Clinical trial results:
Multicenter, Randomized, Open-label, Efficacy Assessor-blinded, Active Comparator-controlled Phase 3b Study to Compare the Efficacy of Guselkumab to Fumaric Acid Esters (FAE [Fumaderm] Initial/ Fumaderm) for Adult Subjects with Moderate to Severe Plaque Psoriasis who are Candidates for and Naive to Systemic Treatment

Summary

EudraCT number	2016-002135-15
Trial protocol	DE
Global end of trial date	06 February 2019

Results information

Result version number	v1 (current)
This version publication date	22 February 2020
First version publication date	22 February 2020

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO3008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02951533
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag GmbH
Sponsor organisation address	Johnson and Johnson Platz 1, Neuss, Germany, 41470
Public contact	Clinical Registry Group, Janssen-Cilag GmbH, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag GmbH, 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	06 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study was to compare the efficacy of Guselkumab with commercially available active comparator FAE initial/FAE tablets for the treatment of adult subjects with moderate to severe plaque-type psoriasis who had not yet received any systemic therapy; and to assess the safety and tolerability of guselkumab in systemic treatment-naïve subjects with moderate to severe plaque-type psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Safety evaluations included monitoring of adverse events (AEs), infections, clinical laboratory parameters (chemistry, hematology, urinalysis), vital signs, and physical examination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 December 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	8 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 119
Worldwide total number of subjects	119
EEA total number of subjects	119

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)	110

From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 119 subjects were enrolled and randomized, 118 (GUS [60], FAE [58 subjects]) were treated in this study. Out of them, 42 subjects completed the study in Part III.

Period 1

Period 1 title	Part I (Week 0 through Week 24)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	Guselkumab (GUS)

Arm description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

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

Dosage and administration details:

In Part I, subjects received 100 mg of Guselkumab as 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0,4,12 and 20.

Arm title	Fumaric Acid Esters (FAE)

Arm description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and were taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets specifically labeled for study (Part IIb) up to Week 56. PASI 75 non-responders of FAE arm were switched to 100 mg GUS SC at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Arm type	Active comparator

Investigational medicinal product name	FAE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In Part I, subjects received FAE tablets by self-administration at Week 0 until Week 24.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Single-blind, Efficacy assessor was blinded.

Number of subjects in period 1	Guselkumab (GUS)	Fumaric Acid Esters (FAE)
Started	60	59
Treated	60	58
Completed	56	36
Not completed	4	23
Consent withdrawn by subject	2	4
Adverse event, non-fatal	-	16
Non-compliance with study drug	-	1
Lost to follow-up	2	2

Period 2

Period 2 title	Part IIa (Week 24 through Week 32)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Guselkumab

Arm description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

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

Dosage and administration details:

In Part IIa, Subjects continued guselkumab 100 milligram (mg) treatment administered as 100 milligram per milliliter (mg/mL) solution subcutaneously (SC) at Week 28.

Arm title	Fumaric Acid Esters (FAE)

Arm description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets labeled for study (Part IIb) up to Week 56. PASI 75 non-responders of FAE arm were switched to 100 mg GUS at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, safety follow-up was done at Week 32 (Part I)/ Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit. Part III was not applicable for this arm.

Arm type	Active comparator
Investigational medicinal product name	Fumaderm
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

In Part IIa, subjects received commercially available FAE tablets specifically labeled for the study from Week 24 through Week 32.

Number of subjects in period 2[2]	Guselkumab	Fumaric Acid Esters (FAE)
Started	56	35
PASI 75 Responder at Week 32	54 [3]	14 [4]
PASI 75 non-responder at Week 32	1 [5]	20 [6]
Completed	55	34
Not completed	1	1
Adverse event	-	1
Withdrawal by subject	1	-

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: One subject did not sign ICF for Part II.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: At Week 32, PASI 75 response evaluated, and 54 subjects were responders and 1 subject was non-responder in GUS group; and 1 subject discontinued prematurely the study treatment between W24 and Week 32.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: At Week 32, PASI 75 response evaluated, and 54 subjects were responders and 1 subject

was non-responder in GUS group; and 1 subject discontinued prematurely the study treatment between W24 and Week 32.
[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: At Week 32, PASI 75 response evaluated, and 54 subjects were responders and 1 subject was non-responder in GUS group; and 1 subject discontinued prematurely the study treatment between W24 and Week 32.
[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: At Week 32, PASI 75 response evaluated, and 54 subjects were responders and 1 subject was non-responder in GUS group; and 1 subject discontinued prematurely the study treatment between W24 and Week 32.

Period 3

Period 3 title	Part IIb (Week 32 through Week 56)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Guselkumab (GUS)

Arm description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

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

Dosage and administration details:

At Week 32 (study Part IIb), PASI 75 response was evaluated. PASI 75 responders and non-responders of guselkumab arm continued to receive guselkumab 100 mg SC every 8 weeks (weeks 36, 44 and 52).

Arm title	Fumaric Acid Esters (FAE)

Arm description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and were taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets up to Week 56 (Part IIb). PASI 75 non-responders of FAE arm were switched to 100 mg GUS at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, safety follow-up was done at Week 32 (Part I)/ Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit. Part III was not applicable for this arm.

Arm type	Active comparator

Investigational medicinal product name	FAE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets specifically labeled for the study during Part IIb up to Week 56.

Arm title	FAE to Guselkumab (GUS)

Arm description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to GUS and received GUS 100 mg SC at week 32, 36, 44 and 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed-up 12 weeks after last treatment dose. Subjects who received GUS in Study Part II (subjects who switched from FAE to GUS treatment at Week 32), had no psoriatic arthritis at baseline and achieved a PASI 90 response at end of Study Part II (Week 56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

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

Dosage and administration details:

At Week 32, PASI 75 response was evlauated and PASI 75 non-responders of FAE arm were switched to guselkumab group and received guselkumab SC at Weeks 32, 36, 44 and Week 52.

Number of subjects in period 3	Guselkumab (GUS)	Fumaric Acid Esters (FAE)	FAE to Guselkumab (GUS)
Started	55	14	20
Completed	54	10	20
Not completed	1	4	0
Adverse event	-	2	-
Lost to follow-up	1	2	-

Period 4

Period 4 title	Part III (Week 64 through Week 100)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Guselkumab

Arm description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	FAE to Guselkumab

Arm description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to GUS and received GUS 100 mg SC at week 32, 36, 44 and 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed-up 12 weeks after last treatment dose. Subjects who received GUS in Study Part II (subjects who switched from FAE to GUS treatment at Week 32), had no psoriatic arthritis at baseline and achieved a PASI 90 response at end of Study Part II (Week 56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4[7]	Guselkumab	FAE to Guselkumab
Started	36	12
Completed	32	10
Not completed	4	2
Consent withdrawn by subject	2	2
Prohibited Medication Therapy	1	-
Lost to follow-up	1	-

Notes:

[7] - 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: 18 subjects in Guselkumab group were not eligible to enter Part III and 8 subjects FAE to Guselkumab group were not eligible to enter Part III.

Baseline characteristics

Reporting groups

Reporting group title	Guselkumab (GUS)

Reporting group description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Reporting group title	Fumaric Acid Esters (FAE)

Reporting group description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and were taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets specifically labeled for study (Part IIb) up to Week 56. PASI 75 non-responders of FAE arm were switched to 100 mg GUS SC at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Reporting group values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)	Total
Number of subjects	60	59	119
Title for AgeCategorical Units: subjects			
Adults (18-64 years)	56	54	110
From 65 to 84 years	4	5	9
Title for AgeContinuous Units: years			
arithmetic mean	39	45.8	
standard deviation	± 13.98	± 13.72	-
Title for Gender Units: subjects			
Female	20	17	37
Male	40	42	82

Subject analysis sets

Subject analysis set title	Part I: Guselkumab (GUS)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received GUS 100 milligram (mg) treatment administered as 100 milligram per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, 12 and 20. Subjects who completed the treatment phase until Week 24 entered the Part II of the study.

Subject analysis set title	Part I: Fumaric Acid Esters (FAE)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received FAE tablets by self-administration at Week 0. The doses were uptitrated and had to be taken every day with different daily doses depending on the optimal individual benefit risk ratio (maximum 6*120 mg/day) according to local prescribing information up to Week 24. Subjects who completed the treatment phase until Week 24 entered the Part II of the study.

Subject analysis set title	Part I/IIa: Guselkumab (GUS)
Subject analysis set type	Full analysis

Subject analysis set description:

In Part I, subjects received GUS 100 mg treatment administered as 100 mg/mL solution SC at Weeks 0, 4, 12 and 20. Subjects who completed treatment phase until Week 24 entered Part II of study. Subjects who completed Part I continued to receive GUS 100 mg SC at Week 28 and 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Subject analysis set title	Part I/IIa: FAE
Subject analysis set type	Full analysis

Subject analysis set description:

In Part I, subjects received FAE tablets by self-administration at Week 0. The doses were up-titrated and had to be taken every day with different daily doses depending on the optimal individual benefit risk ratio (maximum 6*120 mg/day) according to local prescribing information up to Week 24. Subjects who completed the treatment phase until Week 24 entered the Part II of the study. Subjects who completed Part I and consented for Part IIa continued to receive commercially available FAE tablets specifically labeled for the study from Week 24 through Week 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Reporting group values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)	Part I/IIa: Guselkumab (GUS)
Number of subjects	60	59	60
Title for AgeCategorical			
Units: subjects			
Adults (18-64 years)	56	54	
From 65 to 84 years	4	5	
Title for AgeContinuous			
Units: years			
arithmetic mean	39	45.8	
standard deviation	± 13.98	± 13.72	±
Title for Gender			
Units: subjects			
Female	20	17	
Male	40	42	

Reporting group values	Part I/IIa: FAE		
Number of subjects	59		
Title for AgeCategorical			
Units: subjects			
Adults (18-64 years)			
From 65 to 84 years			
Title for AgeContinuous			
Units: years			
arithmetic mean			
standard deviation	±		
Title for Gender			
Units: subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Guselkumab (GUS)

Reporting group description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Reporting group title	Fumaric Acid Esters (FAE)

Reporting group description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and were taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets specifically labeled for study (Part IIb) up to Week 56. PASI 75 non-responders of FAE arm were switched to 100 mg GUS SC at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Reporting group title	Guselkumab

Reporting group description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Reporting group title	Fumaric Acid Esters (FAE)

Reporting group description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets labeled for study (Part IIb) up to Week 56. PASI 75 non-responders of FAE arm were switched to 100 mg GUS at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, safety follow-up was done at Week 32 (Part I)/ Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit. Part III was not applicable for this arm.

Reporting group title	Guselkumab (GUS)

Reporting group description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Reporting group title	Fumaric Acid Esters (FAE)

Reporting group description:

Subjects received FAE tablets by self-administration at Week 0. Doses were up-titrated and were taken every day with different daily doses depending on optimal individual benefit risk ratio (maximum 6*120 mg/day) as per local prescribing information up to Week 24 (Part I). Subjects who completed Part I and consented for Part IIa continued to receive same treatment up to Week 32 (Part IIa). At Week 32, PASI 75 response was evaluated and PASI 75 responders of FAE arm continued to receive commercially available FAE tablets up to Week 56 (Part IIb). PASI 75 non-responders of FAE arm were switched to 100 mg GUS at Weeks 32 and received 100 mg GUS SC at Week 36, 44 and Week 52 (Part IIb). For subjects who discontinued study, safety follow-up was done at Week 32 (Part I)/ Week 64 (Part II) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit. Part III was not applicable for this arm.

Reporting group title	FAE to Guselkumab (GUS)

Reporting group description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to GUS and received GUS 100 mg SC at week 32, 36, 44 and 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed-up 12 weeks after last treatment dose. Subjects who received GUS in Study Part II (subjects who switched from FAE to GUS treatment at Week 32), had no psoriatic arthritis at baseline and achieved a PASI 90 response at end of Study Part II (Week 56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

Reporting group title	Guselkumab

Reporting group description:

Subjects received GUS 100 milligram (mg) administered as 100 mg per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, then every 8 weeks (at Week 12 and 20 - Part I). Subjects who completed Part I continued to receive GUS 100 mg at Week 28 and 32 - Part IIa. At Week 32, PASI 75 response was evaluated. PASI 75 responders and non-responders of GUS arm continued to receive GUS 100 mg SC every 8 weeks (weeks 36, 44 and 52). PASI 75 non-responders of FAE switched to 100 mg GUS SC at Week 32, continued at Week 36, 44 and 52. Safety follow-up was done at Week 32 (Part I), Week 64 (Part II) and up to 12 weeks after discontinuing drug. Subjects who received GUS in Part II (who started GUS at Week 0/ switched from FAE to GUS at Week 32), had no psoriatic arthritis at baseline and achieved PASI 90 response at end of Part II (Week 56), entered follow-up extension at Week 64 in Part III and were followed-up until loss of response/ until Week 100.

Reporting group title	FAE to Guselkumab

Reporting group description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to GUS and received GUS 100 mg SC at week 32, 36, 44 and 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed-up 12 weeks after last treatment dose. Subjects who received GUS in Study Part II (subjects who switched from FAE to GUS treatment at Week 32), had no psoriatic arthritis at baseline and achieved a PASI 90 response at end of Study Part II (Week 56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

Subject analysis set title	Part I: Guselkumab (GUS)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received GUS 100 milligram (mg) treatment administered as 100 milligram per milliliter (mg/mL) solution subcutaneously (SC) at Weeks 0, 4, 12 and 20. Subjects who completed the treatment phase until Week 24 entered the Part II of the study.

Subject analysis set title	Part I: Fumaric Acid Esters (FAE)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received FAE tablets by self-administration at Week 0. The doses were uptitrated and had to be taken every day with different daily doses depending on the optimal individual benefit risk ratio (maximum 6*120 mg/day) according to local prescribing information up to Week 24. Subjects who completed the treatment phase until Week 24 entered the Part II of the study.

Subject analysis set title	Part I/IIa: Guselkumab (GUS)
Subject analysis set type	Full analysis

Subject analysis set description:

In Part I, subjects received GUS 100 mg treatment administered as 100 mg/mL solution SC at Weeks 0, 4, 12 and 20. Subjects who completed treatment phase until Week 24 entered Part II of study. Subjects who completed Part I continued to receive GUS 100 mg SC at Week 28 and 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last

treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Subject analysis set title	Part I/IIa: FAE
Subject analysis set type	Full analysis

Subject analysis set description:

In Part I, subjects received FAE tablets by self-administration at Week 0. The doses were up-titrated and had to be taken every day with different daily doses depending on the optimal individual benefit risk ratio (maximum 6*120 mg/day) according to local prescribing information up to Week 24. Subjects who completed the treatment phase until Week 24 entered the Part II of the study. Subjects who completed Part I and consented for Part IIa continued to receive commercially available FAE tablets specifically labeled for the study from Week 24 through Week 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Primary: Part I: Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24

End point title	Part I: Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Efficacy analysis set (EAS) included all subjects randomized to 1 of 2 treatments (GUS or FAE) at Week 0 regardless of treatment they received. Missing data was imputed by non-responder imputation (NRI) (subjects with missing data at Week 4,16 and 24 were non-responders).

End point type	Primary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	81.7	13.6		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Part I: Guselkumab (GUS) v Part I: Fumaric Acid Esters (FAE)

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Chi-squared

Secondary: Part I: Percentage of Subjects who Achieved PASI 75 Response at Week 24

End point title	Part I: Percentage of Subjects who Achieved PASI 75 Response at Week 24

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 75 response denotes subjects achieving 75% improvement from baseline in PASI score. EAS included all subjects who were randomized to 1 of 2 treatment groups (GUS or FAE) at Week 0 regardless of treatment they actually received. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	90.0	27.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Percentage of Subjects who Achieved a Dermatology Life Quality Index (DLQI) Score of Less Than or Equal to (=<) 1 at Week 24

End point title	Part I: Percentage of Subjects who Achieved a Dermatology Life Quality Index (DLQI) Score of Less Than or Equal to (=<) 1 at Week 24

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large

effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. EAS included all subjects who were randomized to 1 of 2 treatment groups (GUS or FAE) at Week 0 regardless of treatment they actually received. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	61.7	16.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Percentage of Subjects who Achieved PASI 100 Response at Week 24

End point title	Part I: Percentage of Subjects who Achieved PASI 100 Response at Week 24

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 (none) to 4 (severe). The PASI produces a numeric score that can range from 0 (no visible skin involvement) to 72 (maximal skin involvement of the whole body). A higher score indicates more severe disease. A PASI 100 response represents subjects who achieved a 100% improvement from baseline in the PASI score.

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	31.7	3.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Change from Baseline in the Signs and Symptoms Aggregate Scores of the Psoriasis Symptoms and Signs Diary (PSSD) Score at Week 24

End point title	Part I: Change from Baseline in the Signs and Symptoms Aggregate Scores of the Psoriasis Symptoms and Signs Diary (PSSD) Score at Week 24

End point description:

PSSD (7-day version) patient-reported outcome questionnaire designed and validated to measure severity of psoriasis symptoms and signs for assessment of treatment benefit. It consisted 11 items covering symptoms (itch, pain, stinging, burning, skin tightness) and signs (skin dryness, cracking, scaling, shedding/ flaking, redness, bleeding) with 0 (absent) to 10 (worst imaginable) scale for severity. Items averaged on daily symptom score and sign score when at least 3 items >= 50% of 5 items on these scales are answered. Average value converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe, higher score indicates more severe disease. EAS included all subjects randomized to 1 of 2 groups (GUS or FAE) at Week 0 regardless of treatment received. Missing data imputed using last observed carried forward (LOCF) imputation method. Here N (number of subjects analysed) is number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	58		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Sign score	-59.8 (± 18.3)	-39.7 (± 26.7)		
Symptom score	-52.0 (± 22.0)	-34.0 (± 25.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Change from Baseline in the Individual Scale Scores for Itch, Pain, and Scaling of PSSD Components at Week 24

End point title	Part I: Change from Baseline in the Individual Scale Scores for Itch, Pain, and Scaling of PSSD Components at Week 24

End point description:

PSSD (7-day version) patient-reported outcome questionnaire designed and validated to measure severity of psoriasis symptoms and signs for assessment of treatment benefit. It consisted 11 items covering symptoms (itch, pain, stinging, burning, skin tightness) and signs (skin dryness, cracking, scaling, shedding/ flaking, redness, bleeding) with 0 (absent) to 10 (worst imaginable) scale for severity. Items averaged on daily symptom score and sign score when at least 3 items >= 50% of 5 items on these scales are answered. Average value converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe, higher score indicates more severe disease. EAS included all subjects randomized to 1 of 2 groups (GUS or FAE) at Week 0 regardless of treatment received. Missing data imputed using last observed carried forward (LOCF)

imputation method. Here N (number of subjects analysed) is number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	58		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Itch score	-5.85 (± 2.83)	-3.90 (± 2.86)		
Pain score	-5.07 (± 2.86)	-2.93 (± 3.12)		
Scaling score	-6.48 (± 2.25)	-4.43 (± 3.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Percentage of Subjects who Achieved an Absolute PASI Score less Than or Equal to (=<) 1 at Week 24

End point title	Part I: Percentage of Subjects who Achieved an Absolute PASI Score less Than or Equal to (=<) 1 at Week 24

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each areas is assessed separately for percentage of area involved, which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score that range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Percentage of subjects who achieved absolute PASI score <=1 were assessed. EAS included all subjects randomized to 1 of 2 treatment groups (GUS or FAE) at Week 0 regardless of treatment they actually received. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	66.7	10.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score 0 at Week 24

End point title	Part I: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score 0 at Week 24

End point description:

The Investigator’s Global Assessment (IGA) documents the investigator’s assessment of the subject's psoriasis at a given time. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). EAS included all subjects who were randomized to one of the two treatment groups (GUS or FAE) at Week 0 regardless of the treatment they actually received. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	51.7	6.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Change from Baseline in Percent Body Surface Area (%BSA) Psoriatic Involvement at Week 24

End point title	Part I: Change from Baseline in Percent Body Surface Area (%BSA) Psoriatic Involvement at Week 24

End point description:

BSA as physical measure to define disease severity is to determine how much of the Body Surface Area (BSA) is affected by psoriasis. Involved BSA is calculated by using the palm of the subject's hand as equivalent to 1% of the BSA (rule of palm). Psoriasis affected BSA under 5% suggests mild psoriasis, a BSA of 5% to 10% is considered moderate, and an involved BSA of over 10% indicates severe psoriasis. EAS included all subjects who were randomized to one of the two treatment groups (GUS or FAE) at Week 0 regardless of the treatment they actually received. Missing data was imputed using LOCF imputation method. Here N (number of subjects analysed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	59	57		
Units: Change in BSA (% points)				
arithmetic mean (standard deviation)	-18.5 (± 10.4)	-9.2 (± 11.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Change From Baseline in DLQI Score at Week 24

End point title	Part I: Change From Baseline in DLQI Score at Week 24

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6 =small effect; 7-12 =moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. EAS included all subjects randomized to 1 of 2 treatment groups (GUS or FAE) at Week 0 regardless of treatment received. Missing data was imputed using LOCF imputation method. Here N (number of subjects analysed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	58		
Units: Units on a scale				
arithmetic mean (standard deviation)	-15.2 (± 5.1)	-9.4 (± 7.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Percentage of Subjects who Achieved an Scalp Specific

Investigator´s Global Assessment (ss-IGA) Score of Absence of Disease (0) at Week 24

End point title	Part I: Percentage of Subjects who Achieved an Scalp Specific Investigator´s Global Assessment (ss-IGA) Score of Absence of Disease (0) at Week 24

End point description:

The ss-IGA instrument is used to evaluate disease severity of scalp psoriasis (SP). The lesions are assessed in terms of clinical signs of redness, thickness, and scaliness which are scored as: absence of disease (0), very mild disease (1), mild disease (2), moderate disease (3), and severe disease (4). EAS included subjects randomized to one of two treatments (GUS or FAE) at Week 0 regardless of treatment received and SP, ss-IGA Score>=2 at Baseline. Missing data was imputed using NRI (subjects with missing data at Week 4,16, 24 were non-responders).

End point type	Secondary

End point timeframe:

Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	53		
Units: Percentage of Subjects				
number (not applicable)	48.1	13.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Change From Baseline in 36-Item Short-Form Health Survey Version 2 (SF-36 V2) Physical Component Summary (PCS) and Mental Component Summary (MCS) at Week 24

End point title	Part I: Change From Baseline in 36-Item Short-Form Health Survey Version 2 (SF-36 V2) Physical Component Summary (PCS) and Mental Component Summary (MCS) at Week 24

End point description:

SF-36 V2 is 36-item questionnaire measuring health-related quality of life (HRQL) covering 2 summary measures: physical component summary (PCS) and mental component summary (MCS). SF-36 consists of 8 subscales (physical function, role limitations due to physical problems, pain, general health perception, vitality, social function, role limitations due to emotional problems, and mental health). Subjects self-report on items in subscale that have between 2-6 choices per item using Likert-type responses (e.g. none of time, some of time, etc.). Summations of item scores of same subscale give subscale scores, which are transformed into range from 0 to 100; 0= worst HRQL, 100=best HRQL. Higher scores indicate better health status. EAS included all subjects randomized to 1 of 2 groups (GUS or FAE) at Week 0 regardless of treatment received. Missing data was imputed using LOCF. Here N (number of subjects analysed) signifies number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Part I: Guselkumab (GUS)	Part I: Fumaric Acid Esters (FAE)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	59	57		
Units: Units on a scale				
arithmetic mean (standard deviation)				
SF-36 PCS scores	8.0 (± 6.9)	2.3 (± 8.2)		
SF-36 MCS scores	5.8 (± 10.6)	6.5 (± 9.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a PASI 75 Response at Week 32 who Maintained Response at Week 56

End point title	Part IIb: Percentage of Subjects with a PASI 75 Response at Week 32 who Maintained Response at Week 56

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 75 response denotes subjects achieving 75% improvement from baseline in PASI score. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) during treatment period from Week 32 to 56. Missing data imputed using NRI (subjects with missing data at Week 40, 48, and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	98.1	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a PASI 90 Response at Week 32 who Maintained Response at Week 56

End point title	Part IIb: Percentage of Subjects with a PASI 90 Response at

	Week 32 who Maintained Response at Week 56

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) during treatment period from Week 32 to 56. Missing data imputed using NRI (subjects with missing data at Week 40, 48, and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	85.2	35.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with DLQI Score of 0 or 1 at Week 32 who Maintained Response at Week 56

End point title	Part IIb: Percentage of Subjects with DLQI Score of 0 or 1 at Week 32 who Maintained Response at Week 56

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) from Week 32 to 56. Missing data imputed by NRI (subjects missing data at Week 40,48 and 56 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	64.8	21.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a PASI 75 Response at Week 56

End point title	Part IIb: Percentage of Subjects with a PASI 75 Response at Week 56

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 75 response denotes subjects achieving 75% improvement from baseline in PASI score. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) during treatment period from Week 32 to 56. Missing data imputed using NRI (subjects with missing data at Week 40, 48, and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	98.1	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a PASI 90 Response at Week 56

End point title	Part IIb: Percentage of Subjects with a PASI 90 Response at Week 56

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for

erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) during treatment period from Week 32 to 56. Missing data imputed using NRI (subjects with missing data at Week 40, 48, and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	90.7	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a PASI 100 Response at Week 56

End point title	Part IIb: Percentage of Subjects with a PASI 100 Response at Week 56

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 100 response denotes subjects achieving 100% improvement from baseline in PASI score. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) during treatment period from Week 32 to 56. Missing data imputed using NRI (subjects with missing data at Week 40, 48, and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	53.7	21.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 56

End point title	Part IIb: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 56

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. Part IIb analysis set included all subjects who entered Part IIb and treated with 1 of 2 treatments (GUS or FAE) from Week 32 to 56. Missing data imputed by NRI (subjects missing data at Week 40,48 and 56 considered non-responders).

End point type	Secondary

End point timeframe:

Week 56

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	14		
Units: Percentage of Subjects				
number (not applicable)	72.2	28.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I/IIa: Percentage of Subjects who Achieved PASI 75 Response at Week 32

End point title	Part I/IIa: Percentage of Subjects who Achieved PASI 75 Response at Week 32

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90-100% involvement), and for erythema, induration, scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 75 response denotes subjects with 75% improvement from baseline

in PASI score. Population included EAS. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders). Data reported collectively for Part I and Part IIa (that is from Week 0 to Week 32) per planned analysis for this endpoint.

End point type	Secondary

End point timeframe:

Week 32

End point values	Part I/IIa: Guselkumab (GUS)	Part I/IIa: FAE		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	90.0	23.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I/IIa: Percentage of Subjects who Achieved PASI 90 Response at Week 32

End point title	Part I/IIa: Percentage of Subjects who Achieved PASI 90 Response at Week 32

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 - 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Population included EAS. Data reported collectively for Part I and Part IIa (that is from Week 0 to Week 32) per planned analysis for this endpoint.

End point type	Secondary

End point timeframe:

Week 32

End point values	Part I/IIa: Guselkumab (GUS)	Part I/IIa: FAE		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	78.3	11.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I/IIa: Percentage of Subjects who Achieved PASI 100 Response at Week 32

End point title	Part I/IIa: Percentage of Subjects who Achieved PASI 100 Response at Week 32

End point description:

PASI: system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, and translates to numeric score of 0 (indicates no involvement) to 6 (90-100% involvement), and for erythema, induration, scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 100 response denotes subjects with 100% improvement from baseline in PASI score. Population included EAS. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders). Data reported collectively for Part I and Part IIa (that is from Week 0-32) per planned analysis for this endpoint.

End point type	Secondary

End point timeframe:

Week 32

End point values	Part I/IIa: Guselkumab (GUS)	Part I/IIa: FAE		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	43.3	6.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I/IIa: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 32

End point title	Part I/IIa: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 32

End point description:

DLQI: 10-item questionnaire measures impact of skin disease on subject's quality of life, assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question evaluated on 4-point scale range from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score range from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18=very large effect; 19-30=extremely large effect. Higher score indicates low quality of life due to more severe disease. Population included EAS. Missing data was imputed using NRI (subjects with missing data at Week 4,16 and 24 were considered non-responders). Data reported collectively for Part I and Part IIa (that is from Week 0 to Week 32) per planned analysis for this endpoint.

End point type	Secondary

End point timeframe:

Week 32

End point values	Part I/IIa: Guselkumab (GUS)	Part I/IIa: FAE		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	59		
Units: Percentage of Subjects				
number (not applicable)	63.3	16.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects with a PASI 90 Response at Week 56 who Maintained Response (that is who had PASI Score <=5) at Week 100 After Drug Withdrawal

End point title	Part III: Percentage of Subjects with a PASI 90 Response at Week 56 who Maintained Response (that is who had PASI Score <=5) at Week 100 After Drug Withdrawal

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	47.2	25.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Time to Loss of Response (PASI Score >5) from Week 56 After Guselkumab Withdrawal at Week 100

End point title	Part III: Time to Loss of Response (PASI Score >5) from Week 56 After Guselkumab Withdrawal at Week 100

End point description:

Time to loss of response from Week 56 after GUS withdrawal at Week 100 calculated as time from Week 56 to first onset of loss of response (PASI score>5). PASI system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each areas is assessed separately for percentage of area involved, translates 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 (none) to 4 (severe). PASI produces numeric score ranging from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Part III analysis set included all subjects treated with GUS during Part IIb (Weeks 32 to 64) and entered Part III. In Part III GUS arm, 99999 indicates 'upper level of 95% CI was not reached due to insufficient event rate'.

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Days				
median (confidence interval 95%)	315 (301 to 99999)	293 (219 to 315)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Time to PASI Score >3 from Week 56 After Guselkumab Withdrawal at Week 100

End point title	Part III: Time to PASI Score >3 from Week 56 After Guselkumab Withdrawal at Week 100

End point description:

The time to PASI>3 from Week 56 after guselkumab withdrawal at Week 100 was calculated as time from Week 56 to PASI response that is PASI >3. PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score that can range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Results were reported for observed cases.

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Days				
median (confidence interval 95%)	306 (227 to 308)	226 (141 to 308)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Time to Loss of Response (PASI Score >5) from Week 52 After Guselkumab Withdrawal at Week 100

End point title	Part III: Time to Loss of Response (PASI Score >5) from Week 52 After Guselkumab Withdrawal at Week 100

End point description:

Time to loss of response from Week 52 after GUS withdrawal at Week 100 calculated as time from Week 52 to first onset of loss of response (PASI score >5). PASI system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each areas is assessed separately for percentage of area involved, translates 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 (none) to 4 (severe). PASI produces numeric score ranging from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Part III analysis set included all subjects treated with GUS during Part IIb (Weeks 32 to 64) and entered Part III. In Part III GUS arm, 99999 indicates 'upper level of 95% CI was not reached due to insufficient event rate'.

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Days				
median (confidence interval 95%)	336 (322 to 99999)	321 (251 to 350)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Time to PASI Score >3 from Week 52 After Guselkumab Withdrawal at Week 100

End point title	Part III: Time to PASI Score >3 from Week 52 After Guselkumab Withdrawal at Week 100

End point description:

The time to PASI>3 from Week 52 after guselkumab withdrawal at Week 100 was calculated as time

from Week 52 to PASI response that is PASI >3. PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score that can range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Results were reported for observed cases.

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Days				
median (confidence interval 95%)	334 (252 to 337)	254 (173 to 329)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects with PASI 90 Response at Week 56 who Maintained PASI 90 Response at Week 100 After Drug Withdrawal

End point title	Part III: Percentage of Subjects with PASI 90 Response at Week 56 who Maintained PASI 90 Response at Week 100 After Drug Withdrawal

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 90 response denotes subjects achieving 90% improvement from baseline in PASI score. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed by NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	13.9	8.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved PASI 100 Response at Week 100

End point title	Part III: Percentage of Subjects who Achieved PASI 100 Response at Week 100

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. PASI 100 response denotes subjects achieving 100% improvement from baseline in PASI score. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	5.6	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved an Absolute PASI score <=1, <=2, <=3, <=5 at Week 100

End point title	Part III: Percentage of Subjects who Achieved an Absolute PASI score <=1, <=2, <=3, <=5 at Week 100

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower

extremities. Each area is assessed separately for percentage of area involved, which translates to numeric score from 0 (indicates no involvement) to 6 (90 percent [%] to 100% involvement), and for erythema, induration, and scaling, each rated on scale of 0 (none) to 4 (severe). PASI produces numeric score range from 0 (no visible skin involvement) to 72 (maximal skin involvement of whole body). Higher score indicates more severe disease. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)				
PASI Score <=1	8.3	0.0		
PASI Score <=2	19.4	8.3		
PASI Score <=3	30.6	16.7		
PASI Score <=5	47.2	25.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Change from Baseline (Week 56) in Signs and Symptoms Aggregate Scores of the Psoriasis Symptom and Sign Diary (PSSD) at Week 100

End point title	Part III: Change from Baseline (Week 56) in Signs and Symptoms Aggregate Scores of the Psoriasis Symptom and Sign Diary (PSSD) at Week 100

End point description:

PSSD (7-day version) is patient-reported outcome (PRO) questionnaire designed and validated to measure severity of psoriasis symptoms and signs for assessment of treatment benefit. It consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. Items were averaged on daily symptom score and sign score when at least 3 items >= 50 percentage of 5 items on these scales are answered. The average value is converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0= least severe and 100=most severe and higher score indicates more severe disease. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using LOCF imputation method.

End point type	Secondary

End point timeframe:

Baseline (Week 56) and Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Symptom Score at Baseline (Week 56)	3.4 (± 5.4)	11.2 (± 13.2)		
Change in Symptom score at Week 100	25.1 (± 24.7)	30.7 (± 21.7)		
Sign Score at Baseline (Week 56)	5.4 (± 9.3)	13.5 (± 12.9)		
Change in Sign score at Week 100	29.4 (± 24.8)	37.9 (± 28.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score of 0 at Week 100

End point title	Part III: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score of 0 at Week 100

End point description:

The Investigator’s Global Assessment (IGA) documents the investigator’s assessment of the subject's psoriasis at a given time. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Study Part III analysis set included all subjects who were treated with guselkumab during Study Part IIb (Weeks 32 to 64 of the Study) and entered Study Part III. Missing data was imputed using NRI (subjects with missing data at Week 64, 76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	8.3	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score of 0 or 1 at Week 100

End point title	Part III: Percentage of Subjects who Achieved an Investigator’s Global Assessment (IGA) Score of 0 or 1 at Week 100

End point description:

The Investigator’s Global Assessment (IGA) documents the investigator’s assessment of the subject's

psoriasis at a given time. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Study Part III analysis set included all subjects who were treated with guselkumab during Study Part IIb (Weeks 32 to 64 of the Study) and entered Study Part III. Missing data was imputed using NRI (subjects with missing data at Week 64, 76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	30.6	16.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Change from Baseline (Week 56) in Percent Body Surface Area (%BSA) Psoriatic Involvement at Week 100

End point title	Part III: Change from Baseline (Week 56) in Percent Body Surface Area (%BSA) Psoriatic Involvement at Week 100

End point description:

BSA as physical measure to define disease severity is to determine how much of the Body Surface Area (BSA) is affected by psoriasis. Involved BSA is calculated by using the palm of the subject's hand as equivalent to 1% of the BSA (rule of palm). Psoriasis affected BSA under 5% suggests mild psoriasis, a BSA of 5% to 10% is considered moderate, and an involved BSA of over 10% indicates severe psoriasis. Study Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using LOCF imputation method.

End point type	Secondary

End point timeframe:

Baseline (Week 56) and Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Change in BSA (% points)				
arithmetic mean (standard deviation)				
Baseline (Week 56)	0.9 (± 1.2)	1.5 (± 2.1)		
Change at Week 100	6.1 (± 6.3)	9.1 (± 5.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 100

End point title	Part III: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 100

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. Study Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Study Part III. Missing data was imputed using LOCF imputation method.

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	25	8.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Change from Baseline in DLQI Score at Week 100

End point title	Part III: Change from Baseline in DLQI Score at Week 100

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. Study Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using LOCF imputation method.

End point type	Secondary

End point timeframe:

Baseline (Week 56) and Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (Week 56)	0.9 (± 1.3)	3.5 (± 4.0)		
Change at Week 100	5.3 (± 6.0)	8.0 (± 5.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 56 who Maintained Response at Week 100

End point title	Part III: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 56 who Maintained Response at Week 100

End point description:

DLQI is 10-item questionnaire that measures impact of skin disease on subject's quality of life, used to assess 6 different aspects that may affect quality of life 1) symptoms and feelings, 2) daily activities, 3) leisure, 4) work/school performance, 5) personal relationships, 6) treatment. Each question was evaluated on 4-point scale ranging from 0 (not at all) to 3 (very much); higher scores indicate more impact on quality of life. DLQI produces total numeric score ranging from 0 (not at all) to 30 (very much): 0-1=no effect at all on subject's life; 2-6=small effect 7-12=moderate effect; 13-18 =very large effect; 19-30 =extremely large effect. Higher score indicates low quality of life due to more severe disease. Study Part III analysis set included all subjects who were treated with guselkumab during Part II b (Weeks 32 to 64) and entered Part III. Missing data imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	25	8.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved ss-IGA Score of Absence of Disease (0) at Week 100 in Subjects with Scalp Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0)

End point title	Part III: Percentage of Subjects who Achieved ss-IGA Score of Absence of Disease (0) at Week 100 in Subjects with Scalp

	Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0)

End point description:

The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis (SP). The lesions are assessed in terms of the clinical signs of redness, thickness, and scaliness which are scored as: absence of disease (0), very mild disease (1), mild disease (2), moderate disease (3), and severe disease (4). Part III analysis set included all subjects treated with GUS during Part IIb (Weeks 32 to 64) and entered Part III. Missing data imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders). Here N (number of subjects analysed) signifies number of subjects with Scalp Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	12		
Units: Percentage of Subjects				
number (not applicable)	14.7	8.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects who Achieved ss-IGA Score of 0 or 1 at Week 100 in Subjects with Scalp Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0)

End point title	Part III: Percentage of Subjects who Achieved ss-IGA Score of 0 or 1 at Week 100 in Subjects with Scalp Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0)

End point description:

The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis (SP). The lesions are assessed in terms of the clinical signs of redness, thickness, and scaliness which are scored as: absence of disease (0), very mild disease (1), mild disease (2), moderate disease (3), and severe disease (4). Part III analysis set included all subjects treated with GUS during Part IIb (Weeks 32 to 64) and entered Part III. Missing data imputed using NRI (subjects with missing data at Week 64,76,88 and 100 were considered non-responders). Here N (number of subjects analysed) signifies number of subjects with Scalp Psoriasis and ss-IGA Score>=2 (at least mild disease) at Baseline (Week 0).

End point type	Secondary

End point timeframe:

Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	12		
Units: Percentage of Subjects				
number (not applicable)	32.4	25.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Change From Baseline (week 56) in 36-Item Short-Form Health Survey Version 2 (SF-36 V2) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores at Week 100

End point title	Part III: Change From Baseline (week 56) in 36-Item Short-Form Health Survey Version 2 (SF-36 V2) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores at Week 100

End point description:

SF-36 V2 is generic 36-item questionnaire measuring health-related quality of life (HRQL) covering 2 summary measures: PCS and MCS. SF-36 consists of 8 subscales (physical function, role limitations due to physical problems, pain, general health perception, vitality, social function, role limitations due to emotional problems, and mental health). Subjects self-report on items in a subscale that have between 2-6 choices per item using Likert-type responses (e.g. none of time, some of time, etc.). Summations of item scores of same subscale give subscale scores, which are transformed into a range from 0 to 100; zero= worst HRQL, 100=best HRQL. Higher scores indicate better health status. Part III analysis set included all subjects who were treated with guselkumab during Part IIb (Weeks 32 to 64) and entered Part III. Missing data was imputed using LOCF method.

End point type	Secondary

End point timeframe:

Baseline (Week 56) and Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Units on a scale				
arithmetic mean (standard deviation)				
SF-36 PCS scores: Baseline (Week 56)	57.8 (± 3.0)	54.9 (± 5.5)		
SF-36 PCS scores: Change at Week 100	-4.3 (± 6.7)	-3.7 (± 7.0)		
SF-36 MCS scores: Baseline (Week 56)	53.4 (± 6.2)	44.2 (± 11.3)		
SF-36 MCS scores: Change at Week 100	-2.8 (± 5.9)	-3.1 (± 5.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I/IIa: Percentage of Subjects with Treatment-Emergent Adverse

Events (TEAEs) (up to Week 32) as a Measure of Safety and Tolerability

End point title	Part I/IIa: Percentage of Subjects with Treatment-Emergent Adverse Events (TEAEs) (up to Week 32) as a Measure of Safety and Tolerability

End point description:

An adverse event (AE) is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Treatment-emergent AEs (TEAEs) were defined as AEs that occurred during active treatment period through Week 32 after the start of initial study drug administration or AEs that were present at Baseline but worsened in severity after the start of initial study drug administration. Safety analysis set included all randomized subjects treated with at least 1 dose of study drug (guselkumab or FAE). Here N (number of subjects analysed) signifies number of subjects evaluable for this endpoint. Safety reported collectively for Part I and Part IIa (that is from Week 0 to Week 32) per planned analysis.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	Part I/IIa: Guselkumab (GUS)	Part I/IIa: FAE		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	60	58		
Units: Percentage of Subjects				
number (not applicable)	78.3	98.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part IIb: Percentage of Subjects with Treatment-Emergent Adverse Events (TEAEs) (Week 32 to Week 64) as a Measure of safety and Tolerability

End point title	Part IIb: Percentage of Subjects with Treatment-Emergent Adverse Events (TEAEs) (Week 32 to Week 64) as a Measure of safety and Tolerability

End point description:

An AE is any untoward medical event that occurs in a subject administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. TEAEs were defined as those AEs that occurred during the active treatment period from Week 32 to Week 56 or the safety follow-up period from Week 56 through Week 64 or those AEs that were present before Week 32 but worsened in severity after Week 32. Study Part IIb analysis set included all subjects who entered Study Part IIb and were treated with 1 of 2 treatments (GUS or FAE) at least once during the treatment period from Week 32 to Week 56. Here, n (number of subjects analyzed) signifies number of subjects analyzed for this endpoint for specified category.

End point type	Secondary

End point timeframe:

Week 32 to Week 64

End point values	Guselkumab (GUS)	Fumaric Acid Esters (FAE)	FAE to Guselkumab (GUS)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	14	20	
Units: Percentage of Subjects				
number (not applicable)				
PASI75 Responders, n= 54, 14, 0	79.6	92.9	0	
PASI75 Non-responders, n= 1, 0, 20	0	0	70.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Part III: Percentage of Subjects with Adverse Drug Reactions (ADRs) as a Measure of safety and Tolerability

End point title	Part III: Percentage of Subjects with Adverse Drug Reactions (ADRs) as a Measure of safety and Tolerability

End point description:

ADRs were defined as those adverse events with causality 'very likely', 'probable', or 'possible' that occurred during the follow-up extension period from Week 64 to Week 100 or those present before Week 64 but ongoing at Week 64. Study Part III analysis set included all participants who were treated with guselkumab during Study Part IIb (Weeks 32 to 64 of the Study) and entered Study Part III.

End point type	Secondary

End point timeframe:

Week 64 to Week 100

End point values	Guselkumab	FAE to Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	12		
Units: Percentage of Subjects				
number (not applicable)	5.6	0		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Up to Week 100

Adverse event reporting additional description:

Population included safety analysis set, Part IIb and Part III analysis set. AEs/SAEs till Week 64, and ADRs and deaths from Week 64 to 100 were analyzed and reported. Safety reported collectively for Part I and Part IIa (that is from Week 0 to Week 32) per planned analysis.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Part I/IIa (Week 0 to Week 32): Guselkumab (GUS)

Reporting group description:

In Part I, subjects received GUS 100 mg treatment administered as 100 mg/mL solution SC at Weeks 0, 4, 12 and 20. Subjects who completed treatment phase until Week 24 entered Part II of study. Subjects who completed Part I continued to receive GUS 100 mg SC at Week 28 and 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last treatment (whatever came first). For all subjects, who continued study, safety was followed-up at every visit.

Reporting group title	Part I/IIa (Week 0 to Week 32): Fumaric Acid Esters (FAE)

Reporting group description:

In Part I, subjects received FAE initial/FAE tablets by self-administration at Week 0. The doses were up-titrated and had to be taken every day with different daily doses depending on the optimal individual benefit risk ratio (maximum 6*120 mg/day) according to local prescribing information up to Week 24. Subjects who completed the treatment phase until Week 24 entered the Part II of the study. Subjects who completed Part I and consented for Part IIa continued to receive commercially available FAE tablets specifically labeled for the study from Week 24 through Week 32 during study Part IIa. For subjects who discontinued study, a safety follow-up was done at Week 32 (Part I) or 12 weeks after last treatment (whatever came first). For all subjects who continued study, safety was followed-up at every visit.

Reporting group title	Part IIb (Week 32 through Week 56): Guselkumab (GUS)

Reporting group description:

At Week 32 (study Part IIb), PASI 75 response was evaluated and PASI 75 responders and non-responders of guselkumab arm continued to receive guselkumab 100 mg SC every 8 weeks (weeks 36, 44 and 52). Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed up 12 weeks after last treatment dose. For all subjects who continued study, safety was followed-up at every visit.

Reporting group title	Part IIb (Week 32 through Week 56): Fumaric Acid Esters (FAE)

Reporting group description:

At Week 32, PASI 75 response was evaluated and PASI 75 responders of the FAE arm continued to receive commercially available FAE tablets specifically labeled for the study during Part IIb up to Week 56. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed up 12 weeks after last treatment dose. For all subjects who continued study, safety was followed-up at every visit.

Reporting group title	Part IIb (Week 32 through Week 56): FAE to Guselkumab (GUS)

Reporting group description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to 100 mg guselkumab SC at Weeks 32 and continued at Week 36, 44 and Week 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed up 12 weeks after last treatment dose. For all subjects who continued study, safety was followed-up at every visit.

Reporting group title	Part III (Week 64 through Week 100): Guselkumab (GUS)

Reporting group description:

Subjects who received GUS in Study Part II (subjects who started GUS treatment at Week 0), had no psoriatic arthritis diagnosed at baseline and achieved a PASI 90 response at end of Study Part II (Week

56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

Reporting group title	Part III (Week 64 through Week 100): FAE to Guselkumab (GUS)

Reporting group description:

At Week 32, PASI 75 response was evaluated and PASI 75 non-responders of FAE arm were switched to GUS and received GUS 100 mg SC at week 32, 36, 44 and 52. Safety follow-up was done at Week 64 (Part II). Subjects who discontinued at any timepoint were followed-up 12 weeks after last treatment dose. Subjects who switched from FAE to GUS treatment at Week 32), had no psoriatic arthritis diagnosed at baseline and achieved a PASI 90 response at end of Study Part II (Week 56) entered follow-up extension at Week 64 in Study Part III (GUS withdrawal phase) and were followed-up until loss of response or until Week 100.

Serious adverse events	Part I/IIa (Week 0 to Week 32): Guselkumab (GUS)	Part I/IIa (Week 0 to Week 32): Fumaric Acid Esters (FAE)	Part IIb (Week 32 through Week 56): Guselkumab (GUS)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 60 (5.00%)	2 / 58 (3.45%)	3 / 55 (5.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (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
Limb Injury			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			

subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (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
Blood and lymphatic system disorders			
Thymus Enlargement			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Psoriatic Arthropathy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (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			
Tonsillitis			

subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part IIb (Week 32 through Week 56): Fumaric Acid Esters (FAE)	Part IIb (Week 32 through Week 56): FAE to Guselkumab (GUS)	Part III (Week 64 through Week 100): Guselkumab (GUS)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 14 (7.14%)	2 / 20 (10.00%)	0 / 36 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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			
Clavicle Fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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 Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			

subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thymus Enlargement			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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			
Inguinal Hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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			
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (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			
Psoriatic Arthropathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part III (Week 64 through Week 100):		

	FAE to Guselkumab (GUS)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb Injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radius Fracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Thymus Enlargement			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Psoriatic Arthropathy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part I/IIa (Week 0 to Week 32): Guselkumab (GUS)	Part I/IIa (Week 0 to Week 32): Fumaric Acid Esters (FAE)	Part IIb (Week 32 through Week 56): Guselkumab (GUS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 60 (78.33%)	57 / 58 (98.28%)	43 / 55 (78.18%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Dysplastic Naevus			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Giant Cell Tumour of Tendon Sheath			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Lipoma			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Papilloma			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Skin Papilloma			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Vascular disorders			
Aortic Elongation			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 60 (0.00%)	19 / 58 (32.76%)	0 / 55 (0.00%)
occurrences (all)	0	23	0
Hypertension			
subjects affected / exposed	4 / 60 (6.67%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	4	2	0
Hypotension			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Lymphoedema			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Peripheral Venous Disease			

subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Dental Operation			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Skin Neoplasm Excision			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 60 (1.67%)	5 / 58 (8.62%)	0 / 55 (0.00%)
occurrences (all)	1	6	0
Feeling Hot			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Inflammation			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Injection Site Rash			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	2	0
Oedema Peripheral			

subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	4	0	0
Pyrexia			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	1 / 55 (1.82%)
occurrences (all)	1	2	1
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Vaginal Haemorrhage			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 60 (3.33%)	2 / 58 (3.45%)	2 / 55 (3.64%)
occurrences (all)	2	2	3
Oropharyngeal Pain			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	3 / 55 (5.45%)
occurrences (all)	0	1	3
Pharyngeal Erythema			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Pulmonary Arterial Hypertension			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Throat Irritation			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Mood Altered			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Product issues			
Device Breakage			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	4 / 60 (6.67%)	3 / 58 (5.17%)	3 / 55 (5.45%)
occurrences (all)	4	4	3
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	1 / 55 (1.82%)
occurrences (all)	1	2	1
Blood Glucose Decreased			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Blood Glucose Increased			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Breath Sounds Abnormal			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	0 / 60 (0.00%)	3 / 58 (5.17%)	0 / 55 (0.00%)
occurrences (all)	0	3	0
Hepatic Enzyme Increased			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Human Chorionic Gonadotropin			

Increased			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Lymph Node Palpable			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Increased			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Lymphocyte Morphology Abnormal			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Protein Urine Present			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			
subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Weight Decreased			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Weight Increased			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Bone Contusion			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Contusion			

subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Joint Injury			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Ligament Sprain			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	1	2	0
Limb Injury			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Post Procedural Haematoma			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	2
Post-Traumatic Neck Syndrome			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Procedural Pain			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Sunburn			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Traumatic Haematoma			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			

Bradycardia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Ventricular Extrasystoles			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	2	0
Cervicogenic Vertigo			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	1	2	0
Dysaesthesia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	9 / 60 (15.00%)	8 / 58 (13.79%)	3 / 55 (5.45%)
occurrences (all)	13	12	3
Hypoaesthesia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Transient Ischaemic Attack			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	1 / 60 (1.67%)	5 / 58 (8.62%)	0 / 55 (0.00%)
occurrences (all)	1	5	0
Leukopenia			
subjects affected / exposed	0 / 60 (0.00%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Lymphadenopathy			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 60 (0.00%)	21 / 58 (36.21%)	0 / 55 (0.00%)
occurrences (all)	0	25	0
Monocytosis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Ear Pain			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Middle Ear Inflammation			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Tympanic Membrane Perforation			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Eye disorders			

Dry Eye			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Eye Haemorrhage			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Visual Acuity Reduced			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Visual Impairment			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 60 (0.00%)	3 / 58 (5.17%)	0 / 55 (0.00%)
occurrences (all)	0	3	0
Abdominal Distension			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	1 / 60 (1.67%)	9 / 58 (15.52%)	0 / 55 (0.00%)
occurrences (all)	1	9	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 60 (3.33%)	18 / 58 (31.03%)	0 / 55 (0.00%)
occurrences (all)	2	23	0
Constipation			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Defaecation Urgency			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	7 / 60 (11.67%)	34 / 58 (58.62%)	0 / 55 (0.00%)
occurrences (all)	7	67	0
Dry Mouth			

subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Dyspepsia			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	2 / 55 (3.64%)
occurrences (all)	2	2	2
Enteritis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Faeces Soft			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	1	2	0
Gastritis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Gastrointestinal Disorder			
subjects affected / exposed	1 / 60 (1.67%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 60 (1.67%)	6 / 58 (10.34%)	0 / 55 (0.00%)
occurrences (all)	1	8	0
Tooth Disorder			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	2	0	1
Vomiting			

subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	3	0
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Dermatitis Allergic			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Dermatitis Contact			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Hyperhidrosis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Neurodermatitis			

subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Night Sweats			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Polymorphic Light Eruption			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Prurigo			
subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	2 / 60 (3.33%)	5 / 58 (8.62%)	2 / 55 (3.64%)
occurrences (all)	2	6	2
Psoriasis			
subjects affected / exposed	2 / 60 (3.33%)	6 / 58 (10.34%)	0 / 55 (0.00%)
occurrences (all)	2	14	0
Rash			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Rash Erythematous			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Rosacea			
subjects affected / exposed	1 / 60 (1.67%)	3 / 58 (5.17%)	0 / 55 (0.00%)
occurrences (all)	1	3	0
Seborrhoea			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Skin Burning Sensation			
subjects affected / exposed	0 / 60 (0.00%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Skin Exfoliation			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Haematuria			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Ketonuria			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Leukocyturia			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Renal Failure			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 60 (6.67%)	3 / 58 (5.17%)	2 / 55 (3.64%)
occurrences (all)	4	5	2
Arthritis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Articular Calcification			

subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Back Pain			
subjects affected / exposed	3 / 60 (5.00%)	2 / 58 (3.45%)	3 / 55 (5.45%)
occurrences (all)	3	3	4
Bursitis			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Femoroacetabular Impingement			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Muscle Tightness			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Neck Pain			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	3 / 60 (5.00%)	1 / 58 (1.72%)	1 / 55 (1.82%)
occurrences (all)	3	2	1
Osteochondrosis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Pain in Extremity			
subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Spinal Osteoarthritis			

subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Spinal Pain			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	2 / 60 (3.33%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	5 / 55 (9.09%)
occurrences (all)	1	1	5
Bronchitis Viral			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Cystitis			
subjects affected / exposed	2 / 60 (3.33%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	2	1	0
Ear Infection			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Folliculitis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	2 / 60 (3.33%)	2 / 58 (3.45%)	1 / 55 (1.82%)
occurrences (all)	2	2	1
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1

Gastroenteritis Salmonella			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Gastrointestinal Infection			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Herpes Zoster			
subjects affected / exposed	0 / 60 (0.00%)	2 / 58 (3.45%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Impetigo			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	2 / 60 (3.33%)	2 / 58 (3.45%)	1 / 55 (1.82%)
occurrences (all)	2	2	1
Nasopharyngitis			
subjects affected / exposed	25 / 60 (41.67%)	19 / 58 (32.76%)	28 / 55 (50.91%)
occurrences (all)	41	30	41
Onychomycosis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Otitis Media			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	1 / 55 (1.82%)
occurrences (all)	1	1	1
Periodontitis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 60 (0.00%)	2 / 58 (3.45%)	1 / 55 (1.82%)
occurrences (all)	0	2	1
Pulpitis Dental			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1

Pyelonephritis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	5 / 60 (8.33%)	0 / 58 (0.00%)	2 / 55 (3.64%)
occurrences (all)	5	0	3
Root Canal Infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Rotavirus Infection			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	2 / 60 (3.33%)	1 / 58 (1.72%)	1 / 55 (1.82%)
occurrences (all)	2	1	1
Skin Candida			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Tinea Pedis			
subjects affected / exposed	1 / 60 (1.67%)	1 / 58 (1.72%)	1 / 55 (1.82%)
occurrences (all)	1	1	1
Tonsillitis			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Tooth Infection			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	3 / 60 (5.00%)	1 / 58 (1.72%)	2 / 55 (3.64%)
occurrences (all)	4	1	2
Viral Infection			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Diabetes Mellitus			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Food Intolerance			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 60 (0.00%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 60 (1.67%)	0 / 58 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 60 (0.00%)	1 / 58 (1.72%)	1 / 55 (1.82%)
occurrences (all)	0	1	1

Non-serious adverse events	Part IIb (Week 32 through Week 56): Fumaric Acid Esters (FAE)	Part IIb (Week 32 through Week 56): FAE to Guselkumab (GUS)	Part III (Week 64 through Week 100): Guselkumab (GUS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 14 (92.86%)	14 / 20 (70.00%)	2 / 36 (5.56%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dysplastic Naevus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Giant Cell Tumour of Tendon Sheath			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lipoma			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Papilloma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin Papilloma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Aortic Elongation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Peripheral Venous Disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental Operation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin Neoplasm Excision			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Feeling Hot			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injection Site Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Balanoposthitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pharyngeal Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pulmonary Arterial Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	2 / 20 (10.00%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Throat Irritation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Mood Altered			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Product issues			

Device Breakage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Blood Glucose Decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Blood Glucose Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Human Chorionic Gonadotropin Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymph Node Palpable			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Morphology Abnormal			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Protein Urine Present			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Transaminases Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Weight Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Bone Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Joint Injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			

subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Limb Injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Post Procedural Haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Post-Traumatic Neck Syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Traumatic Haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ventricular Extrasystoles			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carpal Tunnel Syndrome			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Cervicogenic Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0

Lymphadenopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	5 / 14 (35.71%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	6	1	0
Monocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Ear Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Middle Ear Inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Dry Eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eye Haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Visual Acuity Reduced			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Defaecation Urgency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Faeces Soft			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic Steatosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Polymorphic Light Eruption			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rash Erythematous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Seborrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin Burning Sensation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin Exfoliation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ketonuria			

subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Leukocyturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Renal Failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Arthritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Articular Calcification			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Femoroacetabular Impingement			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Muscle Tightness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Neck Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Osteochondrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Bronchitis Viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Ear Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Herpes Zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Impetigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	8 / 14 (57.14%)	8 / 20 (40.00%)	0 / 36 (0.00%)
occurrences (all)	11	13	0
Onychomycosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Otitis Media			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Pulpitis Dental			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Root Canal Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Rotavirus Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin Candida			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Urinary Tract Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Diabetes Mellitus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Food Intolerance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 20 (5.00%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 20 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part III (Week 64 through Week 100): FAE to Guselkumab (GUS)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysplastic Naevus			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Giant Cell Tumour of Tendon Sheath			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lipoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Papilloma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Skin Papilloma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vascular disorders			

Aortic Elongation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Flushing			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Peripheral Venous Disease			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Dental Operation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Skin Neoplasm Excision			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Feeling Hot			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypothermia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Injection Site Rash			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oedema Peripheral			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vaginal Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Pharyngeal Erythema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Pulmonary Arterial Hypertension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Throat Irritation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Mood Altered subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Restlessness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Product issues Device Breakage subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Investigations Alanine Aminotransferase Increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Aspartate Aminotransferase Increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Blood Glucose Decreased			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Blood Glucose Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Breath Sounds Abnormal				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gamma-Glutamyltransferase Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hepatic Enzyme Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Human Chorionic Gonadotropin Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Lymph Node Palpable				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Lymphocyte Count Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Lymphocyte Morphology Abnormal				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Protein Urine Present				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Transaminases Increased				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Weight Decreased				

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Weight Increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bone Contusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Joint Injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ligament Sprain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Limb Injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Post Procedural Haematoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Post Procedural Haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Post-Traumatic Neck Syndrome			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Procedural Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Traumatic Haematoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ventricular Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cervicogenic Vertigo			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysaesthesia			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Transient Ischaemic Attack			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Monocytosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ear Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Middle Ear Inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry Eye			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eye Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Visual Acuity Reduced			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Visual Impairment			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal Distension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal Pain			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Abdominal Pain Upper				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Defaecation Urgency				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Dry Mouth				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Enteritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Faeces Soft				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal Disorder				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal Pain				

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Haematochezia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Tooth Disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hepatobiliary disorders			
Hepatic Steatosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Alopecia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Dermatitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Dermatitis Allergic			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Dermatitis Contact				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hyperkeratosis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Neurodermatitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Night Sweats				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Polymorphic Light Eruption				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Prurigo				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Psoriasis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rash Erythematous				

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Rosacea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Seborrhoea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Skin Burning Sensation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Skin Exfoliation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Urticaria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Renal and urinary disorders Glycosuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Haematuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Ketonuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Leukocyturia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Proteinuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Renal Failure subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		

Ureterolithiasis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Articular Calcification			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Femoroacetabular Impingement			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle Tightness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Myalgia			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neck Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Osteochondrosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pain in Extremity			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Spinal Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Spinal Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchitis Viral			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Ear Infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastroenteritis Norovirus				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastroenteritis Salmonella				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal Infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Herpes Zoster				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Onychomycosis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			

Oral Herpes				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Otitis Media				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Periodontitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pulpitis Dental				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pyelonephritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Root Canal Infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rotavirus Infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Skin Candida				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Tinea Pedis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			

Tonsillitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Tooth Infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Urinary Tract Infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Viral Infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Diabetes Mellitus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Food Intolerance subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vitamin D Deficiency subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 April 2017	As per protocol amendment-1, the study was split into two parts (Study Part I and II), allowing subjects to enter a 32-week study extension until Week 56.
22 January 2018	Protocol amendment -2 was implemented to investigate maintenance of response after guselkumab withdrawal in 36-week study extension in subjects who responded well (Psoriasis Area and Severity Index [PASI] 90 response) to guselkumab.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

In Part III, small groups with less subjects generated through Part IIb, and further decline in subjects enrolled in Part III (ie, subjects started guselkumab (GUS) at Week 0/ switched from FAE to GUS in Week 32, and had PASI 90 response at Week 56).

Notes: