Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator-controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis

Summary

EudraCT number	2014-000719-15
Trial protocol	DE HU PL ES
Global end of trial date	17 June 2020

Results information

Result version number	v1 (current)
This version publication date	01 July 2021
First version publication date	01 July 2021

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02207231
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Pharmaceutical
Sponsor organisation address	1400 McKean Rd., Spring House, United States,
Public contact	Clinical Registry Group, Janssen Research and Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research and Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this study were to evaluate the efficacy, safety, and tolerability of guselkumab in the treatment of subjects with moderate to severe plaque-type psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. The safety and tolerability of guselkumab and adalimumab were monitored by collecting information on adverse events (AEs), including injection-site reactions (ISRs) and allergic reactions, clinical laboratory tests, physical examinations, vital signs, electrocardiograms (ECGs), concomitant medication review, and early detection of active tuberculosis (TB).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 57
Country: Number of subjects enrolled	Canada: 122
Country: Number of subjects enrolled	Germany: 107
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	Hungary: 30
Country: Number of subjects enrolled	Korea, Republic of: 28
Country: Number of subjects enrolled	Poland: 107
Country: Number of subjects enrolled	Russian Federation: 118
Country: Number of subjects enrolled	Taiwan: 73
Country: Number of subjects enrolled	United States: 170
Worldwide total number of subjects	837
EEA total number of subjects	269

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)	793
From 65 to 84 years	43
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1036 subjects were screened. Of these 1036 subjects, 837 subjects were enrolled and 836 were treated.

Period 1

Period 1 title	Placebo Controlled Period: Week 0 - 16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12, and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and once every 2 weeks (q2w) thereafter through Week 15 in the placebo controlled period (PCP).

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

Dosage and administration details:

Placebo matching to guselkumab was administered subcutaneously at Weeks 0, 4 and 12.

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

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose at Weeks 1, 3 and 5 once q2w through Week 15.

Arm title	Guselkumab 100 mg

Arm description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and q2w thereafter through Week 15.

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

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Weeks 0, 4, and 12.

Arm title	Adalimumab Then Guselkumab 100 mg

Arm description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12.

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

Dosage and administration details:

Adalimumab 80 mg was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose of adalimumab 40 mg at Weeks 1, 3, 5, and once q2w through Week 15.

Number of subjects in period 1	Placebo	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg
Started	174	329	334
Treated	174	329	333
Completed	167	322	324
Not completed	7	7	10
Consent withdrawn by subject	2	-	4
Adverse event, non-fatal	2	4	2
Non-compliance with study drug	-	2	1
Lost to follow-up	1	1	1
Lack of efficacy	2	-	1
Protocol deviation	-	-	1

Period 2

Period 2 title	Active Controlled Period: Week 16 - 48
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Placebo Then Guselkumab 100 mg

Arm description:

Subjects receiving placebo crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and once q8w thereafter through Week 44 and placebo matched to adalimumab SC injection at Weeks 17, 19, 21, and 23 and q2w thereafter through Week 47 in the active controlled period (ACP).

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

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously at Weeks 17, 19, 21, 23, and q2w through Week 47.

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

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to subjects receiving matching placebo in PCP and crossed over to receive guselkumab in ACP.

Arm title	Guselkumab 100 mg (ACP)

Arm description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and once q8w 8 weeks thereafter through Week 44, placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and q2w thereafter through Week 47.

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

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously q8w in ACP to subjects initially receiving guselkumab 100 mg in PCP.

Arm title	Adalimumab (ACP)

Arm description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 47 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12, 16, 20 and once q8w thereafter through Week 44.

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

Dosage and administration details:

Adalimumab 40 mg was administered to subcutaneously q2w in ACP to subjects who were initially receiving adalimumab in PCP.

Number of subjects in period 2[1]	Placebo Then Guselkumab 100 mg	Guselkumab 100 mg (ACP)	Adalimumab (ACP)
Started	165	322	324
Completed	162	301	281
Not completed	3	21	43
Consent withdrawn by subject	1	4	10
Adverse event, non-fatal	1	6	10
Pregnancy	-	-	1
Non-compliance with study drug	-	3	3
Unspecified	-	2	3
Lost to follow-up	1	2	5
Protocol deviation	-	1	-
Lack of efficacy	-	3	11

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 2 subjects did not crossover from placebo to guselkumab.

