 8.9336)	
Week 52: Mental Health Score(n=230,234,229)	5.153 (± 10.0724)	4.829 (± 9.3665)	4.741 (± 9.3825)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved \geq 5-point Improvement from Baseline in SF-36 PCS Score at Weeks 24 and 52

End point title	Percentage of Participants who Achieved \geq 5-point Improvement from Baseline in SF-36 PCS Score at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=237,238,234)	42.2	63.4	58.5	
Week 52 (n=230,234,229)	63.0	67.1	65.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved \geq 5-point Improvement from Baseline in SF-36 MCS Score at Weeks 24 and 52

End point title	Percentage of Participants who Achieved \geq 5-point Improvement from Baseline in SF-36 MCS Score at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=237,238,234)	32.5	40.3	36.8	
Week 52 (n=230,234,229)	41.7	44.9	38.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in FACIT-Fatigue Score at Weeks 24 and 52

End point title	Change From Baseline in FACIT-Fatigue Score at Weeks 24 and 52
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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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,238,234)	3.844 (± 9.0440)	8.034 (± 9.8888)	6.970 (± 8.6274)	
Week 52 (n=230,234,229)	7.548 (± 9.3745)	8.927 (± 9.4646)	7.686 (± 9.0833)	

Statistical analyses

Secondary: Percentage of Participants who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score Improvement at Weeks 24 and 52

End point title	Percentage of Participants who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score Improvement at Weeks 24 and 52
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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. 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 participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: percentage of participants				
number (not applicable)				
Week 24 (n=237,238,234)	49.4	63.9	62.8	
Week 52 (n=230,234,229)	68.3	69.7	68.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L at Weeks 24 and 52: EQ-VAS

End point title	Change From Baseline in EQ-5D-5L at Weeks 24 and 52: EQ-VAS
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End point description:

EQ-5D-5L is a 2-part instrument for use as a measure of health outcome, designed for self-completion by respondents. It consists of EQ-5D-5L descriptive system and EQ VAS. The EQ VAS self-rating records the respondent's own assessment of his or her overall health status at the time of completion, on a vertical line VAS with scale of 0 (the worst health you can imagine) to 100 (the best health you can imagine). A higher score indicates better health and positive changes from baseline indicate improvement of health status. Analysis population is FAS2. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,238,234)	8.456 (± 25.7204)	19.282 (± 23.5220)	17.500 (± 22.6981)	
Week 52 (n=230,234,229)	21.474 (± 25.5974)	23.295 (± 23.6270)	19.983 (± 24.7643)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L at Weeks 24 and 52: EQ-5D Index

End point title	Change From Baseline in EQ-5D-5L at Weeks 24 and 52: EQ-5D Index
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End point description:

EQ-5D-5L is a 2-part instrument for use as a measure of health outcome, designed for self-completion by respondents. It consists of EQ-5D-5L descriptive system and EQ VAS. EQ-5D-5L descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). Participant selects answer for each of 5 dimensions considering response that best matches his/her health "today". Responses were used to generate a weighted summary index (EQ-5D index), which ranges from 0 (dead) to 1.00 (full health). A higher score indicates better health and positive changes from baseline indicate improvement of health. Analysis population is FAS2. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,238,234)	0.060 (± 0.1558)	0.124 (± 0.1476)	0.117 (± 0.1307)	
Week 52 (n=230,234,229)	0.137 (± 0.1605)	0.146 (± 0.1587)	0.135 (± 0.1469)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire Scores (Percent Work Time Missed) at Weeks 24 and 52

End point title	Change From Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire Scores (Percent Work Time Missed) at Weeks 24 and 52
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS2. Here, N (number of participants analyzed) signifies number of participants evaluable for this outcome measure. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=148,141,136)	-5.64 (± 28.355)	-3.77 (± 28.029)	-1.20 (± 17.127)	
Week 52 (n=138,131,132)	-5.37 (± 25.365)	-4.47 (± 20.454)	-1.74 (± 17.084)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Impairment While Working) at Weeks 24 and 52

End point title	Change From Baseline in WPAI Scores (Percent Impairment While Working) at Weeks 24 and 52
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS2. Here, N (number of participants analyzed) signifies number of participants evaluable for this outcome measure. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=126,125,123)	-12.14 (± 29.027)	-21.28 (± 25.621)	-20.08 (± 22.084)	
Week 52 (n=118,121,124)	-21.27 (± 31.502)	-27.93 (± 25.263)	-22.10 (± 26.172)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Overall Work Impairment) at Weeks 24 and 52

End point title	Change From Baseline in WPAI Scores (Percent Overall Work Impairment) at Weeks 24 and 52
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS2. Here, N (number of participants analyzed) signifies number of participants evaluable for this outcome measure. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=126,125,123)	-13.42 (± 29.916)	-21.68 (± 27.065)	-20.90 (± 22.814)	
Week 52 (n=118,121,124)	-22.06 (± 32.092)	-28.19 (± 25.536)	-22.24 (± 26.920)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Activity Impairment Outside of Work) at Weeks 24 and 52

End point title	Change From Baseline in WPAI Scores (Percent Activity Impairment Outside of Work) at Weeks 24 and 52
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS2. Here, N (number of participants analyzed) signifies number of participants evaluable for this outcome measure. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24 and 52

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	238	240	234	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24 (n=237,238,234)	-10.80 (± 26.131)	-23.03 (± 25.559)	-21.07 (± 21.493)	
Week 52 (n=230,234,229)	-24.13 (± 27.436)	-27.14 (± 25.657)	-26.11 (± 25.361)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ACR 20 Response at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants who Achieved ACR 20 Response at Weeks 52, 68, 76, 84 and 100
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End point description:

ACR 20 response was defined as $\geq 20\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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 3 (FAS3) which included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=227,232,226)	68.7	78.9	77.0	
Week 68 (n=222,229,218)	77.0	85.2	80.7	
Week 76 (n=221,225,223)	75.6	83.1	82.5	
Week 84 (n=216,221,217)	80.1	85.1	80.6	
Week 100 (n=212,223,219)	79.2	82.1	84.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ACR 50 Response at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants who Achieved ACR 50 Response at Weeks 52, 68, 76, 84 and 100
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End point description:

ACR 50 response was defined as $\geq 50\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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 FAS3 which included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number

of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=228,232,226)	44.3	50.9	49.6	
Week 68 (n=222,227,220)	49.5	60.8	58.6	
Week 76 (n=222,225,223)	50.9	56.0	58.3	
Week 84 (n=215,221,218)	56.3	63.8	57.8	
Week 100 (n=212,224,220)	55.2	60.7	62.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ACR 70 Response at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants who Achieved ACR 70 Response at Weeks 52, 68, 76, 84 and 100
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End point description:

ACR 70 response was defined as $\geq 70\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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 FAS3 which included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=226,232,226)	19.5	29.7	28.3	
Week 68 (n=223,228,219)	27.8	35.5	36.1	
Week 76 (n=222,225,223)	27.9	36.4	32.7	
Week 84 (n=216,222,218)	29.6	42.8	39.4	
Week 100 (n=213,224,220)	34.3	39.3	38.6	

Statistical analyses

No statistical analyses for this end point

Secondary: ACR Components at Weeks 52, 68, 76, 84 and 100

End point title	ACR Components at Weeks 52, 68, 76, 84 and 100
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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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 (mg/dL). Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.	
End point type	Secondary
End point timeframe:	
Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52: Swollen Joint Count (n=228,232,226)	2.1 (± 3.58)	2.1 (± 4.18)	2.5 (± 4.83)	
Week 68: Swollen Joint Count (n=223,229,220)	1.6 (± 3.10)	1.7 (± 3.87)	2.0 (± 3.79)	
Week 76: Swollen Joint Count (n=222,225,223)	1.6 (± 3.17)	1.8 (± 3.72)	2.3 (± 4.59)	
Week 84: Swollen Joint Count (n=215,220,216)	1.6 (± 3.02)	1.6 (± 3.82)	2.0 (± 5.01)	
Week 100: Swollen Joint Count (n=213,224,220)	1.8 (± 3.75)	1.6 (± 3.99)	2.0 (± 4.11)	
Week 52: Tender Joint Count (n=228,232,226)	7.4 (± 10.30)	6.3 (± 8.20)	7.2 (± 9.49)	

Week 68: Tender Joint Count (n=223,229,220)	6.0 (± 8.83)	5.0 (± 6.83)	6.3 (± 9.27)
Week 76: Tender Joint Count (n=222,225,223)	5.7 (± 8.31)	5.2 (± 7.18)	6.2 (± 8.90)
Week 84: Tender Joint Count (n=215,220,216)	5.1 (± 7.32)	4.7 (± 7.20)	5.9 (± 9.22)
Week 100: Tender Joint Count (n=213,224,220)	5.5 (± 8.44)	4.7 (± 6.80)	6.0 (± 8.90)
Week52:Patient's Assessment of Pain(n=228,232,226)	3.53 (± 2.267)	3.12 (± 2.335)	3.17 (± 2.343)
Week68:Patient's Assessment of Pain(n=223,230,222)	3.26 (± 2.313)	2.68 (± 2.240)	2.64 (± 2.105)
Week76:Patient's Assessment of Pain(n=222,225,223)	3.17 (± 2.271)	2.73 (± 2.217)	2.70 (± 2.115)
Week84:Patient's Assessment of Pain(n=217,222,219)	2.97 (± 2.150)	2.67 (± 2.181)	2.65 (± 2.217)
Week100:Patient Assessment of Pain(n=215,224,220)	2.90 (± 2.221)	2.59 (± 2.290)	2.57 (± 2.138)
Week 52: PtGA of Disease Activity (n=228,232,226)	3.68 (± 2.331)	3.25 (± 2.380)	3.24 (± 2.322)
Week 68: PtGA of Disease Activity (n=223,230,222)	3.50 (± 2.355)	2.95 (± 2.282)	2.85 (± 2.213)
Week 76: PtGA of Disease Activity (n=222,225,223)	3.25 (± 2.356)	2.90 (± 2.273)	2.95 (± 2.222)
Week 84: PtGA of Disease Activity (n=217,222,219)	3.09 (± 2.273)	2.88 (± 2.252)	2.83 (± 2.222)
Week 100: PtGA of Disease (n=215,224,220)	3.15 (± 2.395)	2.85 (± 2.378)	2.60 (± 2.165)
Week 52: PGA of Disease Activity (n=226,232,226)	1.89 (± 1.654)	1.78 (± 1.647)	1.77 (± 1.617)
Week 68: PGA of Disease Activity (n=223,227,217)	1.63 (± 1.514)	1.56 (± 1.538)	1.61 (± 1.466)
Week 76: PGA of Disease Activity (n=221,223,223)	1.45 (± 1.469)	1.67 (± 1.660)	1.57 (± 1.524)
Week 84: PGA of Disease Activity (n=213,220,216)	1.55 (± 1.492)	1.51 (± 1.619)	1.50 (± 1.558)
Week 100: PGA of Disease Activity (n=212,224,220)	1.39 (± 1.510)	1.49 (± 1.581)	1.41 (± 1.405)
Week 52: HAQ-DI score (n=228,232,226)	0.9073 (± 0.63812)	0.7942 (± 0.59711)	0.7317 (± 0.58430)
Week 68: HAQ-DI score (n=223,230,222)	0.8425 (± 0.61757)	0.7625 (± 0.59524)	0.6836 (± 0.56049)
Week 76: HAQ-DI score (n=222,225,223)	0.8311 (± 0.62101)	0.6978 (± 0.56588)	0.6996 (± 0.55988)
Week 84: HAQ-DI score (n=217,222,219)	0.8076 (± 0.62465)	0.7134 (± 0.59528)	0.6775 (± 0.58870)
Week 100: HAQ-DI score (n=215,224,220)	0.7692 (± 0.59960)	0.6747 (± 0.57213)	0.6420 (± 0.56838)
Week 52: CRP (n=225,232,226)	0.904 (± 1.6039)	0.930 (± 1.2443)	0.886 (± 1.2366)
Week 68: CRP (n=218,228,220)	0.861 (± 1.1586)	0.884 (± 1.3520)	0.796 (± 1.1109)
Week 76: CRP (n=220,224,223)	0.903 (± 1.4624)	0.882 (± 1.2504)	0.839 (± 1.1693)
Week 84: CRP (n=217,222,217)	0.898 (± 1.3229)	0.856 (± 1.1926)	0.872 (± 1.3239)
Week 100: CRP (n=211,223,220)	0.880 (± 1.3415)	0.826 (± 1.2277)	0.820 (± 1.1227)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in ACR Components at Weeks 52, 68, 76, 84 and 100

End point title	Change From Baseline in ACR Components at Weeks 52, 68, 76, 84 and 100
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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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 (mg/dL). Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.	
End point type	Secondary
End point timeframe:	
Baseline, Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52: Swollen Joint Count (n=228,232,226)	-10.2 (± 6.72)	-9.6 (± 6.30)	-10.4 (± 6.16)	
Week 68: Swollen Joint Count(n=223,229,220)	-10.7 (± 6.76)	-10.0 (± 6.50)	-10.9 (± 7.22)	
Week 76: Swollen Joint Count(n=222,225,223)	-10.7 (± 5.98)	-10.0 (± 6.33)	-10.7 (± 6.18)	
Week 84: Swollen Joint Count(n=215,220,216)	-10.6 (± 6.06)	-10.1 (± 6.34)	-10.7 (± 7.08)	
Week 100: Swollen Joint Count(n=213,224,220)	-10.6 (± 6.15)	-10.2 (± 6.88)	-10.8 (± 6.66)	
Week 52: Tender Joint Count(n=228,232,226)	-14.1 (± 11.38)	-13.5 (± 10.04)	-15.2 (± 10.45)	
Week 68: Tender Joint Count(n=223,229,220)	-15.7 (± 10.94)	-14.8 (± 10.15)	-16.0 (± 11.02)	
Week 76: Tender Joint Count(n=222,225,223)	-16.1 (± 10.97)	-14.7 (± 10.22)	-16.1 (± 10.91)	
Week 84: Tender Joint Count(n=215,220,216)	-16.6 (± 11.33)	-15.3 (± 10.50)	-16.0 (± 11.22)	
Week 100: Tender Joint Count(n=213,224,220)	-16.3 (± 11.27)	-15.3 (± 11.10)	-16.4 (± 10.70)	
Week52:Patient's Assessment of Pain(n=228,232,226)	-2.78 (± 2.645)	-3.20 (± 2.557)	-2.92 (± 2.686)	
Week68:Patient's Assessment of Pain(n=223,230,222)	-3.10 (± 2.707)	-3.62 (± 2.530)	-3.46 (± 2.574)	
Week76:Patient's Assessment of Pain(n=222,225,223)	-3.18 (± 2.724)	-3.57 (± 2.566)	-3.38 (± 2.620)	
Week84:Patient's Assessment of Pain(n=217,222,219)	-3.35 (± 2.595)	-3.64 (± 2.568)	-3.42 (± 2.669)	

Week100:Patient Assessment of Pain(n=215,224,220)	-3.41 (± 2.578)	-3.69 (± 2.625)	-3.52 (± 2.615)	
Week 52: PtGA of Disease Activity(n=228,232,226)	-2.87 (± 2.761)	-3.29 (± 2.553)	-3.09 (± 2.523)	
Week 68: PtGA of Disease Activity(n=223,230,222)	-3.08 (± 2.786)	-3.58 (± 2.446)	-3.49 (± 2.500)	
Week 76: PtGA of Disease Activity(n=222,225,223)	-3.32 (± 2.860)	-3.63 (± 2.512)	-3.38 (± 2.501)	
Week 84: PtGA of Disease Activity(n=217,222,219)	-3.46 (± 2.752)	-3.67 (± 2.572)	-3.50 (± 2.579)	
Week 100: PtGA of Disease Activity(n=215,224,220)	-3.40 (± 2.846)	-3.67 (± 2.612)	-3.73 (± 2.493)	
Week 52: PGA of Disease Activity(n=226,232,226)	-4.79 (± 1.992)	-4.77 (± 2.001)	-4.82 (± 2.117)	
Week 68: PGA of Disease Activity(n=223,227,217)	-5.06 (± 2.037)	-4.98 (± 1.992)	-5.01 (± 2.105)	
Week 76: PGA of Disease Activity(n=221,223,223)	-5.23 (± 1.995)	-4.86 (± 2.044)	-5.03 (± 2.078)	
Week 84: PGA of Disease Activity(n=213,220,216)	-5.13 (± 2.040)	-5.06 (± 2.074)	-5.09 (± 2.142)	
Week 100: PGA of Disease Activity(n=212,224,220)	-5.26 (± 2.098)	-5.05 (± 2.011)	-5.18 (± 2.044)	
Week 52: HAQ-DI score(n=227,232,226)	-0.3899 (± 0.58250)	-0.4801 (± 0.56246)	-0.5111 (± 0.58347)	
Week 68: HAQ-DI score(n=222,230,222)	-0.4668 (± 0.59226)	-0.5120 (± 0.54928)	-0.5631 (± 0.54528)	
Week 76: HAQ-DI score(n=221,225,223)	-0.4740 (± 0.57852)	-0.5694 (± 0.56421)	-0.5448 (± 0.54739)	
Week 84: HAQ-DI score(n=216,222,219)	-0.5041 (± 0.59716)	-0.5653 (± 0.59488)	-0.5656 (± 0.57921)	
Week 100: HAQ-DI score(n=214,224,220)	-0.5356 (± 0.56707)	-0.5859 (± 0.58199)	-0.6000 (± 0.56858)	
Week 52: CRP(n=225,232,226)	-1.262 (± 2.8315)	-1.021 (± 2.2301)	-0.959 (± 2.4188)	
Week 68: CRP(n=218,228,220)	-1.212 (± 2.3061)	-1.081 (± 2.1585)	-1.060 (± 2.3334)	
Week 76: CRP(n=220,224,223)	-1.283 (± 2.8163)	-1.098 (± 2.3654)	-1.017 (± 2.2801)	
Week 84: CRP(n=217,222,217)	-1.230 (± 2.4262)	-1.101 (± 2.1216)	-0.940 (± 2.3781)	
Week 100: CRP(n=211,223,220)	-1.244 (± 2.5828)	-1.129 (± 2.2261)	-1.042 (± 2.0600)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in ACR Components at Weeks 52, 68, 76, 84 and 100

End point title	Percent Change From Baseline in ACR Components at Weeks 52, 68, 76, 84 and 100
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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; 0-10 cm, 0=no pain and 10=worst possible pain), patient's global assessment of disease activity (arthritis, VAS; 0-10 cm, 0=excellent and 10= poor), physician's global assessment of disease activity (VAS; 0-10 cm, 0=no arthritis activity and 10=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 (mg/dL). Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percent change				
arithmetic mean (standard deviation)				
Week 52: Swollen Joint Count(n=228,232,226)	-82.64 (± 30.161)	-83.03 (± 30.210)	-84.27 (± 23.698)	
Week 68: Swollen Joint Count(n=223,229,220)	-87.41 (± 24.049)	-86.08 (± 29.764)	-86.41 (± 22.642)	
Week 76: Swollen Joint Count(n=222,225,223)	-87.98 (± 20.617)	-86.05 (± 21.096)	-85.82 (± 22.291)	
Week 84: Swollen Joint Count(n=215,220,216)	-87.72 (± 22.243)	-87.68 (± 23.304)	-87.16 (± 24.888)	
Week 100: Swollen Joint Count(n=213,224,220)	-87.61 (± 21.214)	-86.19 (± 40.865)	-86.31 (± 24.106)	
Week 52: Tender Joint Count(n=228,232,226)	-67.29 (± 35.725)	-70.18 (± 32.062)	-70.54 (± 31.311)	
Week 68: Tender Joint Count(n=223,229,220)	-74.28 (± 29.764)	-75.63 (± 29.437)	-74.40 (± 29.760)	
Week 76: Tender Joint Count(n=222,225,223)	-75.71 (± 27.653)	-74.71 (± 29.728)	-75.11 (± 28.559)	
Week 84: Tender Joint Count(n=215,220,216)	-77.21 (± 27.045)	-78.01 (± 26.112)	-75.45 (± 32.489)	
Week 100: Tender Joint Count(n=213,224,220)	-77.04 (± 27.510)	-75.96 (± 32.600)	-76.21 (± 27.345)	
Week52:Patient's Assessment of Pain(n=228,232,226)	-39.52 (± 44.939)	-48.81 (± 39.191)	-43.86 (± 45.891)	
Week68:Patient's Assessment of Pain(n=223,230,222)	-44.91 (± 44.371)	-55.77 (± 38.780)	-52.43 (± 41.186)	
Week76:Patient's Assessment of Pain(n=222,225,223)	-46.02 (± 44.989)	-54.38 (± 39.135)	-51.34 (± 41.903)	
Week84:Patient's Assessment of Pain(n=217,222,219)	-49.64 (± 40.991)	-55.28 (± 40.388)	-52.59 (± 43.131)	
Week100:Patient Assessment of Pain(n=215,224,220)	-50.82 (± 42.970)	-56.36 (± 41.310)	-54.27 (± 40.819)	
Week 52: PtGA of Disease Activity(n=228,232,226)	-39.70 (± 44.981)	-48.48 (± 38.982)	-46.07 (± 40.614)	
Week 68: PtGA of Disease Activity(n=223,230,222)	-42.93 (± 44.220)	-53.84 (± 35.096)	-52.47 (± 38.155)	
Week 76: PtGA of Disease Activity(n=222,225,223)	-46.42 (± 45.106)	-54.41 (± 35.276)	-50.66 (± 40.992)	
Week 84: PtGA of Disease Activity(n=217,222,219)	-49.38 (± 42.315)	-54.17 (± 37.132)	-51.86 (± 44.532)	
Week 100: PtGA of Disease Activity(n=215,224,220)	-48.17 (± 44.804)	-55.08 (± 37.052)	-57.09 (± 34.970)	
Week 52: PGA of Disease Activity(n=228,232,226)	-71.24 (± 24.771)	-72.95 (± 24.168)	-72.58 (± 24.579)	

Week 68: PGA of Disease Activity(n=223,227,217)	-74.76 (± 23.290)	-76.00 (± 22.550)	-74.48 (± 26.280)	
Week 76: PGA of Disease Activity(n=221,223,223)	-77.68 (± 23.015)	-74.42 (± 25.014)	-75.56 (± 23.613)	
Week 84: PGA of Disease Activity(n=213,220,216)	-75.77 (± 23.674)	-76.77 (± 24.433)	-76.49 (± 24.355)	
Week 100: PGA of Disease Activity(n=212,224,220)	-78.11 (± 24.049)	-77.15 (± 23.217)	-77.82 (± 22.733)	
Week 52: HAQ-DI score(n=224,223,223)	-27.27 (± 54.587)	-33.28 (± 64.067)	-35.17 (± 66.105)	
Week 68: HAQ-DI score(n=220,221,219)	-33.34 (± 49.027)	-37.47 (± 57.370)	-44.33 (± 44.064)	
Week 76: HAQ-DI score(n=219,216,220)	-34.38 (± 47.311)	-40.08 (± 58.932)	-41.84 (± 47.877)	
Week 84: HAQ-DI score(n=214,214,216)	-36.73 (± 47.541)	-40.10 (± 58.703)	-43.18 (± 52.116)	
Week 100: HAQ-DI score(n=212,215,217)	-40.36 (± 44.407)	-42.84 (± 54.187)	-47.54 (± 47.265)	
Week 52: CRP(n=225,232,226)	-2.67 (± 205.761)	-23.41 (± 104.622)	-1.34 (± 194.673)	
Week 68: CRP(n=218,228,220)	-1.68 (± 330.574)	-28.38 (± 138.159)	-13.91 (± 174.522)	
Week 76: CRP(n=220,224,223)	-10.76 (± 226.332)	7.85 (± 502.170)	-24.22 (± 110.486)	
Week 84: CRP(n=217,222,217)	-0.72 (± 387.986)	-26.87 (± 114.471)	-19.89 (± 131.695)	
Week 100: CRP(n=211,223,220)	-4.33 (± 196.246)	-23.99 (± 150.816)	-14.35 (± 171.666)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Maintained an ACR 20 Response at Week 100 Among Participants Who Achieved an ACR 20 Response at Week 52

End point title	Percentage of Participants Who Maintained an ACR 20 Response at Week 100 Among Participants Who Achieved an ACR 20 Response at Week 52
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End point description:

ACR 20 response was defined as $\geq 20\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 20\%$ 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. FAS3 among participants who achieved ACR20 response at Week 52.

End point type	Secondary
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End point timeframe:

Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	178	171	
Units: percentage of participants				
number (not applicable)	94.6	90.4	93.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Maintained an ACR 50 Response at Week 100 Among Participants Who Achieved an ACR 50 Response at Week 52

End point title	Percentage of Participants Who Maintained an ACR 50 Response at Week 100 Among Participants Who Achieved an ACR 50 Response at Week 52
End point description:	ACR 50 response was defined as $\geq 50\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 50\%$ 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. FAS3 among participants who achieved ACR50 response at Week 52.
End point type	Secondary
End point timeframe:	Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	96	116	111	
Units: percentage of participants				
number (not applicable)	81.3	81.9	83.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Maintained an ACR 70 Response at Week 100 Among Participants Who Achieved an ACR 70 Response at Week 52

End point title	Percentage of Participants Who Maintained an ACR 70 Response at Week 100 Among Participants Who Achieved an ACR 70 Response at Week 52
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End point description:

ACR 70 response was defined as $\geq 70\%$ improvement from baseline in both swollen joint count (66 joints) and tender joint count (68 joints), and $\geq 70\%$ 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), 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. FAS3 among participants who achieved ACR70 response at Week 52.

End point type	Secondary
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End point timeframe:

Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	68	64	
Units: percentage of participants				
number (not applicable)	65.1	80.9	71.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HAQ-DI Score at Weeks 52, 68, 76, 84 and 100

End point title	Change From Baseline in HAQ-DI Score at Weeks 52, 68, 76, 84 and 100
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End point description:

HAQ-DI score assess functional status of participant. 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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	-0.3899 (± 0.58250)	-0.4801 (± 0.56246)	-0.5111 (± 0.58347)	
Week 68 (n=222,230,222)	-0.4668 (± 0.59226)	-0.5120 (± 0.54928)	-0.5631 (± 0.54528)	
Week 76 (n=221,225,223)	-0.4740 (± 0.57852)	-0.5694 (± 0.56421)	-0.5448 (± 0.54739)	
Week 84 (n=216,222,219)	-0.5041 (± 0.59716)	-0.5653 (± 0.59488)	-0.5656 (± 0.57921)	
Week 100 (n=214,224,220)	-0.5356 (± 0.56707)	-0.5859 (± 0.58199)	-0.6000 (± 0.56858)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved a Clinically Meaningful Improvement (≥ 0.35 Improvement from Baseline) in HAQ-DI Score at Weeks 52, 68, 76, 84 and 100 Among Participants With HAQ-DI score ≥ 0.35 at Baseline

End point title	Percentage of Participants who Achieved a Clinically Meaningful Improvement (≥ 0.35 Improvement from Baseline) in HAQ-DI Score at Weeks 52, 68, 76, 84 and 100 Among Participants With HAQ-DI score ≥ 0.35 at Baseline
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End point description:

HAQ-DI score assess functional status of participant. 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 FAS3 among participants with HAQ-DI score ≥ 0.35 at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	219	213	211	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=219,213,210)	51.1	60.6	63.3	
Week 68 (n=215,211,206)	57.2	64.9	69.4	
Week 76 (n=214,206,207)	59.3	68.4	64.7	

Week 84 (n=209,205,203)	58.9	66.8	65.5	
Week 100 (n=207,205,204)	63.3	70.7	70.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Maintained a HAQ-DI Response (≥ 0.35 Improvement From Baseline in HAQ-DI Score) at Week 100 Among Participants Who Achieved a HAQ-DI Response at Week 52

End point title	Percentage of Participants Who Maintained a HAQ-DI Response (≥ 0.35 Improvement From Baseline in HAQ-DI Score) at Week 100 Among Participants Who Achieved a HAQ-DI Response at Week 52
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End point description:

HAQ-DI score assess functional status of participant. 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 FAS3 among participants with HAQ-DI Score ≥ 0.35 at Baseline and who achieved a HAQ-DI response at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	125	131	
Units: percentage of participants				
number (not applicable)	91.6	90.4	88.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a DAS28 (CRP) Response at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants Who Achieved a DAS28 (CRP) Response at Weeks 52, 68, 76, 84 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of subjects analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=225, 232, 225)	89.3	89.7	90.2	
Week 68 (n=218, 227, 218)	92.7	92.5	92.7	
Week 76 (n=220, 224, 223)	94.1	90.2	93.3	
Week 84 (n=213, 218, 212)	94.8	92.7	92.5	
Week 100 (n=210, 223, 219)	94.3	90.6	92.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a DAS28 (CRP) Remission at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants Who Achieved a DAS28 (CRP) Remission at Weeks 52, 68, 76, 84 and 100
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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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 68, 76, 84 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=225,232,225)	34.7	39.7	40.4	
Week 68 (n=218,227,218)	39.0	44.9	49.1	
Week 76 (n=220,224,223)	43.2	44.2	43.5	
Week 84 (n=213,218,212)	41.8	50.9	48.1	
Week 100 (n=210,223,219)	42.4	47.5	51.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAS28 (CRP) Score at Weeks 52, 68, 76, 84 and 100

End point title	Change From Baseline in DAS28 (CRP) Score at Weeks 52, 68, 76, 84 and 100
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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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=225,232,225)	-2.14 (± 1.142)	-2.08 (± 1.124)	-2.14 (± 1.118)	
Week 68 (n=218,227,218)	-2.29 (± 1.132)	-2.25 (± 1.170)	-2.30 (± 1.143)	
Week 76 (n=220,224,223)	-2.35 (± 1.110)	-2.24 (± 1.147)	-2.24 (± 1.087)	
Week 84 (n=213,218,212)	-2.40 (± 1.087)	-2.35 (± 1.181)	-2.31 (± 1.156)	
Week 100 (n=210,223,219)	-2.42 (± 1.144)	-2.37 (± 1.215)	-2.36 (± 1.120)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants Who Achieved a Response Based on Modified Psoriatic Arthritis Responder Criteria (PsARC) at Weeks 52, 68, 76, 84 and 100
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End point description:

The modified PsARC response was defined as improvement in at least 2 of the four criteria: $\geq 30\%$ decrease in swollen joint count, $\geq 30\%$ decrease in tender joint count, $\geq 20\%$ improvement in patient's Global Assessment of Disease Activity (arthritis) on a VAS (0-100 mm, 0=excellent and 100=poor), $\geq 20\%$ 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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=226,232,226)	81.4	86.2	83.6	
Week 68 (n=223,227,218)	84.3	89.9	87.6	
Week 76 (n=221,223,223)	84.6	88.8	90.6	
Week 84 (n=214,220,217)	87.4	87.7	87.6	
Week 100 (n=212,224,220)	86.3	89.3	88.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Resolution of Enthesitis (LEI) at Weeks 52, 76 and 100 Among the Participants with Enthesitis (LEI) at Baseline

End point title	Percentage of Participants With Resolution of Enthesitis (LEI) at Weeks 52, 76 and 100 Among the Participants with Enthesitis (LEI) at Baseline
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End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in participants 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 FAS3 among the participants with enthesitis (LEI) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	165	147	160	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=165,147,159)	67.3	66.0	61.0	
Week 76 (n=159,142,157)	72.3	71.8	67.5	
Week 100 (n=153,142,155)	75.2	77.5	67.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 52, 76 and 100 Among the Participants with Enthesitis at Baseline

End point title	Change From Baseline in Enthesitis Score (Based on LEI) at Weeks 52, 76 and 100 Among the Participants with Enthesitis at Baseline
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End point description:

Enthesitis was assessed using the LEI, a tool developed to assess enthesitis in participants 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.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	165	147	160	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=163,146,155)	-2.1 (± 1.59)	-1.9 (± 1.66)	-2.1 (± 1.72)	
Week 76 (n=157,141,154)	-2.3 (± 1.52)	-2.1 (± 1.66)	-2.2 (± 1.69)	
Week 100 (n=151,141,152)	-2.4 (± 1.70)	-2.1 (± 1.65)	-2.2 (± 1.80)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Resolution of Dactylitis at Weeks 52, 76 and 100 Among Participants with Dactylitis at Baseline

End point title	Percentage of Participants With Resolution of Dactylitis at Weeks 52, 76 and 100 Among Participants 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 FAS3 among participants with dactylitis at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.
End point type	Secondary
End point timeframe:	Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	92	104	110	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=92,104,109)	78.3	81.7	80.7	
Week 76 (n=91,100,108)	80.2	84.0	82.4	
Week 100 (n=86,101,105)	83.7	91.1	82.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dactylitis Scores at Weeks 52, 76 and 100

Among the Participants with Dactylitis at Baseline

End point title	Change From Baseline in Dactylitis Scores at Weeks 52, 76 and 100 Among the Participants with Dactylitis at Baseline
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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. Negative changes from baseline indicate improvement of dactylitis. Analysis population is FAS3 among the participants with dactylitis at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	92	104	110	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=92,104,109)	-7.4 (± 9.22)	-7.3 (± 9.78)	-7.4 (± 8.66)	
Week 76 (n=91,100,108)	-8.0 (± 9.55)	-7.8 (± 10.24)	-7.6 (± 8.93)	
Week 100 (n=86,101,105)	-8.1 (± 9.63)	-7.9 (± 10.12)	-7.9 (± 9.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASDAS Score at Weeks 52, 76 and 100

End point title	Change From Baseline in PASDAS Score at Weeks 52, 76 and 100
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End point description:

PASDAS (score range of 0 to 10, where higher score=more severe disease) is composite 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 (VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen (66 joints), tender joint count (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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=220,230,221)	-3.054 (± 1.4954)	-3.189 (± 1.5216)	-3.184 (± 1.4576)	
Week 76 (n=215,220,220)	-3.503 (± 1.4708)	-3.418 (± 1.5646)	-3.436 (± 1.4428)	
Week 100 (n=204,221,215)	-3.574 (± 1.4785)	-3.586 (± 1.5425)	-3.549 (± 1.4635)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with low or very low Disease Activity Based on PASDAS at Weeks 52, 76 and 100

End point title	Percentage of Participants with low or very low Disease Activity Based on PASDAS at Weeks 52, 76 and 100
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End point description:

PASDAS (score range of 0 to 10, where higher score=more severe disease) is composite 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 (VAS [0-100 mm, 0=no arthritis activity and 100=extremely active arthritis]), swollen (66 joints), tender joint count (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. Low: PASDAS ≤ 3.2; Very low: PASDAS ≤ 1.9. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52: Low (n=223, 232, 225)	39.0	44.8	46.7	
Week 52: Very Low (n=223, 232, 225)	13.0	22.0	16.0	
Week 76: Low (n=219, 222, 223)	52.1	50.0	49.8	
Week 76: Very Low (n=219, 222, 223)	18.3	23.4	22.0	
Week 100: Low (n=206, 223, 218)	55.3	54.7	57.8	
Week 100: Very Low (n=206, 223, 218)	19.9	26.0	23.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in GRAPPA Composite Score (GRACE) at Weeks 52, 76 and 100

End point title	Change From Baseline in GRAPPA Composite Score (GRACE) at Weeks 52, 76 and 100
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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. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=225,232,226)	-3.105 (± 1.6208)	-3.266 (± 1.6443)	-3.298 (± 1.5457)	
Week 76 (n=220,223,223)	-3.499 (± 1.6303)	-3.528 (± 1.5778)	-3.541 (± 1.5048)	
Week 100 (n=211,223,220)	-3.561 (± 1.6389)	-3.656 (± 1.6071)	-3.664 (± 1.5205)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Low Disease Activity Based on Group of Research and Assessment of Psoriasis and Psoriatic Arthritis Composite (GRACE) Score Index at Weeks 52, 76 and 100

End point title	Percentage of Participants with Low Disease Activity Based on Group of Research and Assessment of Psoriasis and Psoriatic
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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= $25.355 + [2.367 * \text{HAQ-DI}] - [0.234 * \text{SF-PCS}] - [0.244 * \text{SF-MCS}]$), Total score: 0-10, lower score=better response. Higher score: more active disease activity. Negative change from baseline indicates improvement of PsA disease activity. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=226,232,226)	35.4	42.7	43.8	
Week 76 (n=221,223,223)	45.7	48.9	49.8	
Week 100 (n=212,223,220)	48.1	51.1	54.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in DAPSA at Weeks 52, 68, 76, 84 and 100

End point title	Change From Baseline in DAPSA at Weeks 52, 68, 76, 84 and 100
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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, value <lower limit of quantification [LLOQ] is considered equal to half of the value of LLOQ for numerical calculations), 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 FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=225,232,225)	-31.274 (± 18.8900)	-30.604 (± 17.5366)	-32.563 (± 16.4765)	
Week 68 (n=218,227,218)	-33.918 (± 18.0463)	-33.146 (± 18.1727)	-34.900 (± 17.5749)	
Week 76 (n=220,224,223)	-34.391 (± 17.4074)	-33.062 (± 17.5186)	-34.590 (± 16.5401)	
Week 84 (n=213,218,212)	-35.240 (± 17.7891)	-33.622 (± 18.0612)	-34.570 (± 18.2685)	
Week 100 (n=210,223,219)	-34.819 (± 17.9807)	-34.019 (± 19.2678)	-35.549 (± 16.5533)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with low Disease Activity or Remission Based on DAPSA at Weeks 52, 68, 76, 84 and 100

End point title	Percentage of Participants with low Disease Activity or Remission Based on DAPSA at Weeks 52, 68, 76, 84 and 100
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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. Low: DAPSA≤14; Remission: DAPSA≤4. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 68, 76, 84 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52: Low Disease Activity (n=225,232,225)	50.7	55.2	55.6	
Week 52: Remission (n=225,232,225)	10.2	19.4	17.3	
Week 68: Low Disease Activity (n=218,227,218)	54.1	64.3	63.3	
Week 68: Remission (n=218,227,218)	15.6	23.8	23.9	

Week 76: Low Disease Activity (n=220,224,223)	58.2	61.2	61.4	
Week 76: Remission (n=220,224,223)	16.4	26.8	19.7	
Week 84: Low Disease Activity (n=213,218,212)	60.6	66.5	64.6	
Week 84: Remission (n=213,218,212)	17.8	28.0	23.6	
Week 100: Low Disease Activity (n=210,223,219)	61.9	65.9	68.9	
Week 100: Remission (n=210,223,219)	18.6	26.9	23.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in mCPDAI Score at Weeks 52, 76 and 100

End point title	Change From Baseline in mCPDAI Score at Weeks 52, 76 and 100
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End point description:

The mCPDAI assessed 4 domains (joints, skin, entheses, and dactylitis). The mCPDAI scores were calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ-DI score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0–3) was assigned, where 0= Not involved, 1= Mild, 2= Moderate and 3= Severe. The scores for each domain were then added together to give a final score range of 0 to 12. A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=223,230,222)	-3.78 (± 2.392)	-3.83 (± 2.458)	-4.14 (± 2.358)	
Week 76 (n=217,221,220)	-4.39 (± 2.425)	-4.16 (± 2.539)	-4.47 (± 2.347)	
Week 100 (n=207,221,216)	-4.44 (± 2.484)	-4.38 (± 2.433)	-4.52 (± 2.519)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Low Disease Activity based on mCPDAI

at Weeks 52, 76 and 100

End point title	Percentage of Participants with Low Disease Activity based on mCPDAI at Weeks 52, 76 and 100
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End point description:

The mCPDAI assessed 4 domains (joints, skin, entheses, and dactylitis). The mCPDAI scores were calculated using the following assessments: joints (66 swollen and 68 tender joint counts), HAQ-DI score, PASI, dactylitis, and enthesitis. Within each domain a score (range 0–3) was assigned, where 0= Not involved, 1= Mild, 2= Moderate and 3= Severe. The scores for each domain were then added together to give a final score range of 0 to 12. A higher score indicates more active disease activity. Negative changes from baseline indicate improvement of PsA disease activity. mCPDAI low disease activity is defined as mCPDAI score ≤ 3.2 at the analysis visit. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=226,232,226)	56.6	61.2	60.6	
Week 76 (n=221,223,223)	64.3	63.7	68.6	
Week 100 (n=209,223,219)	67.5	71.7	68.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Minimal Disease Activity (MDA) at Weeks 52, 76 and 100

End point title	Percentage of Participants Who Achieved Minimal Disease Activity (MDA) at Weeks 52, 76 and 100
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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 participant was considered as having achieved the PsA MDA at a visit if the participant 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 entheses points ≤ 1 (LEI index score ≤ 1). Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=228,232,226)	32.0	32.8	37.2	
Week 76 (n=222,225,223)	34.7	40.0	39.0	
Week 100 (n=212,224,220)	42.5	44.6	42.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with VLDA at Weeks 52, 76 and 100

End point title	Percentage of Participants with VLDA at Weeks 52, 76 and 100
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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 participant was considered as having achieved VLDA at a visit if the participant 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 entheses points ≤ 1) at that visit. Analysis population is FAS3, included all participants still on treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=228,232,226)	7.0	16.8	12.4	
Week 76 (n=222,225,223)	12.2	19.6	14.8	
Week 100 (n=213,224,220)	14.6	18.8	15.0	

Statistical analyses

Secondary: Change From Baseline in BASDAI Score at Weeks 52, 76 and 100 Among Participants with Spondylitis and Peripheral Arthritis and BASDAI Score>0 at Baseline

End point title	Change From Baseline in BASDAI Score at Weeks 52, 76 and 100 Among Participants with Spondylitis and Peripheral Arthritis and BASDAI Score>0 at Baseline
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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. FAS3 among participants with spondylitis and peripheral arthritis and BASDAI Score>0 at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	63	79	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=88,63,79)	-2.986 (± 2.4945)	-2.923 (± 2.5194)	-3.084 (± 2.1843)	
Week 76 (n=85,61,77)	-3.311 (± 2.6106)	-3.377 (± 2.5969)	-3.129 (± 2.1122)	
Week 100 (n=82,61,76)	-3.718 (± 2.3960)	-3.472 (± 2.5233)	-3.330 (± 2.1598)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement from Baseline in BASDAI Score at Weeks 52, 76 and 100 Among the Participants With Spondylitis and Peripheral Arthritis and BASDAI Score >0 at Baseline

End point title	Percentage of Participants who Achieved >= 20%, >=50%, >=70%, and >=90% Improvement from Baseline in BASDAI Score at Weeks 52, 76 and 100 Among the Participants With Spondylitis and Peripheral Arthritis and BASDAI Score >0 at Baseline
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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. FAS3 among participants with spondylitis and peripheral arthritis and BASDAI score >0 at Baseline. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	63	79	
Units: percentage of participants				
number (not applicable)				
Week52:Subjects with >=20% Improvement(n=88,63,79)	71.6	69.8	79.7	
Week76:Subjects with >=20% Improvement(n=85,61,77)	74.1	82.0	81.8	
Week100:Subjects with>=20% Improvement(n=82,61,76)	87.8	77.0	82.9	
Week52:Subjects with >=50% Improvement(n=88,63,79)	50.0	42.9	50.6	
Week76:Subjects with >=50% Improvement(n=85,61,77)	52.9	52.5	50.6	
Week100:Subjects with>=50% Improvement(n=82,61,76)	59.8	57.4	55.3	
Week52:Subjects with >=70% Improvement(n=88,63,79)	23.9	27.0	30.4	
Week76:Subjects with >=70% Improvement(n=85,61,77)	31.8	31.1	26.0	
Week100:Subjects with>=70% Improvement(n=82,61,76)	32.9	39.3	32.9	
Week52:Subjects with >=90% Improvement(n=88,63,79)	6.8	11.1	8.9	
Week76:Subjects with >=90% Improvement(n=85,61,77)	11.8	13.1	7.8	
Week100:Subjects with>=90% Improvement(n=82,61,76)	18.3	11.5	9.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Score at Weeks 52, 76 and 100 Among the Participants 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 52, 76 and 100 Among the Participants with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (mild) at Baseline
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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 change from baseline indicates improvement of psoriasis. Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=171,169,173)	-11.030 (\pm 10.0077)	-11.991 (\pm 12.1194)	-12.875 (\pm 11.2905)	
Week 76 (n=166,165,172)	-11.313 (\pm 10.0631)	-11.991 (\pm 12.2656)	-13.242 (\pm 11.8845)	
Week 100 (n=160,164,170)	-11.089 (\pm 10.0239)	-12.101 (\pm 12.1322)	-13.274 (\pm 11.9673)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 50 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 50 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 50 response: $\geq 50\%$ improvement in PASI score from baseline. Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	95.9	97.0	98.3	
Week 76 (n=166,165,172)	97.6	96.4	97.1	
Week 100 (n=160,164,170)	95.6	97.0	98.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 75 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 75 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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: $\geq 75\%$ improvement in PASI score from baseline. Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	88.3	88.8	91.9	
Week 76 (n=166,165,172)	92.8	87.9	93.0	
Week 100 (n=160,164,170)	91.9	87.8	89.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 90 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 90 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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: $\geq 90\%$ improvement in PASI score from baseline. Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	76.6	76.9	81.5	
Week 76 (n=166,165,172)	85.5	75.8	80.2	
Week 100 (n=160,164,170)	87.5	75.0	80.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved PASI 100 Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants Who Achieved PASI 100 Response at
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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 FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	55.0	54.4	60.7	
Week 76 (n=166,165,172)	65.1	59.4	68.0	
Week 100 (n=160,164,170)	69.4	57.3	64.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved both PASI 75 and ACR 20 Responses at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved both PASI 75 and ACR 20 Responses at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 severity. PASI produces numeric score from 0-72. Higher scores=more severe disease. PASI 75: $\geq 75\%$ improvement in PASI score from baseline. FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=170,169,173)	59.4	73.4	70.5	
Week 76 (n=166,165,172)	71.1	75.8	76.7	
Week 100 (n=159,163,169)	73.0	76.1	77.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved both PASI 75 and Modified PsARC Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved both PASI 75 and Modified PsARC Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 severity. PASI produces numeric score range 0-72. Higher scores = more severe disease. PASI 75 response: $\geq 75\%$ improvement in PASI score from baseline. PASI 75 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	70.8	79.3	76.9	
Week 76 (n=166,165,172)	78.3	79.4	82.6	
Week 100 (n=160,164,170)	78.8	81.1	78.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with an IGA Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants with an IGA Response at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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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 participant's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). IGA Response is defined as achieving IGA score of 0 or 1, and ≥ 2 grade reduction from baseline. Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	84.2	76.9	84.4	
Week 76 (n=166,165,172)	85.5	77.6	86.0	
Week 100 (n=160,165,170)	88.1	76.4	82.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with an IGA Score of 0 (Cleared) at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants with an IGA Score of 0 (Cleared) at Weeks 52, 76 and 100 Among Participants With $\geq 3\%$ BSA
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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 participant's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Analysis population is FAS3 among participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type Secondary

End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=171,169,173)	66.7	59.8	65.9	
Week 76 (n=166,165,172)	72.9	64.2	72.1	
Week 100 (n=160,165,170)	76.9	58.8	67.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved a DLQI Score of 0 or 1 at Weeks 52, 76 and 100 Among the Participants with DLQI Score >1 , with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved a DLQI Score of 0 or 1 at Weeks 52, 76 and 100 Among the Participants with DLQI Score >1 , with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. A DLQI score of 0 or 1 indicates psoriasis had no effect at all on patient's life. Analysis population is FAS3 among the participants with DLQI Score >1 , with $\geq 3\%$ BSA psoriatic involvement and an IGA score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified

End point type Secondary

End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	161	152	163	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=161,152,162)	56.5	68.4	68.5	
Week 76 (n=157,150,161)	66.9	66.7	68.9	
Week 100 (n=154,148,159)	74.7	69.6	64.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ≥ 5 -point Improvement From Baseline in DLQI Score at Weeks 52, 76 and 100 Among the Participants with DLQI score ≥ 5 , $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Percentage of Participants who Achieved ≥ 5 -point Improvement From Baseline in DLQI Score at Weeks 52, 76 and 100 Among the Participants with DLQI score ≥ 5 , $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. An improvement of 5 points was considered clinically meaningful. Analysis population is FAS3 among the participants with DLQI score ≥ 5 , $\geq 3\%$ BSA psoriatic involvement and an IGA score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	129	143	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=138,129,142)	84.8	92.2	89.4	
Week 76 (n=135,127,141)	91.9	89.0	90.1	
Week 100 (n=132,125,139)	91.7	94.4	88.5	

Statistical analyses

Secondary: Change from Baseline in DLQI Score at Weeks 52, 76 and 100 Among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline

End point title	Change from Baseline in DLQI Score at Weeks 52, 76 and 100 Among the Participants with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of ≥ 2 (mild) at Baseline
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End point description:

Dermatology Life Quality Index (DLQI) is a 10-item instrument questionnaire used to assess the patient's perspective of the impact of psoriasis on daily living. Each item was scored on a 4-point scale (0 =not at all /not relevant; 1 =a little; 2 =a lot; 3 =very much), and the total score (0-30) is the sum of the 10 items. The higher the score, the more quality of life is impaired. Negative changes from baseline indicate improvement of life quality impacted by psoriasis. Analysis population is FAS3 among the participants with $\geq 3\%$ BSA psoriatic involvement and an IGA Score of ≥ 2 (mild) at baseline. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	169	174	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=172,169,173)	-8.855 (\pm 7.2738)	-9.272 (\pm 7.3903)	-9.873 (\pm 6.8832)	
Week 76 (n=167,167,172)	-10.090 (\pm 7.0888)	-9.180 (\pm 7.2977)	-9.610 (\pm 7.0383)	
Week 100 (n=162,165,170)	-10.130 (\pm 7.2798)	-9.291 (\pm 7.2851)	-9.635 (\pm 7.0884)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-S Score from Baseline to Week 100

End point title	Change in Modified vdH-S Score from Baseline to Week 100
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	1.49 (± 6.859)	1.50 (± 4.393)	1.68 (± 7.018)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Total Modified vdH-S Score from Week 52 to Week 100

End point title	Change in Total Modified vdH-S Score from Week 52 to Week 100
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

From Week 52 to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	0.13 (± 3.742)	0.46 (± 2.419)	0.75 (± 4.021)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-s Erosion Score from Baseline to Week 100

End point title	Change in Modified vdH-s Erosion Score from Baseline to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: Baseline to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	1.01 (± 4.034)	1.01 (± 3.355)	1.02 (± 4.676)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-s Erosion Score from Week 52 to Week 100

End point title	Change in Modified vdH-s Erosion Score from Week 52 to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: From Week 52 to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	0.09 (± 1.978)	0.26 (± 1.751)	0.45 (± 2.900)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-s JSN Score from Baseline to Week 100

End point title	Change in Modified vdH-s JSN Score from Baseline to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: Baseline to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	0.49 (± 2.984)	0.50 (± 1.387)	0.66 (± 2.722)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified vdH-s JSN Score from Week 52 to Week 100

End point title	Change in Modified vdH-s JSN Score from Week 52 to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation	

from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3-SD included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
End point timeframe:	
From Week 52 to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	216	211	
Units: units on a scale				
arithmetic mean (standard deviation)	0.04 (± 1.904)	0.20 (± 0.917)	0.30 (± 1.319)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 100 in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores)

End point title	Change from Baseline to Week 100 in modified vdH-S Score by Region and Type of Damage (ie, Hand Erosion, Hand JSN, Foot Erosion, Foot JSN Subscores)
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Baseline to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Hand Erosion Score (n=204,216,211)	0.67 (± 2.917)	0.67 (± 2.807)	0.49 (± 3.007)	
Hand JSN Score (n=204,216,211)	0.35 (± 2.443)	0.34 (± 1.247)	0.32 (± 1.845)	

Hand Score (n=204,216,211)	1.02 (± 5.244)	1.02 (± 3.815)	0.81 (± 4.532)	
Foot Erosion Score (n=204,216,211)	0.34 (± 1.596)	0.33 (± 1.362)	0.53 (± 2.436)	
Foot JSN Score (n=204,216,211)	0.13 (± 0.912)	0.15 (± 0.652)	0.34 (± 1.608)	
Foot Score (n=204,216,211)	0.48 (± 2.373)	0.48 (± 1.652)	0.87 (± 3.761)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S Score

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S Score
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score: 0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=204,216,211)	60.8	55.6	62.6	
Change of ≤ 0.5 from Baseline(n=204,216,211)	72.1	63.9	72.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S Erosion Score

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S Erosion Score
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=204,216,211)	64.2	61.1	65.4	
Change of ≤ 0.5 from Baseline(n=204,216,211)	75.0	73.1	75.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S JSN Score

End point title	Percentage of Participants with a Change of ≤ 0 or ≤ 0.5 from Baseline to Week 100 in modified vdH-S JSN Score
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Change of ≤ 0 from Baseline(n=204,216,211)	77.5	68.5	73.9	
Change of ≤ 0.5 from Baseline(n=204,216,211)	84.3	79.6	81.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic Modified vdH-S Progression Based on (SDC) from Baseline to Week 100

End point title	Percentage of Participants without Radiographic Modified vdH-S Progression Based on (SDC) from Baseline to Week 100
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End point description:

Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline to Week 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: percentage of participants				
number (not applicable)	86.8	84.7	87.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic Erosion Progression Based on (SDC) from Baseline to Week 100

End point title	Percentage of Participants without Radiographic Erosion Progression Based on (SDC) from Baseline to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: Baseline to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: percentage of participants				
number (not applicable)	86.8	87.0	88.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants without Radiographic JSN Progression (Based on SDC) from Baseline to Week 100

End point title	Percentage of Participants without Radiographic JSN Progression (Based on SDC) from Baseline to Week 100
End point description: Modified vdH-S score: erosion score (hand, feet) + JSN score (hand, feet). Joint erosion score is summary of erosion severity in 40 joints of hand, from 0=no erosion to 5=complete collapse of bone and 12 joints of 2 feet (maximum erosion score for a foot joint is 10), for a maximum erosion score of 320. JSN score is total JSN score in same 52 joints as above, each joint scored according to subluxation from 0=normal to 4=bony ankylosis or complete luxation, for maximum JSN score of 208. Total score:0(best) to 528(worst). Higher score indicates more joint damage. Positive changes from baseline in modified vdH-S total, erosion and JSN scores indicate progression of joint damage. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, 'N' (number of participants analyzed) signifies number of participants evaluable for this outcome measure.	
End point type	Secondary
End point timeframe: Baseline to Week 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	216	211	
Units: percentage of participants				
number (not applicable)	90.7	89.4	88.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Pencil in cup or Gross Osteolysis Deformities at Baseline, Weeks 24, 52, and 100

End point title	Percentage of Participants with Pencil in cup or Gross Osteolysis Deformities at Baseline, Weeks 24, 52, and 100
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End point description:

Pencil in Cup or Gross Osteolysis Deformities are radiographic features specific for psoriatic arthritis. FAS3 for structural damage (FAS3-SD) included all randomized participants who were continuing study treatment at Week 52. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 24, 52, and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Baseline (n=215,228,221)	3.7	3.9	3.6	
Week 24 (n=215,228,221)	3.7	3.9	4.1	
Week 52 (n=213,228,221)	4.2	4.4	3.6	
Week 100 (n=204,216,211)	4.9	4.6	3.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 PCS Score at Weeks 52, 76 and 100

End point title	Change from Baseline in SF-36 PCS Score at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	8.170 (± 8.2195)	9.438 (± 8.2854)	9.023 (± 8.6263)	
Week 76 (n=221,225,223)	9.762 (± 8.5908)	10.814 (± 9.0290)	9.707 (± 8.5010)	
Week 100 (n=214,224,220)	10.508 (± 8.6819)	11.282 (± 9.2753)	10.559 (± 8.7449)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SF-36 MCS Score at Weeks 52, 76 and 100

End point title	Change from Baseline in SF-36 MCS Score at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	4.383 (± 10.9402)	4.540 (± 9.7848)	4.127 (± 9.1368)	
Week 76 (n=221,225,223)	4.838 (± 11.0526)	5.034 (± 10.0334)	5.194 (± 9.4899)	
Week 100 (n=214,224,220)	4.610 (± 11.2527)	4.718 (± 9.9014)	4.936 (± 9.5935)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 52, 76 and 100

End point title	Change from Baseline in Norm Based Scores of SF-36 Scales at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed for specified categories at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52: Physical Function Score(n=227,232,226)	7.757 (± 8.9727)	8.406 (± 8.8407)	8.493 (± 8.7691)	
Week 76: Physical Function Score(n=221,225,223)	8.824 (± 9.6648)	9.807 (± 9.5044)	9.294 (± 8.2020)	
Week 100: Physical Function Score(n=214,224,220)	9.738 (± 9.8405)	10.953 (± 9.7761)	10.126 (± 8.9271)	
Week 52: Role-physical Score(n=227,232,226)	6.538 (± 8.5151)	7.665 (± 8.2925)	7.372 (± 7.7581)	
Week 76: Role-physical Score(n=221,225,223)	8.372 (± 8.7202)	9.171 (± 8.5844)	8.579 (± 7.6709)	

Week 100: Role-physical Score(n=214,224,220)	9.181 (± 8.6596)	9.342 (± 9.1746)	8.921 (± 8.1775)	
Week 52: Bodily Pain Score(n=227,232,226)	8.536 (± 8.4602)	10.201 (± 8.7312)	9.525 (± 9.8357)	
Week 76: Bodily Pain Score(n=221,225,223)	10.368 (± 9.1058)	11.552 (± 9.8591)	10.300 (± 9.0504)	
Week 100: Bodily Pain Score(n=214,224,220)	10.696 (± 9.3854)	11.585 (± 10.3527)	10.998 (± 8.9230)	
Week 52: General Health Score(n=227,232,226)	6.533 (± 8.5245)	7.097 (± 7.2500)	6.450 (± 8.4316)	
Week 76: General Health Score(n=221,225,223)	7.203 (± 8.3372)	7.470 (± 7.6119)	6.761 (± 7.9631)	
Week 100: General Health Score(n=214,224,220)	6.710 (± 8.7265)	7.066 (± 7.5829)	7.132 (± 8.4887)	
Week 52: Vitality Score(n=227,232,226)	7.997 (± 9.3878)	8.695 (± 9.5033)	7.637 (± 9.4393)	
Week 76: Vitality Score(n=221,225,223)	8.859 (± 9.4372)	9.388 (± 9.8618)	8.659 (± 9.6026)	
Week 100: Vitality Score(n=214,224,220)	9.648 (± 9.4778)	9.827 (± 9.9348)	9.155 (± 9.3569)	
Week 52: Social Function Score(n=227,232,226)	6.361 (± 10.9927)	7.304 (± 10.1003)	6.810 (± 9.5118)	
Week 76: Social Function Score(n=221,225,223)	7.509 (± 10.4249)	8.623 (± 9.5176)	7.914 (± 9.5191)	
Week 100: Social Function Score(n=214,224,220)	7.825 (± 10.8558)	8.080 (± 9.5383)	8.113 (± 9.4847)	
Week 52: Role-emotional Score(n=227,232,226)	4.111 (± 10.9413)	4.998 (± 10.1964)	4.699 (± 8.7759)	
Week 76: Role-emotional Score(n=221,225,223)	5.199 (± 11.1875)	5.757 (± 10.0737)	5.433 (± 9.2389)	
Week 100: Role-emotional Score(n=214,224,220)	4.784 (± 11.9482)	5.720 (± 10.1991)	5.128 (± 9.7998)	
Week 52: Mental Health Score(n=227,232,226)	5.209 (± 10.0958)	4.826 (± 9.4038)	4.839 (± 9.4029)	
Week 76: Mental Health Score(n=221,225,223)	5.481 (± 10.5927)	5.430 (± 10.0802)	6.124 (± 8.7930)	
Week 100: Mental Health Score(n=214,224,220)	5.514 (± 10.6204)	5.477 (± 10.1202)	6.148 (± 8.8743)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ≥5-point Improvement from Baseline in SF-36 PCS Score at Weeks 52, 76 and 100

End point title	Percentage of Participants who Achieved ≥5-point Improvement from Baseline in SF-36 PCS Score at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=227,232,226)	63.4	66.8	65.9	
Week 76 (n=221,225,223)	70.6	73.8	65.5	
Week 100 (n=214,224,220)	72.4	70.1	68.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ≥ 5 -point Improvement from Baseline in SF-36 MCS Score at Weeks 52, 76 and 100

End point title	Percentage of Participants who Achieved ≥ 5 -point Improvement from Baseline in SF-36 MCS Score at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
End point timeframe:	
Weeks 52, 76 and 100	

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=227,232,226)	42.3	45.3	38.9	
Week 76 (n=221,225,223)	43.9	44.4	43.5	
Week 100 (n=214,224,220)	42.1	46.4	43.6	

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 52, 76 and 100

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Score at Weeks 52, 76 and 100
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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 FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	7.692 (± 9.3071)	8.935 (± 9.5033)	7.699 (± 9.1417)	
Week 76 (n=221,225,223)	9.167 (± 9.0455)	9.596 (± 10.4788)	8.632 (± 8.8429)	
Week 100 (n=214,224,220)	9.435 (± 9.4513)	10.107 (± 10.2076)	9.127 (± 8.9948)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score at Weeks 52, 76 and 100

End point title	Percentage of Participants who Achieved ≥ 4 -point Improvement From Baseline in FACIT-Fatigue Score at Weeks
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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. Items were reverse scored when appropriate to provide a scale in which higher scores represent better functioning or less fatigue. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: percentage of participants				
number (not applicable)				
Week 52 (n=227,232,226)	68.7	69.4	68.1	
Week 76 (n=221,225,223)	70.6	69.3	74.4	
Week 100 (n=214,224,220)	72.0	72.8	74.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L at Weeks 52, 76 and 100: EQ-VAS

End point title	Change From Baseline in EQ-5D-5L at Weeks 52, 76 and 100: EQ-VAS
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End point description:

EQ-5D-5L is a 2-part instrument for use as a measure of health outcome, designed for self-completion by respondents. It consists of EQ-5D-5L descriptive system and EQ VAS. The EQ VAS self-rating records the respondent's own assessment of his or her overall health status at the time of completion, on a vertical line VAS with scale of 0 (the worst health you can imagine) to 100 (the best health you can imagine). A higher score indicates better health and positive changes from baseline indicate improvement of health status. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	21.608 (± 25.5992)	23.392 (± 23.6990)	20.190 (± 24.8348)	
Week 76 (n=221,225,223)	24.176 (± 27.7205)	25.053 (± 26.0372)	22.251 (± 24.6934)	
Week 100 (n=213,224,219)	25.901 (± 28.4028)	27.152 (± 26.5221)	25.909 (± 26.0995)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L at Weeks 52, 76 and 100: EQ-5D Index

End point title	Change From Baseline in EQ-5D-5L at Weeks 52, 76 and 100: EQ-5D Index
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End point description:

EQ-5D-5L is a 2-part instrument for use as a measure of health outcome, designed for self-completion by respondents. It consists of EQ-5D-5L descriptive system and EQ VAS. EQ-5D-5L descriptive system comprises of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each has 5 levels of perceived problems (1-no problem, 2-slight problems, 3-moderate problems, 4-severe problems, 5-extreme problems). Participant selects answer for each of 5 dimensions considering response that best matches his/her health "today". Responses were used to generate a weighted summary index (EQ-5D index), which ranges from 0 (dead) to 1.00 (full health). A higher score indicates better health and positive changes from baseline indicate improvement of health. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	0.138 (± 0.1608)	0.150 (± 0.1445)	0.138 (± 0.1458)	
Week 76 (n=221,225,223)	0.154 (± 0.1744)	0.169 (± 0.1564)	0.147 (± 0.1471)	
Week 100 (n=213,224,219)	0.164 (± 0.1605)	0.164 (± 0.1596)	0.156 (± 0.1543)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Work Time Missed) at Weeks 52, 76 and 100

End point title	Change From Baseline in WPAI Scores (Percent Work Time Missed) at Weeks 52, 76 and 100
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=136,130,130)	-5.45 (± 25.544)	-4.50 (± 20.530)	-1.83 (± 17.191)	
Week 76 (n=134,126,125)	-5.92 (± 26.032)	-6.22 (± 23.133)	-2.39 (± 19.277)	
Week 100 (n=125,120,115)	-8.81 (± 24.313)	-5.81 (± 21.606)	-1.56 (± 16.956)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Impairment While Working) at Weeks 52, 76 and 100

End point title	Change From Baseline in WPAI Scores (Percent Impairment While Working) at Weeks 52, 76 and 100
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=116,121,122)	-21.81 (± 31.391)	-27.93 (± 25.263)	-22.62 (± 26.058)	
Week 76 (n=116,113,111)	-26.90 (± 28.965)	-29.91 (± 24.549)	-26.13 (± 25.412)	
Week 100 (n=109,108,103)	-30.73 (± 30.933)	-30.65 (± 24.771)	-27.77 (± 26.119)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Overall Work Impairment) at Weeks 52, 76 and 100

End point title	Change From Baseline in WPAI Scores (Percent Overall Work Impairment) at Weeks 52, 76 and 100
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=116,121,122)	-22.61 (± 31.979)	-28.19 (± 25.536)	-22.79 (± 26.793)	
Week 76 (n=116,113,111)	-27.98 (± 29.709)	-30.27 (± 26.058)	-26.21 (± 28.115)	
Week 100 (n=109,108,103)	-31.87 (± 31.013)	-31.75 (± 25.615)	-25.21 (± 26.317)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in WPAI Scores (Percent Activity Impairment Outside of Work) at Weeks 52, 76 and 100

End point title	Change From Baseline in WPAI Scores (Percent Activity Impairment Outside of Work) at Weeks 52, 76 and 100
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End point description:

WPAI-PsA included 6 questions to determine employment status, hours missed from work due to PsA and from work for other reasons, hours actually worked, degree to which PsA affected work productivity and degree to which PsA affected activities outside of work during past 7 days. WPAI outcomes included percent work time missed due to PsA, percent impairment while working due to PsA, percent overall work impairment due to PsA, and percent activity impairment outside of work due to PsA, expressed as impairment percentages (0-100, 0=no impairment and 100=100% impaired), higher numbers=greater impairment and less productivity. Negative changes from baseline=improvement of work productivity and activity impairment. Analysis population is FAS3. Here, n (number analyzed) signifies the number of participants analyzed at specified timepoints.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 52, 76 and 100

End point values	Placebo to Guselkumab 100 mg q4w	Guselkumab 100 mg q8w	Guselkumab 100 mg q4w	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	228	232	227	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 52 (n=227,232,226)	-24.67 (± 27.106)	-27.16 (± 25.662)	-26.24 (± 25.113)	
Week 76 (n=221,225,2263)	-28.05 (± 26.411)	-31.38 (± 25.449)	-28.70 (± 24.635)	
Week 100 (n=213,224,219)	-30.70 (± 28.632)	-30.98 (± 26.650)	-30.68 (± 25.305)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline after the first administration of study drug through End of Study (up to Week 112)

Adverse event reporting additional description:

Safety population included participants randomized at Week 0 who received at least 1 (partial or complete) dose 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 52.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Placebo (CP)
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Reporting group description:

Participants 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 participant did not receive any guselkumab, were included.

Reporting group title	Guselkumab 100 mg q8w (CP)
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Reporting group description:

Participants received guselkumab 100 milligram (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 participant did not receive any study drug at or after Week 24, were included.

Reporting group title	Guselkumab 100 mg q4w (CP)
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Reporting group description:

Participants received guselkumab 100 milligram (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 participant did not receive any study drug at or after Week 24, were included.

Reporting group title	Placebo to Guselkumab 100 mg q4w (after CP through Week 112)
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Reporting group description:

Participants who received placebo matched to guselkumab subcutaneous injections every 4 weeks through Week 20 in the placebo controlled period (CP) received guselkumab 100 milligram (mg) subcutaneous injections every 4 weeks from Week 24 through Week 100. Data from the first administration of guselkumab through Week 112 (End of Study) were included.

Reporting group title	Guselkumab 100 mg q8w (through Week 112)
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Reporting group description:

Participants received guselkumab 100 milligram (mg) subcutaneous injections at Weeks 0 and 4 then every 8 weeks and placebo matched to guselkumab injections at other visits through Week 100. Data from Week 0 through Week 112 (End of Study) were included.

Reporting group title	Guselkumab 100 mg q4w (through Week 112)
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Reporting group description:

Participants received guselkumab 100 milligram (mg) subcutaneous injections every 4 weeks from Week 0 through Week 100. Data from Week 0 through Week 112 (End of Study) 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	7 / 246 (2.85%)	3 / 248 (1.21%)	8 / 245 (3.27%)

number of deaths (all causes) number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Clear Cell Renal Cell Carcinoma subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Ovarian Adenoma subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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 Blue Toe Syndrome subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Pelvic Venous Thrombosis subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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 Pyrexia subjects affected / exposed	0 / 246 (0.00%)	1 / 248 (0.40%)	0 / 245 (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 Cervical Polyp subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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

Dysfunctional Uterine Bleeding subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Endometrial Hyperplasia subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Endometriosis subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Metrorrhagia subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Sinus Perforation subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle Fracture subjects affected / exposed	0 / 246 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Femur Fracture			

subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metal Poisoning			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Muscle Rupture			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Post Procedural Fistula			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Road Traffic Accident			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Thermal Burn			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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			
Acute Myocardial Infarction			

subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Angina Unstable			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 246 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Pericarditis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Extrapyramidal Disorder			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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			

Diverticular Perforation			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Gastric Ulcer			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Inflammatory Bowel Disease			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Pancreatitis Chronic			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Umbilical Hernia			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Hepatobiliary disorders			
Cholecystitis Chronic			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Cholelithiasis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Drug-Induced Liver Injury			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Post Cholecystectomy Syndrome			

subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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			
Calculus Urinary			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Tubulointerstitial Nephritis			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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			
Costochondritis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Foot Deformity			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Osteoarthritis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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 Acute Hepatitis B subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	1 / 245 (0.41%) 1 / 1 0 / 0
Acute Hepatitis C subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Complicated Appendicitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Cystitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Dacryocystitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Dengue Fever subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Diverticulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 246 (0.00%) 0 / 0 0 / 0	0 / 248 (0.00%) 0 / 0 0 / 0	0 / 245 (0.00%) 0 / 0 0 / 0
Herpes Zoster Disseminated			

subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Infective Periostitis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Influenza			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Medical Device Site Joint Infection			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Meningitis Listeria			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Oophoritis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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 Influenzal			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Necrotising			

subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Tracheitis			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Vaginitis Gardnerella			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Vulvovaginitis Trichomonal			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Metabolism and nutrition disorders			
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 246 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Obesity			
subjects affected / exposed	1 / 246 (0.41%)	0 / 248 (0.00%)	0 / 245 (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
Serious adverse events	Placebo to Guselkumab 100 mg q4w (after CP through Week 112)	Guselkumab 100 mg q8w (through Week 112)	Guselkumab 100 mg q4w (through Week 112)
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 238 (6.72%)	22 / 248 (8.87%)	22 / 245 (8.98%)
number of deaths (all causes)	1	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Clear Cell Renal Cell Carcinoma subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Ovarian Adenoma subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Vascular disorders Blue Toe Syndrome subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Pelvic Venous Thrombosis subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
General disorders and administration site conditions Pyrexia subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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 Cervical Polyp subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Dysfunctional Uterine Bleeding			

subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Endometrial Hyperplasia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Endometriosis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Metrorrhagia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	2 / 245 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Perforation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle Fracture			
subjects affected / exposed	0 / 238 (0.00%)	3 / 248 (1.21%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower Limb Fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metal Poisoning			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Rupture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Fistula			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Thermal Burn			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Unstable			

subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Nervous system disorders			
Extrapyramidal Disorder			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	2 / 245 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Eye disorders			
Iridocyclitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Gastrointestinal disorders			
Diverticular Perforation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastric Ulcer			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Pancreatitis Chronic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Umbilical Hernia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Chronic			
subjects affected / exposed	0 / 238 (0.00%)	2 / 248 (0.81%)	0 / 245 (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
Cholelithiasis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Post Cholecystectomy Syndrome			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Renal and urinary disorders			

Calculus Urinary			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Tubulointerstitial Nephritis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	0 / 245 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	2 / 238 (0.84%)	0 / 248 (0.00%)	0 / 245 (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
Musculoskeletal and connective tissue disorders			
Costochondritis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Foot Deformity			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 238 (0.84%)	0 / 248 (0.00%)	2 / 245 (0.82%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Infections and infestations			
Acute Hepatitis B			

subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Hepatitis C			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Appendicitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Complicated Appendicitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Dacryocystitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Dengue Fever			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Diverticulitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Herpes Zoster Disseminated			

subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Infective Periostitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Influenza			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Medical Device Site Joint Infection			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Meningitis Listeria			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Oophoritis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 238 (0.42%)	2 / 248 (0.81%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	1 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Influenzal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Necrotising			

subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Tracheitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 248 (0.00%)	0 / 245 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Vaginitis Gardnerella			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Vulvovaginitis Trichomonal			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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
Metabolism and nutrition disorders			
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 238 (0.00%)	0 / 248 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 238 (0.00%)	1 / 248 (0.40%)	0 / 245 (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

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	30 / 246 (12.20%)	42 / 248 (16.94%)	52 / 245 (21.22%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	11 / 246 (4.47%)	15 / 248 (6.05%)	22 / 245 (8.98%)
occurrences (all)	13	19	27
Aspartate Aminotransferase Increased			
subjects affected / exposed	6 / 246 (2.44%)	14 / 248 (5.65%)	11 / 245 (4.49%)
occurrences (all)	6	19	14
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 246 (0.81%)	6 / 248 (2.42%)	3 / 245 (1.22%)
occurrences (all)	2	6	3
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 246 (1.22%)	1 / 248 (0.40%)	10 / 245 (4.08%)
occurrences (all)	3	1	11
Nasopharyngitis			
subjects affected / exposed	9 / 246 (3.66%)	10 / 248 (4.03%)	12 / 245 (4.90%)
occurrences (all)	9	11	12
Upper Respiratory Tract Infection			
subjects affected / exposed	8 / 246 (3.25%)	7 / 248 (2.82%)	13 / 245 (5.31%)
occurrences (all)	10	8	14

Non-serious adverse events	Placebo to Guselkumab 100 mg q4w (after CP through Week 112)	Guselkumab 100 mg q8w (through Week 112)	Guselkumab 100 mg q4w (through Week 112)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 238 (20.17%)	88 / 248 (35.48%)	79 / 245 (32.24%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	11 / 238 (4.62%)	29 / 248 (11.69%)	31 / 245 (12.65%)
occurrences (all)	15	47	47
Aspartate Aminotransferase Increased			
subjects affected / exposed	10 / 238 (4.20%)	23 / 248 (9.27%)	23 / 245 (9.39%)
occurrences (all)	13	37	29
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	7 / 238 (2.94%) 10	16 / 248 (6.45%) 21	7 / 245 (2.86%) 10
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	7 / 238 (2.94%) 8	10 / 248 (4.03%) 11	15 / 245 (6.12%) 19
Nasopharyngitis subjects affected / exposed occurrences (all)	9 / 238 (3.78%) 14	25 / 248 (10.08%) 38	21 / 245 (8.57%) 32
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	18 / 238 (7.56%) 20	24 / 248 (9.68%) 36	20 / 245 (8.16%) 31

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 January 2018	The amendment was considered substantial and included the following key changes: (a) 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"; (b) To allow for a one-time dose decrease in oral corticosteroids after Week 24 and through Week 52; (c) To update the version names of the eC-SSRS and to clarify when the eC-SSRS should be performed during the screening visit; (d) 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