Period 3

Period 3 title	Open-label Guselkumab: Week 48 - 264
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Adalimumab Then Guselkumab 100 mg

Arm description:

Subjects receiving adalimumab entered a washout period after their final dose of adalimumab at Week 47 and received guselkumab 100 mg SC q8w at Week 52 and thereafter through Week 252.

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

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Week 52 and q8w through Week 252 in open-label period.

Arm title	Guselkumab Combined

Arm description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 52 and thereafter through Week 252.

Arm type	Experimental

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

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Week 52 and q8w through Week 252.

Number of subjects in period 3	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined
Started	280	463
Completed	242	380
Not completed	38	83
Adverse event, serious fatal	1	3
Consent withdrawn by subject	10	28
Adverse event, non-fatal	12	19
Pregnancy	3	7
Unspecified	4	11
Lost to follow-up	6	11
Lack of efficacy	2	4

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12, and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and once every 2 weeks (q2w) thereafter through Week 15 in the placebo controlled period (PCP).	
Reporting group title	Guselkumab 100 mg
Reporting group description:	
Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and q2w thereafter through Week 15.	
Reporting group title	Adalimumab Then Guselkumab 100 mg
Reporting group description:	
Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12.	

Reporting group values	Placebo	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg
Number of subjects	174	329	334
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	164	311	318
From 65 to 84 years	10	18	15
85 years and over	0	0	1
Title for AgeContinuous Units: years			
arithmetic mean	44.9	43.9	42.9
standard deviation	± 12.9	± 12.74	± 12.58
Title for Gender Units: subjects			
Female	55	89	85
Male	119	240	249

Reporting group values	Total		
Number of subjects	837		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	793		
From 65 to 84 years	43		
85 years and over	1		

Title for AgeContinuous Units: years arithmetic mean standard deviation	- 		
Title for Gender Units: subjects			
Female	229		
Male	608		

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12, and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and once every 2 weeks (q2w) thereafter through Week 15 in the placebo controlled period (PCP).

Reporting group title	Guselkumab 100 mg

Reporting group description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and q2w thereafter through Week 15.

Reporting group title	Adalimumab Then Guselkumab 100 mg

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12.

Reporting group title	Placebo Then Guselkumab 100 mg

Reporting group description:

Subjects receiving placebo crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and once q8w thereafter through Week 44 and placebo matched to adalimumab SC injection at Weeks 17, 19, 21, and 23 and q2w thereafter through Week 47 in the active controlled period (ACP).

Reporting group title	Guselkumab 100 mg (ACP)

Reporting group description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and once q8w 8 weeks thereafter through Week 44, placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, and 5 and q2w thereafter through Week 47.

Reporting group title	Adalimumab (ACP)

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 47 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12, 16, 20 and once q8w thereafter through Week 44.

Reporting group title	Adalimumab Then Guselkumab 100 mg

Reporting group description:

Subjects receiving adalimumab entered a washout period after their final dose of adalimumab at Week 47 and received guselkumab 100 mg SC q8w at Week 52 and thereafter through Week 252.

Reporting group title	Guselkumab Combined

Reporting group description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 52 and thereafter through Week 252.

Subject analysis set title	Adalimumab Then Guselkumab 100 mg
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once q2w thereafter through Week 47 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12, 16, 20 and once q8w thereafter through Week 44. Subjects entered a washout period after their final dose of adalimumab at Week 47 and received guselkumab 100 mg SC q8w at Week 52 and thereafter through Week 252.

Subject analysis set title	Guselkumab Combined
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects who crossed over to receive guselkumab 100 mg subcutaneously at Week 16 from placebo group and subjects who were randomized to guselkumab 100 mg group at Week 0. Placebo crossover

subjects were included in the guselkumab column after crossover to guselkumab.

Primary: Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16

End point title	Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16[1]

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set include all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Primary

End point timeframe:

Week 16

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo	Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	329		
Units: percentage of subjects				
number (not applicable)	6.9	85.1		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Primary: Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16

End point title	Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16[2]

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates

to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set include all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Primary

End point timeframe:

Week 16

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo	Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	329		
Units: percentage of subjects				
number (not applicable)	2.9	73.3		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Guselkumab 100 mg
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48[3]

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or 48 who did not come for evaluation at week 24 or 48 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Weeks 24 and 48

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)				
Week 24	52.6	29.3		
Week 48	50.5	25.7		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Week 24	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Statistical analysis title	Statistical Analysis 4
Statistical analysis description: Week 48	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48[4]

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject’s psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or 48 or who did not come for evaluation at Week 24 or 48 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Weeks 24 and 48

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)				
Week 24	84.2	61.7		
Week 48	80.5	55.4		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Week 24	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Week 48	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48

End point title	Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Weeks 24 and 48[5]

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or 48 who did not come for evaluation at week 24 or 48 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Weeks 24 and 48

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)				
Week 24	80.2	53.0		
Week 48	76.3	47.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Week 24

Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Week 48

Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg

Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group[6]

End point description:

The DLQI is a 10-item questionnaire that measures the impact of skin disease on subject's quality of life. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicate more impact on quality of life. The DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1 = no effect at all on the subject's life; 2-6 = small effect on the subject's life; 7-12 = moderate effect on the subject's life; 13-18 = very large effect on the subject's life; 19-30 = extremely large effect on the subject's life. Higher scores indicate more impact on quality of life of subjects. This secondary endpoint was planned to include only the placebo and guselkumab arms. Randomized analysis set included all subjects who were randomized at Week 0 and had a baseline DLQI score.

End point type	Secondary

End point timeframe:

Baseline, Week 16

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo	Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	174	329		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.6 (± 6.36)	-11.2 (± 7.24)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

p value is based on analysis of variance (ANOVA) model stratified by investigator site (pooled).

Comparison groups	Placebo v Guselkumab 100 mg
Number of subjects included in analysis	503
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16[7]

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)	85.1	65.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

p value is based on 1-sided Mantel Haenszel (MH) Z-test adjusted for investigator site (pooled).

Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in Percentage
Point estimate	19.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.9
upper limit	25.7

Notes:

[8] - non-inferiority margin= 10.0%

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:	
p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16[9]

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set include all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)	73.3	49.7		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
p value is based on 1-sided MH Z-test adjusted for investigator site (pooled).	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg

Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	non-inferiority[10]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in Percentage
Point estimate	24.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	17
upper limit	31

Notes:

[10] - non-inferiority margin= 10.0%

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16[11]

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 75 response represents subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Randomized analysis set include all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg	Adalimumab Then Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	334		
Units: percentage of subjects				
number (not applicable)	91.2	73.1		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: p value is based on 1-sided MH Z-test adjusted for investigator site (pooled).	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in percentage
Point estimate	18
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	23.8

Notes:
[12] - non-inferiority margin= 10%

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).	
Comparison groups	Guselkumab 100 mg v Adalimumab Then Guselkumab 100 mg
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group[13]

End point description:

The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis. The lesions were assessed in terms of the clinical signs of redness, thickness, and scaliness, which are scored on a 5-point scale ranging from 0 = absence of disease, 1 = very mild disease, 2 = mild disease, 3 = moderate disease, and 4 = severe disease. This secondary endpoint was planned to include only the placebo and guselkumab arms. Population analyzed included only randomized subjects at Week 0 who had an ss-IGA score greater than or equal to (>=) 2 at baseline. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo	Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	277		
Units: percentage of subjects				
number (not applicable)	14.5	83.4		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

Comparison groups	Placebo v Guselkumab 100 mg
Number of subjects included in analysis	422
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group[14]

End point description:

The PSSD (24-hour version) is a patient-reported outcome (PRO) questionnaire designed and validated to measure the severity of psoriasis symptoms and signs for the 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. Higher score indicates more severe disease. This secondary endpoint was planned to include only the placebo and guselkumab arms. PSSD analysis set included all subjects who had baseline PSSD scores as the average score of at least 4 days out of the 7 days prior to the Week 0 visit. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Week 16

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo	Guselkumab 100 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	249		
Units: units on a scale				
arithmetic mean (standard deviation)	-3.0 (± 19.56)	-41.9 (± 24.61)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

p value is based on ANOVA model stratified by investigator site (pooled).

Comparison groups	Placebo v Guselkumab 100 mg
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA

Secondary: Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point title	Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point description:

The PSSD (24-hour version) is a patient-reported outcome (PRO) questionnaire designed and validated to measure the severity of psoriasis symptoms and signs for the 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. Higher score indicates more severe disease. PSSD analysis set included all those subjects who were randomized at Week 0 and had baseline PSSD score greater than 0. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

End point type	Secondary

End point timeframe:

Week 24

End point values	Guselkumab 100 mg (ACP)	Adalimumab (ACP)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248	273		
Units: percentage of subjects				
number (not applicable)	36.3	21.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).	
Comparison groups	Guselkumab 100 mg (ACP) v Adalimumab (ACP)
Number of subjects included in analysis	521
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 90 Response at Week 252

End point title	Percentage of Subjects Who Achieved PASI 90 Response at Week 252
End point description:	
In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 90 response signify subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.	
End point type	Secondary
End point timeframe:	
Week 252	

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	391		
Units: percentage of subjects				
number (not applicable)	82.5	84.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 75 Response at Week 252

End point title	Percentage of Subjects Who Achieved PASI 75 Response at Week 252

End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 75 response signify subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary

End point timeframe:

Week 252

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	391		
Units: percentage of subjects				
number (not applicable)	93.1	93.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies

subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary

End point timeframe:

Week 252

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	391		
Units: percentage of subjects				
number (not applicable)	82.9	82.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252

End point title	Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252

End point description:

DLQI measures impact of skin disease on subject's QoL. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much). DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1=no effect on subject's life; 2-6=small effect; 7-12=moderate effect; 13-18=very large effect; 19-30=extremely large effect. DLQI was calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. Higher scores indicate more impact on subject's QoL. Population analyzed included subjects randomized at Week 0 and treated with guselkumab with baseline DLQI score >1. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary

End point timeframe:

Week 252

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	235	347		
Units: percentage of subjects				
number (not applicable)	74.0	72.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With who Achieved a PSSD Symptom Score of 0 at Week 252

End point title	Percentage of Subjects With who Achieved a PSSD Symptom Score of 0 at Week 252

End point description:

The PSSD 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. Higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD symptom score >0. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary

End point timeframe:

Week 252

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	200	297		
Units: percentage of subjects				
number (not applicable)	48.0	42.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252

End point title	Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252

End point description:

The PSSD 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. Higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD sign score >0. The analysis was performed using

observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary

End point timeframe:

Week 252

End point values	Adalimumab Then Guselkumab 100 mg	Guselkumab Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	201	297		
Units: percentage of subjects				
number (not applicable)	37.8	33.0		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline (Week 0) up to Week 264

Adverse event reporting additional description:

Safety analysis included all subjects who were randomized at Week 0 and received at least 1 dose of study agent (partial or complete). Subjects who discontinued in 1st period and had safety follow-up beyond Week 16, counted in both the periods for safety data.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	Placebo (PCP)

Reporting group description:

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

Reporting group title	Guselkumab 100 mg (PCP)

Reporting group description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 during the placebo controlled period.

Reporting group title	Adalimumab (PCP)

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Week 1 and once every other week thereafter through Week 15 during the placebo controlled period.

Reporting group title	Placebo Then Guselkumab 100 mg (ACP)

Reporting group description:

Subjects initially randomized to placebo crossed over to receive guselkumab 100 milligram (mg) SC injection at Weeks 16 and 20 and once every 8 weeks thereafter through Week 44 in the active controlled period (ACP).

Reporting group title	Guselkumab 100 mg (ACP)

Reporting group description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4, and 12 and once every 8 weeks thereafter through Week 44, placebo matched to guselkumab SC injection at Week 16, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injections) at Weeks 1, 3, and 5 and every 2 weeks thereafter through Week 47.

Reporting group title	Adalimumab (ACP)

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 and adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and once every 2 weeks thereafter through Week 47 and placebo matched to guselkumab SC injection at Weeks 0, 4, 12, 16, 20 and once every 8 weeks thereafter through Week 44.

Reporting group title	Adalimumab then Guselkumab 100 mg (After ACP)

Reporting group description:

Subjects initially randomized to adalimumab entered a washout period after their final dose at Week 47 and crossed over to receive guselkumab 100 mg subcutaneously q8w at Week 52 and thereafter through Week 252. This arm reports safety data for subjects that crossed over to guselkumab from adalimumab.

Reporting group title	Guselkumab Combined

Reporting group description:

All subjects who crossed over to receive guselkumab 100 mg subcutaneously at Week 16 from placebo group and subjects who were randomized to guselkumab 100 mg group at Week 0. Placebo crossover subjects were included in the guselkumab column after crossover to guselkumab. Subjects that discontinued treatment prematurely were followed up for safety and hence were included in the safety

data. Therefore, combined safety results are reported for this arm. This arm reports safety data for guselkumab.

Serious adverse events	Placebo (PCP)	Guselkumab 100 mg (PCP)	Adalimumab (PCP)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 174 (1.72%)	8 / 329 (2.43%)	6 / 333 (1.80%)
number of deaths (all causes)	1	3	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Astrocytoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
B-Cell Lymphoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Bladder Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Breast Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Colon Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Epiglottic Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastric Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Invasive Papillary Breast Carcinoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Laryngeal Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Lipoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Malignant Melanoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Papillary Cystadenoma Lymphomatosum			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Prostate Cancer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Rectal Adenocarcinoma			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Sarcoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Uterine Leiomyoma			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Deep Vein Thrombosis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Peripheral Artery Stenosis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	1 / 333 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis Superficial			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Missed			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Abortion Spontaneous			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Uterine Polyp			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Pulmonary Embolism			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Pulmonary Oedema			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Pulmonary Sarcoidosis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 174 (0.57%)	0 / 329 (0.00%)	0 / 333 (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
Completed Suicide			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Psychotic Disorder			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Substance Abuse			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Suicidal Ideation			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Suicide Attempt			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Investigations			
Human Chorionic Gonadotropin Increased			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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			
Abdominal Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Ankle Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Avulsion Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Vertebral Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	1 / 333 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chest Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Clavicle Fracture			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Concussion			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Craniocerebral Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Femoral Neck Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Foreign Body			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Humerus Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Jaw Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Joint Dislocation			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Ligament Rupture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Multiple Injuries			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Fistula			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Procedural Hypotension			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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 / 174 (0.00%)	0 / 329 (0.00%)	1 / 333 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Soft Tissue Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Spinal Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Tendon Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Congenital, familial and genetic disorders			
Dermoid Cyst			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	1 / 333 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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

Aortic Valve Incompetence			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	1 / 333 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Myocardial Infarction			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Myocardial Ischaemia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Node Dysfunction			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Cerebrovascular Accident			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Idiopathic Partial Epilepsy			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Lacunar Infarction			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Paraesthesia			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Sciatica			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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			
Abdominal Hernia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Colitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Duodenal Ulcer			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Enterocutaneous Fistula			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Gastritis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Haemorrhoids			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Inguinal Hernia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Intestinal Strangulation			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Large Intestine Polyp			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis Acute			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Cholecystitis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Cholecystitis Acute			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Hepatic Failure			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Hepatitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Dermatitis Contact			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Erythema Nodosum			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Erythrodermic Psoriasis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Lichen Planus			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Psoriasis			
subjects affected / exposed	1 / 174 (0.57%)	0 / 329 (0.00%)	0 / 333 (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			
Acute Kidney Injury			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Nephrolithiasis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Ureterolithiasis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Urinary Retention			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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			
Arthralgia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Back Pain			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Chondromalacia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Dupuytren's Contracture			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Lateral Patellar Compression Syndrome			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Meniscal Degeneration			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Metatarsalgia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 174 (0.57%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Spondylolisthesis			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (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
Synovitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Trigger Finger			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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			
Abdominal Abscess			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Abscess Limb			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Acute Sinusitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Anal Abscess			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Appendicitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	2 / 333 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Tonsillitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Diverticulitis			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Erysipelas			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Postoperative Wound Infection			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Scrotal Abscess			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Sepsis			

subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (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
Varicella			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	0 / 333 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Then Guselkumab 100 mg (ACP)	Guselkumab 100 mg (ACP)	Adalimumab (ACP)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 165 (3.03%)	8 / 324 (2.47%)	10 / 326 (3.07%)
number of deaths (all causes)	1	3	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Astrocytoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
B-Cell Lymphoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Bladder Cancer			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Breast Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Colon Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Epiglottic Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Invasive Papillary Breast Carcinoma			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Laryngeal Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Lipoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Malignant Melanoma			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Papillary Cystadenoma Lymphomatosum			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Prostate Cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Sarcoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Uterine Leiomyoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Deep Vein Thrombosis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Peripheral Artery Stenosis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Missed			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Abortion Spontaneous			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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

Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Uterine Polyp			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Pulmonary Embolism			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Pulmonary Oedema			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Pulmonary Sarcoidosis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Completed Suicide			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Psychotic Disorder			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Substance Abuse			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Suicidal Ideation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Suicide Attempt			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Human Chorionic Gonadotropin Increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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			
Abdominal Injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Ankle Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Avulsion Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Vertebral Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Chest Injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Clavicle Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Concussion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Craniocerebral Injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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

Femoral Neck Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Foreign Body			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Humerus Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Jaw Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Joint Dislocation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Multiple Injuries			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Fistula			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Hypotension			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Soft Tissue Injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Spinal Fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Tendon Injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Thoracic Vertebral Fracture			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Congenital, familial and genetic disorders			
Dermoid Cyst			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Aortic Valve Incompetence			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Myocardial Infarction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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

Myocardial Ischaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Node Dysfunction			
subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Cerebrovascular Accident			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Idiopathic Partial Epilepsy			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Lacunar Infarction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Paraesthesia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Sciatica			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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			
Abdominal Hernia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Colitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Duodenal Ulcer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Enterocutaneous Fistula			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Gastritis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Haemorrhoids			
subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Inguinal Hernia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Intestinal Strangulation			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Large Intestine Polyp			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Hepatobiliary disorders			
Cholangitis Acute			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Cholecystitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Cholecystitis Acute			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Failure			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Hepatitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Dermatitis Contact			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Erythema Nodosum			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Erythrodermic Psoriasis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen Planus			
subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Psoriasis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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			
Acute Kidney Injury			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Nephrolithiasis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Ureterolithiasis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Back Pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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

Dupuytren's Contracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Lateral Patellar Compression Syndrome			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Meniscal Degeneration			
subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Metatarsalgia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Rhabdomyolysis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Spondylolisthesis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Synovitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Trigger Finger			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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			
Abdominal Abscess			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Limb			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Acute Sinusitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Anal Abscess			

subjects affected / exposed	1 / 165 (0.61%)	0 / 324 (0.00%)	0 / 326 (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
Appendicitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	2 / 326 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Chronic Tonsillitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Diverticulitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Erysipelas			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			

subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	1 / 326 (0.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Postoperative Wound Infection			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (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
Pyelonephritis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Scrotal Abscess			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Sepsis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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
Varicella			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 165 (0.00%)	0 / 324 (0.00%)	0 / 326 (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	Adalimumab then	Guselkumab	

	Guselkumab 100 mg (After ACP)	Combined	
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 280 (12.14%)	79 / 494 (15.99%)	
number of deaths (all causes)	1	4	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Astrocytoma			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
B-Cell Lymphoma			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cancer			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer			
subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic Cancer			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric Cancer			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Invasive Papillary Breast Carcinoma			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal Cancer			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Melanoma in Situ			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary Cystadenoma Lymphomatosum			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate Cancer			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			

subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Leiomyoma			
subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep Vein Thrombosis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Crisis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Stenosis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			

Abortion Missed			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion Spontaneous			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine Polyp			
subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Oedema			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Sarcoidosis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed Suicide			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychotic Disorder			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance Abuse			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal Ideation			

subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide Attempt			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Human Chorionic Gonadotropin Increased			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal Injury			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle Fracture			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion Fracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Vertebral Fracture			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Injury			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Clavicle Fracture			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral Injury			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign Body			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus Fracture			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw Fracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint Dislocation			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Rupture			

subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb Injury			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus Injury			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Injuries			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Procedural Fistula			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Hypotension			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius Fracture			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Laceration			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Injury			

subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Fracture			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Injury			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Dermoid Cyst			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Pectoris			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Valve Incompetence			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac Failure			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Disease			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Infarction			
subjects affected / exposed	1 / 280 (0.36%)	3 / 494 (0.61%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Ischaemia			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Node Dysfunction			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular Accident			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Idiopathic Partial Epilepsy			

subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar Infarction			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Hernia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous Fistula			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			

subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal Hernia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Strangulation			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large Intestine Polyp			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical Hernia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis Acute			

subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Failure			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic Hepatitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Contact			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema Nodosum			

subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythrodermic Psoriasis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen Planus			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondromalacia			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's Contracture			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 280 (0.00%)	2 / 494 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lateral Patellar Compression Syndrome			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscal Degeneration			

subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metatarsalgia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	2 / 280 (0.71%)	3 / 494 (0.61%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger Finger			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Abscess			

subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Limb			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Sinusitis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Abscess			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 280 (0.00%)	4 / 494 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 280 (0.00%)	3 / 494 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Tonsillitis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			

subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Abscess			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 280 (0.36%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Infection			
subjects affected / exposed	0 / 280 (0.00%)	0 / 494 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal Abscess			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			

subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	0 / 280 (0.00%)	1 / 494 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo (PCP)	Guselkumab 100 mg (PCP)	Adalimumab (PCP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 174 (29.31%)	101 / 329 (30.70%)	98 / 333 (29.43%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 174 (2.30%)	10 / 329 (3.04%)	7 / 333 (2.10%)
occurrences (all)	4	10	7
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 174 (4.02%)	14 / 329 (4.26%)	13 / 333 (3.90%)
occurrences (all)	7	14	15
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	1 / 174 (0.57%)	6 / 329 (1.82%)	17 / 333 (5.11%)
occurrences (all)	1	8	35
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 174 (1.15%)	2 / 329 (0.61%)	4 / 333 (1.20%)
occurrences (all)	4	2	4
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 174 (0.57%)	2 / 329 (0.61%)	4 / 333 (1.20%)
occurrences (all)	1	2	4
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	10 / 174 (5.75%)	5 / 329 (1.52%)	7 / 333 (2.10%)
occurrences (all)	13	5	7
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 174 (1.72%)	11 / 329 (3.34%)	8 / 333 (2.40%)
occurrences (all)	4	13	8
Back Pain			
subjects affected / exposed	2 / 174 (1.15%)	6 / 329 (1.82%)	5 / 333 (1.50%)
occurrences (all)	3	6	5
Psoriatic Arthropathy			
subjects affected / exposed	0 / 174 (0.00%)	1 / 329 (0.30%)	0 / 333 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 174 (1.15%)	2 / 329 (0.61%)	3 / 333 (0.90%)
occurrences (all)	2	2	3
Gastroenteritis			
subjects affected / exposed	2 / 174 (1.15%)	5 / 329 (1.52%)	2 / 333 (0.60%)
occurrences (all)	2	5	2
Influenza			
subjects affected / exposed	0 / 174 (0.00%)	2 / 329 (0.61%)	2 / 333 (0.60%)
occurrences (all)	0	2	2
Nasopharyngitis			
subjects affected / exposed	17 / 174 (9.77%)	30 / 329 (9.12%)	36 / 333 (10.81%)
occurrences (all)	19	34	42
Pharyngitis			
subjects affected / exposed	0 / 174 (0.00%)	0 / 329 (0.00%)	2 / 333 (0.60%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 174 (0.00%)	3 / 329 (0.91%)	1 / 333 (0.30%)
occurrences (all)	0	3	1

Upper Respiratory Tract Infection			
subjects affected / exposed	9 / 174 (5.17%)	25 / 329 (7.60%)	16 / 333 (4.80%)
occurrences (all)	9	32	18

Non-serious adverse events	Placebo Then Guselkumab 100 mg (ACP)	Guselkumab 100 mg (ACP)	Adalimumab (ACP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	67 / 165 (40.61%)	134 / 324 (41.36%)	137 / 326 (42.02%)
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 165 (3.64%)	5 / 324 (1.54%)	10 / 326 (3.07%)
occurrences (all)	8	6	10
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 165 (0.61%)	7 / 324 (2.16%)	16 / 326 (4.91%)
occurrences (all)	1	7	16
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	3 / 165 (1.82%)	4 / 324 (1.23%)	11 / 326 (3.37%)
occurrences (all)	4	9	33
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 165 (3.64%)	8 / 324 (2.47%)	4 / 326 (1.23%)
occurrences (all)	6	9	4
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 165 (3.64%)	10 / 324 (3.09%)	8 / 326 (2.45%)
occurrences (all)	6	10	8
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 165 (0.00%)	3 / 324 (0.93%)	6 / 326 (1.84%)
occurrences (all)	0	3	6
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 165 (1.21%)	10 / 324 (3.09%)	8 / 326 (2.45%)
occurrences (all)	2	11	8
Back Pain			

subjects affected / exposed	1 / 165 (0.61%)	7 / 324 (2.16%)	12 / 326 (3.68%)
occurrences (all)	1	8	13
Psoriatic Arthropathy			
subjects affected / exposed	0 / 165 (0.00%)	1 / 324 (0.31%)	0 / 326 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 165 (3.03%)	4 / 324 (1.23%)	7 / 326 (2.15%)
occurrences (all)	7	4	8
Gastroenteritis			
subjects affected / exposed	3 / 165 (1.82%)	11 / 324 (3.40%)	4 / 326 (1.23%)
occurrences (all)	3	13	5
Influenza			
subjects affected / exposed	1 / 165 (0.61%)	2 / 324 (0.62%)	2 / 326 (0.61%)
occurrences (all)	1	2	2
Nasopharyngitis			
subjects affected / exposed	34 / 165 (20.61%)	65 / 324 (20.06%)	57 / 326 (17.48%)
occurrences (all)	45	89	75
Pharyngitis			
subjects affected / exposed	1 / 165 (0.61%)	5 / 324 (1.54%)	7 / 326 (2.15%)
occurrences (all)	1	5	8
Sinusitis			
subjects affected / exposed	3 / 165 (1.82%)	7 / 324 (2.16%)	6 / 326 (1.84%)
occurrences (all)	3	7	6
Upper Respiratory Tract Infection			
subjects affected / exposed	17 / 165 (10.30%)	31 / 324 (9.57%)	33 / 326 (10.12%)
occurrences (all)	24	38	41

Non-serious adverse events	Adalimumab then Guselkumab 100 mg (After ACP)	Guselkumab Combined	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	193 / 280 (68.93%)	307 / 494 (62.15%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	17 / 280 (6.07%)	40 / 494 (8.10%)	
occurrences (all)	17	43	
Nervous system disorders			

Headache			
subjects affected / exposed	17 / 280 (6.07%)	28 / 494 (5.67%)	
occurrences (all)	24	42	
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	7 / 280 (2.50%)	5 / 494 (1.01%)	
occurrences (all)	35	14	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	13 / 280 (4.64%)	28 / 494 (5.67%)	
occurrences (all)	14	40	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	20 / 280 (7.14%)	24 / 494 (4.86%)	
occurrences (all)	23	30	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	7 / 280 (2.50%)	16 / 494 (3.24%)	
occurrences (all)	8	20	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	26 / 280 (9.29%)	37 / 494 (7.49%)	
occurrences (all)	32	43	
Back Pain			
subjects affected / exposed	22 / 280 (7.86%)	28 / 494 (5.67%)	
occurrences (all)	25	37	
Psoriatic Arthropathy			
subjects affected / exposed	14 / 280 (5.00%)	12 / 494 (2.43%)	
occurrences (all)	14	14	
Infections and infestations			
Bronchitis			
subjects affected / exposed	19 / 280 (6.79%)	23 / 494 (4.66%)	
occurrences (all)	19	30	
Gastroenteritis			
subjects affected / exposed	14 / 280 (5.00%)	25 / 494 (5.06%)	
occurrences (all)	20	31	

Influenza			
subjects affected / exposed	16 / 280 (5.71%)	20 / 494 (4.05%)	
occurrences (all)	16	20	
Nasopharyngitis			
subjects affected / exposed	89 / 280 (31.79%)	148 / 494 (29.96%)	
occurrences (all)	190	313	
Pharyngitis			
subjects affected / exposed	17 / 280 (6.07%)	18 / 494 (3.64%)	
occurrences (all)	20	20	
Sinusitis			
subjects affected / exposed	14 / 280 (5.00%)	19 / 494 (3.85%)	
occurrences (all)	16	26	
Upper Respiratory Tract Infection			
subjects affected / exposed	69 / 280 (24.64%)	107 / 494 (21.66%)	
occurrences (all)	119	222	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 February 2015	Amendment-1 included the following major changes: to address the regulatory, ethics committee, and investigator feedback. The key changes done ensured consistency in the assessments and the timepoints across all the guselkumab Phase 3 psorias protocols. The major changes were additional timepoints for antibody assessments were added to the Time and Events Schedule; The secondary objective was corrected to delete the mention of health economics outcomes, which were not actually collected in this study; Body surface area (BSA) assessment at Week 48 was deleted; physical examination was added at Week 148 and deleted at Weeks 60, 68, and 76; and weight measurement was added at Week 160; The follow-up visits and time frames for subjects who discontinued study treatment before the last scheduled injection were revised; Information was added about the presence of dry natural rubber on the adalimumab prefilled syringe (PFS) needle cover; The inclusion criteria for female subjects of childbearing potential and male subjects who were sexually active with women of childbearing potential were clarified to indicate that barrier methods should be used with a spermicidal agent if spermicidal agents were available in the subjects' locale; The exclusion criterion for major surgery was clarified, and an exclusion criterion was added to exclude Sponsor employees from participation in the study; The dosage and administration description for Group II was revised to clarify administrations after Week 16; The time point after which antimalarial agents could be used was corrected to Week 48 (from Week 52); and the study visit for assessments for subjects who withdrew from study participation after Week 48 was corrected to Week 148 (from Week 160).
04 April 2017	Amendment-3 included the following major change: the duration of open-label treatment period by 2 years thereby changing the final study visit (end of study) from Week 160 to Week 264 (5 years).

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.

All subjects were on guselkumab after Week 48; therefore, there was no concurrent control group within the study after Week 48.

Notes: