Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind Study Evaluating the Comparative Efficacy of CNTO 1959 (Guselkumab) and Secukinumab for the Treatment of Moderate to Severe Plaque-type Psoriasis

Summary

EudraCT number	2016-002995-29
Trial protocol	DE ES HU CZ PL
Global end of trial date	20 September 2018

Results information

Result version number	v1 (current)
This version publication date	22 August 2019
First version publication date	22 August 2019

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO3009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03090100
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry group, Janssen- Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen-Cilag International NV, 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	20 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 August 2018
Global end of trial reached?	Yes
Global end of trial date	20 September 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study is to evaluate the efficacy of guselkumab compared with secukinumab for 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 assessments included adverse events (AEs), clinical laboratory tests (hematology, chemistry, lipids, serology, and pregnancy testing), vital signs and Electrocardiogram (ECG) parameters.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 April 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 158
Country: Number of subjects enrolled	Czech Republic: 55
Country: Number of subjects enrolled	Australia: 71
Country: Number of subjects enrolled	Germany: 122
Country: Number of subjects enrolled	Spain: 68
Country: Number of subjects enrolled	France: 58
Country: Number of subjects enrolled	Hungary: 45
Country: Number of subjects enrolled	Poland: 238
Country: Number of subjects enrolled	United States: 233
Worldwide total number of subjects	1048
EEA total number of subjects	586

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)	949
From 65 to 84 years	98
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of total 1,048 randomized subjects, 534 were assigned to receive Guselkumab + Placebo and 514 subjects were assigned to receive Secukinumab.

Period 1

Period 1 title	Overall Study (overall period)
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	Guselkumab 100 mg + Placebo

Arm description:

Subjects received 1 injection of active guselkumab and 1 injection of placebo when guselkumab is scheduled to be administered (Weeks 0, 4, 12, 20, 28, 36, and 44) or 2 injections of placebo when no guselkumab is scheduled to be administered (Weeks 1, 2, 3, 8, 16, 24, 32, and 40). Placebo injections were administered to maintain the blind. Subjects were continued to follow-up period from Week 44 through Week 56.

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

Dosage and administration details:

Subjects received 1 injection of Placebo at Week 0, 4 and 12 and thereafter q8w through Week 44 or 2 injections of Placebo at Week 1, 2, 3, and 8 and thereafter every q8w through Week 40.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Guselkumab 100 mg SC injection at Week 0, 4 and 12 and thereafter q8w through Week 44.

Arm title	Secukinumab 300 mg

Arm description:

Subjects received 2 injections of active secukinumab subcutaneously (SC) at Weeks 0, 1, 2, 3, 4 and every 4 weeks (q4w) thereafter through Week 44. Subjects were continued to follow-up period from Week 44 through Week 56.

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

Dosage and administration details:

Subjects received a single dose of Secukinumab 300 mg SC injection (2*150 mg) at Week 0, 1, 2, 3, and 4 and thereafter every 4 weeks (q4w) through Week 44.

Number of subjects in period 1	Guselkumab 100 mg + Placebo	Secukinumab 300 mg
Started	534	514
Treated	507	511
Completed	507	466
Not completed	27	48
Consent withdrawn by subject	7	19
Adverse event, non-fatal	5	5
Pregnancy	1	1
Non-compliance with study drug	2	-
Adverse event, serious non-fatal	3	5
Unspecified	2	2
Lost to follow-up	2	2
Adverse event - worsening of psoriasis	1	1
Protocol deviation	2	6
Lack of efficacy	2	7

Baseline characteristics

Reporting groups	
Reporting group title	Guselkumab 100 mg + Placebo
Reporting group description:	
Subjects received 1 injection of active guselkumab and 1 injection of placebo when guselkumab is scheduled to be administered (Weeks 0, 4, 12, 20, 28, 36, and 44) or 2 injections of placebo when no guselkumab is scheduled to be administered (Weeks 1, 2, 3, 8, 16, 24, 32, and 40). Placebo injections were administered to maintain the blind. Subjects were continued to follow-up period from Week 44 through Week 56.	
Reporting group title	Secukinumab 300 mg
Reporting group description:	
Subjects received 2 injections of active secukinumab subcutaneously (SC) at Weeks 0, 1, 2, 3, 4 and every 4 weeks (q4w) thereafter through Week 44. Subjects were continued to follow-up period from Week 44 through Week 56.	

Reporting group values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg	Total
Number of subjects	534	514	1048
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	480	469	949
From 65 to 84 years	53	45	98
85 years and over	1	0	1
Title for AgeContinuous Units: years			
arithmetic mean	46.3	45.3	
standard deviation	± 13.67	± 13.57	-
Title for Gender Units: subjects			
Female	169	172	341
Male	365	342	707

End points

End points reporting groups

Reporting group title	Guselkumab 100 mg + Placebo
Reporting group description:	
Subjects received 1 injection of active guselkumab and 1 injection of placebo when guselkumab is scheduled to be administered (Weeks 0, 4, 12, 20, 28, 36, and 44) or 2 injections of placebo when no guselkumab is scheduled to be administered (Weeks 1, 2, 3, 8, 16, 24, 32, and 40). Placebo injections were administered to maintain the blind. Subjects were continued to follow-up period from Week 44 through Week 56.	
Reporting group title	Secukinumab 300 mg
Reporting group description:	
Subjects received 2 injections of active secukinumab subcutaneously (SC) at Weeks 0, 1, 2, 3, 4 and every 4 weeks (q4w) thereafter through Week 44. Subjects were continued to follow-up period from Week 44 through Week 56.	

Primary: Percentage of Subjects who Achieved a Psoriasis Area and Severity Index (PASI)-90 Response at Week 48

End point title	Percentage of Subjects who Achieved a Psoriasis Area and Severity Index (PASI)-90 Response at Week 48
End point description:	
PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 90 response: at least 90 percent (%) reduction in PASI relative to baseline. Full analysis set (FAS): subjects randomized at Week 0. Subjects who met treatment failure criteria (who discontinued study agent due to lack of efficacy or adverse event of psoriasis and/or who initiated protocol-prohibited psoriasis medications/therapies) prior to Week 48 or who had a missing PASI score at Week 48 were considered PASI 90 non-responders at Week 48.	
End point type	Primary
End point timeframe:	
Week 48	

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	84.5	70.0		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg

Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001
Method	z-test
Parameter estimate	Difference in percentage
Point estimate	14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.2
upper limit	19.2

Statistical analysis title	Statistical Analysis 2
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects who Achieved a PASI-75 Response at Both Week 12 and 48

End point title	Percentage of Subjects who Achieved a PASI-75 Response at Both Week 12 and 48

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 75 response: at least a 75% reduction in PASI relative to baseline. Full analysis set: subjects randomized at Week 0. Subjects who met treatment failure criteria (who discontinued study agent due to lack of efficacy or adverse event of psoriasis and/or who initiated protocol-prohibited psoriasis medications/therapies) prior to Week 48 or who had a missing PASI score at Week 12 or Week 48 were considered as non-responders for this endpoint.

End point type	Secondary

End point timeframe:

Week 12 and 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	84.6	80.2		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001
Method	z-test
Parameter estimate	Difference in percentage
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	8.9

Statistical analysis title	Statistical Analysis 2
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.062
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects who Achieved a PASI-90 Response at Week 12

End point title	Percentage of Subjects who Achieved a PASI-90 Response at Week 12

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 90 response: at least 90% reduction in PASI relative to baseline. Full analysis set included. Subjects who met treatment failure criteria prior to Week 12, who had a missing PASI score at Week 12 were considered PASI 90 non-responders at Week 12. Due to failing to achieve superiority of prior secondary endpoint, no formal statistical testing was performed for endpoints from this point onwards.

End point type	Secondary

End point timeframe:

Weak 12

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	69.1	76.1		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	-7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	-1.7

Secondary: Percentage of Subjects who Achieved a PASI-75 Response at Week 12

End point title	Percentage of Subjects who Achieved a PASI-75 Response at Week 12

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 75 response: at least 75% reduction in PASI relative to baseline. Full analysis set included. Subjects who met treatment failure criteria prior to Week 12 or who had a missing PASI score at Week 12 were considered PASI 75 non-responders at Week 12.

End point type	Secondary

End point timeframe:

Week 12

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	89.3	91.6		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	1.2

Secondary: Percentage of Subjects who Achieved a PASI-100 Response at Week 48

End point title	Percentage of Subjects who Achieved a PASI-100 Response at Week 48

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 100 response: at least 100% reduction in PASI relative to baseline. Full analysis set included. Subjects who met treatment failure criteria prior to Week 48 or who had a missing PASI score at Week 48 were considered PASI 100 non-responders at Week 48.

End point type	Secondary

End point timeframe:

Week 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	58.2	48.4		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	9.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	15.5

Secondary: Percentage of Subjects with Investigator's Global Assessment (IGA) Score Cleared (0) at Week 48

End point title	Percentage of Subjects with Investigator's Global Assessment (IGA) Score Cleared (0) at Week 48

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 is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 48 or who had a missing IGA score at Week 48 were considered IGA cleared (0) non-responders at Week 48.

End point type	Secondary

End point timeframe:

Week 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	62.2	50.4		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	11.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.8
upper limit	17.4

Secondary: Percentage of Subjects with Investigator's Global Assessment (IGA) Score Cleared (0) or Minimal (1) at Week 48	
End point title	Percentage of Subjects with Investigator's Global Assessment (IGA) Score Cleared (0) or Minimal (1) at Week 48
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 is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 48 or who had a missing IGA score at Week 48 were considered IGA cleared (0) or minimal (1) non-responders at Week 48.	
End point type	Secondary
End point timeframe:	
Week 48	

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	85.0	74.9		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg

Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	9.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.9
upper limit	14.5

Secondary: Percentage of Subjects who Achieved a PASI-90 Response at Both Week 16 and 48

End point title	Percentage of Subjects who Achieved a PASI-90 Response at Both Week 16 and 48

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions, their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each of these areas is assessed separately for percentage of area involved, which translates to a numeric score (0 (no involvement) to 6 [90-100% involvement]), for erythema, induration, scaling, rated on scale of 0 to 4. PASI produces numeric score (0 [no psoriasis]-72). Higher score indicates more severe disease. PASI 90 response: at least 90% reduction in PASI relative to baseline. Full analysis set: subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 48 or who had a missing PASI score at Week 16 or Week 48 were considered as non-responders for this endpoint.

End point type	Secondary

End point timeframe:

Week 16 and 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	72.3	64.4		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	7.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	13.2

Secondary: Percentage of Subjects who Achieved a PASI-75 Response at Week 16

End point title	Percentage of Subjects who Achieved a PASI-75 Response at Week 16

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90%-100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that could range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. PASI 75 response was defined as at least a 75% reduction in PASI relative to baseline. Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 16 or who had a missing PASI score at Week 16 were considered PASI 75 non-responders at Week 16.

End point type	Secondary

End point timeframe:

Week 16

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	92.7	92.8		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	3.1

Secondary: Percentage of Subjects who Achieved a PASI-90 Response at Week 16

End point title	Percentage of Subjects who Achieved a PASI-90 Response at Week 16

End point description:

he PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90%-100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that could range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. PASI 90 response was defined as at least a 90 percent (%) reduction in PASI relative to baseline. Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 16 or who had a missing PASI score at Week 16 were considered PASI 90 non-responders at Week 16.

End point type	Secondary

End point timeframe:

Week 16

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	78.5	79.6		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentages
Point estimate	-1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	3.4

Secondary: Percentage of Subjects who Achieved a PASI-90 Response at all 7 Visits From Week 24 Through Week 48

End point title	Percentage of Subjects who Achieved a PASI-90 Response at

	all 7 Visits From Week 24 Through Week 48

End point description:

PASI is system used for assessing and grading severity of psoriatic lesions and their response to therapy. PASI system, body is divided into 4 regions: head, trunk, upper extremities, lower extremities. Each areas is assessed separately for percentage of area involved, which translates to numeric score (0: no involvement to 6: 90%-100% involvement), and for erythema, induration, scaling, which are each rated on scale of 0 to 4. PASI produces a numeric score that could range from 0 (no psoriasis) to 72. Higher score indicates more severe disease. PASI 90 response was defined as at least a 90% reduction in PASI relative to baseline. FAS population included. Subjects who met treatment failure criteria prior to Week 48 or who had missing PASI score at any visit from Week 24 through Week 48 were considered as non-responders for this endpoint.

End point type	Secondary

End point timeframe:

Week 24 up to Week 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	71.0	61.5		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	9.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.2
upper limit	15.3

Secondary: Percentage of Subjects with Investigator’s Global Assessment (IGA) Score Cleared (0) or Minimal (1) at Week 16

End point title	Percentage of Subjects with Investigator’s Global Assessment (IGA) Score Cleared (0) or Minimal (1) at Week 16

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 is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria prior to Week 16 or who had a missing IGA score at Week 16 were considered non-responders for this endpoint.

End point type	Secondary

Week 16

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)	85.6	86.4		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Guselkumab 100 mg + Placebo v Secukinumab 300 mg
Number of subjects included in analysis	1048
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	3.3

Secondary: Percentage of Subjects who Achieved PASI-75 Response at Week 48 Among PASI-75 Responders at Week 12

End point title	Percentage of Subjects who Achieved PASI-75 Response at Week 48 Among PASI-75 Responders at Week 12

End point description:

PASI is system used for assessing and grading the severity of psoriatic lesions and their response to therapy. PASI system, body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90%-100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that could range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. PASI 75 response was defined as at least a 75% reduction in PASI relative to baseline. Full analysis set included all the subjects randomized at Week 0 and who achieved PASI 75 response at Week 12. Subjects who met treatment failure criteria prior to Week 48 or who had missing PASI score at Week 48 were considered as non-responders for this endpoint.

End point type	Secondary

End point timeframe:

Week 48

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	477	471		
Units: Percentage of subjects				
number (not applicable)	94.8	87.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved PASI-90 Response at Week 48 Among PASI-90 Responders at Week 16

End point title	Percentage of Subjects who Achieved PASI-90 Response at Week 48 Among PASI-90 Responders at Week 16

End point description:

PASI is system used for assessing and grading the severity of psoriatic lesions and their response to therapy. PASI system, body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90%-100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that could range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. PASI 90 response was defined as at least a 90% reduction in PASI relative to baseline. Full analysis set included all the subjects randomized at Week 0 and who achieved PASI 90 response at Week 16. Subjects who met treatment failure criteria prior to Week 48 or who had missing PASI score at Week 48 were considered as non-responders for this endpoint.

End point type	Secondary

End point timeframe:

Week 16

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	419	409		
Units: Percentage of subjects				
number (not applicable)	92.1	80.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved PASI Response (PASI 100, PASI-90, PASI-75 and PASI-50) Over Time From Week 1 to Week 56

End point title	Percentage of Subjects who Achieved PASI Response (PASI 100, PASI-90, PASI-75 and PASI-50) Over Time From Week 1 to Week 56

End point description:

PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In PASI system, body is divided into 4 regions: head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 (no psoriasis) to 72. Subjects with >=50%, >= 75%, >=90% and >= 100% improvement in PASI from baseline were considered PASI 50, 75, 90 and PASI 100 responders, respectively. Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria or who had missing PASI score were considered as non-responders for the specific visit.

End point type	Secondary

End point timeframe:

Week 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 56

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)				
Week 1: 100% improvement	0	0		
Week 1: >=90% improvement	0	0		
Week 1: >=75% improvement	2.1	1.8		
Week 1: >=50% improvement	10.7	12.8		
Week 2: 100 improvement	0.2	0.6		
Week 2: >=90% improvement	1.1	2.7		
Week 2: >=75% improvement	6.4	11.5		
Week 2: >=50% improvement	30.9	42.0		
Week 3: 100% improvement	1.7	1.6		
Week 3: >=90% improvement	5.6	8.6		
Week 3: >=75% improvement	19.5	28.4		
Week 3: >=50% improvement	56.4	66.9		
Week 4: 100% improvement	4.1	5.1		
Week 4: >=90% improvement	13.1	21.8		
Week 4: >=75% improvement	39.3	50.2		
Week 4: >=50% improvement	73.4	85.4		
Week 8: 100% improvement	20.0	27.2		
Week 8: >=90% improvement	48.7	62.1		
Week 8: >=75% improvement	76.4	86.2		
Week 8: >=50% improvement	95.3	96.9		
Week 12: 100% improvement	37.8	42.0		
Week 12: >=50% improvement	96.8	96.1		
Week 16: 100% improvement	47.8	46.1		
Week 16: >=50% improvement	97.6	96.3		
Week 20: 100% improvement	51.3	48.6		
Week 20: >=90% improvement	80.1	81.1		
Week 20: >=75% improvement	93.6	92.4		
Week 20: >=50% improvement	97.6	95.1		
Week 24: 100% improvement	54.7	50.4		
Week 24: >=90% improvement	83.1	78.2		

Week 24: >=75% improvement	94.2	90.3		
Week 24: >=50% improvement	97.8	93.0		
Week 28: 100% improvement	57.1	51.0		
Week 28: >=90% improvement	85.4	77.2		
Week 28: >=75% improvement	94.0	90.3		
Week 28: >=50% improvement	97.2	93.0		
Week 32: 100% improvement	57.5	50.2		
Week 32:>=90 % improvement	84.8	77.4		
Week 32: >=75% improvement	94.0	89.3		
Week 32: >=50% improvement	97.0	93.0		
Week 36: 100% improvement	58.6	50.0		
Week 36: >=90% improvement	84.5	75.7		
Week 36: >=75% improvement	93.6	87.0		
Week 36: >=50% improvement	97.2	92.2		
Week 40: 100% improvement	58.2	48.6		
Week 40: >=90% improvement	84.6	73.7		
Week 40: >=75% improvement	92.9	85.8		
Week 40: >=50% improvement	95.9	90.9		
Week 44: 100% improvement	58.6	49.4		
Week 44: >=90% improvement	84.1	72.6		
Week 44: >=75% improvement	92.3	85.2		
Week 44: >=50% improvement	94.2	91.4		
Week 48: >=75% improvement	92.1	83.5		
Week 48: >=50% improvement	94.0	89.3		
Week 56: 100% improvement	50.4	27.0		
Week 56: >=90% improvement	77.3	51.4		
Week 56: >=75% improvement	88.0	70.4		
Week 56: >=50% improvement	91.0	82.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with IGA Responses Through Week 56

End point title	Percentage of Subjects with IGA Responses Through Week 56

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 is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Full analysis set included all the subjects randomized at Week 0. Subjects who met treatment failure criteria or who had missing IGA score were considered as non-responders for the specific visit.

End point type	Secondary

End point timeframe:

Week 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, and 56

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percentage of subjects				
number (not applicable)				
Week 1: cleared (0)	0	0		
Week 1: cleared (0) or minimal (1)	3.4	2.5		
Week 1: mild or better (=<2)	27.2	34.2		
Week 2: cleared (0)	0.2	0.8		
Week 2: cleared (0) or minimal (1)	12.4	20.2		
Week 2: mild or better (=<2)	54.1	63.8		
Week 3: cleared (0)	2.6	3.3		
Week 3: cleared (0) or minimal (1)	27.2	39.9		
Week 3: mild or better (=<2)	75.3	82.5		
Week 4: cleared (0)	6.7	9.7		
Week 4: cleared (0) or minimal (1)	44.2	59.3		
Week 4: mild or better (=<2)	85.6	92.2		
Week 8: cleared (0)	29.2	35.8		
Week 8: cleared (0) or minimal (1)	76.6	83.5		
Week 8: mild or better (=<2)	96.3	96.3		
Week 12: cleared (0)	46.3	50.2		
Week 12: mild or better (=<2)	96.8	95.3		
Week 16: cleared (0)	55.4	53.5		
Week 16: mild or better (=<2)	96.8	94.7		
Week 20: cleared (0)	56.9	53.9		
Week 20: cleared (0) or minimal (1)	87.8	85.6		
Week 20: mild or better (=<2)	95.3	93.2		
Week 24: cleared (0)	61.0	56.0		
Week 24: cleared (0) or minimal (1)	88.6	82.7		
Week 24: mild or better (=<2)	96.3	91.6		
Week 28: cleared (0)	62.2	56.2		
Week 28: cleared (0) or minimal (1)	87.8	82.9		
Week 28: mild or better (<=2)	95.5	90.9		
Week 32: cleared (0)	63.1	54.5		
Week 32: cleared (0) or minimal (1)	88.6	81.5		
Week 32: mild or better (=<2)	95.5	90.5		
Week 36: cleared (0)	60.7	53.7		
Week 36: cleared (0) or minimal (1)	86.5	79.6		
Week 36: mild or better (=<2)	95.5	88.9		
Week 40: cleared (0)	63.1	52.3		
Week 40: cleared (0) or minimal (1)	86.3	78.0		
Week 40: mild or better (=<2)	93.6	87.9		
Week 44: cleared (0)	62.2	51.9		
Week 44: cleared (0) or minimal (1)	86.0	76.5		
Week 44: mild or better (=<2)	92.3	87.5		
Week 48: cleared (0)	62.2	50.4		
Week 48: cleared (0) or minimal (1)	85.0	74.9		
Week 48: mild or better (=<2)	92.7	86.8		
Week 56: cleared (0)	54.3	29.4		
Week 56: cleared (0) or minimal (1)	78.8	58.2		

Week 56: mild or better (=<2)	87.5	76.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Improvement From Baseline in PASI Through Week 56

End point title	Percent Improvement From Baseline in PASI Through Week 56

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90%-100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that could range from 0 (no psoriasis) to 72. A higher score indicates more severe disease. Here 'n' signifies the number of subjects analyzed at specified time point. Full analysis set: subjects randomized at Week 0. Zero percent improvement was assigned from the point when subjects met treatment failure criteria and no other data imputation was applied.

End point type	Secondary

End point timeframe:

Week 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and Week 56

End point values	Guselkumab 100 mg + Placebo	Secukinumab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	534	514		
Units: Percent improvement				
arithmetic mean (standard deviation)				
Week 1 (n=531, 510)	20.30 (± 20.743)	24.72 (± 20.711)		
Week 2 (n=533, 509)	37.85 (± 23.567)	44.56 (± 23.600)		
Week 3 (n=531, 507)	52.76 (± 24.186)	60.57 (± 21.871)		
Week 4 (n=531, 507)	64.63 (± 22.862)	72.80 (± 19.478)		
Week 8 (n=531, 506)	84.36 (± 17.278)	89.40 (± 13.579)		
Week 12 (n=527, 505)	90.85 (± 14.484)	92.60 (± 13.703)		
Week 16 (n=526, 501)	93.65 (± 12.849)	93.94 (± 12.123)		
Week 20 (n=525, 495)	94.35 (± 11.525)	94.41 (± 12.152)		
Week 24 (n=525, 490)	95.27 (± 9.848)	93.75 (± 14.314)		
Week 28 (n=521, 492)	95.58 (± 9.663)	92.96 (± 16.835)		
Week 32 (n=521, 491)	95.74 (± 9.336)	92.95 (± 16.641)		

Week 36 (n=523, 487)	95.45 (± 11.119)	92.40 (± 17.125)		
Week 40 (n=516, 484)	95.78 (± 10.456)	91.77 (± 17.733)		
Week 44 (n=511, 486)	95.45 (± 12.293)	91.34 (± 18.246)		
Week 48 (n=508, 478)	95.76 (± 11.629)	90.87 (± 19.181)		
Week 56 (n=499, 469)	93.35 (± 16.116)	81.67 (± 27.627)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to Week 56	
Adverse event reporting additional description:	
Safety analysis set included all randomized and treated subjects who received at least 1 dose of study agent (partial or complete) at Week 0 according to the actual treatment received during the study.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	Secukinumab 300 mg
Reporting group description:	
Subjects received single dose of Secukinumab 300 mg SC injection on Week 0, 1, 2, 3, and 4 and thereafter every 4 weeks (q4w) through Week 44. Subjects go under the follow-up phase from Week 44 through Week 56.	
Reporting group title	Guselkumab 100 mg
Reporting group description:	
Subjects received Guselkumab 100 milligrams (mg) subcutaneous (SC) injection and Placebo on Week 0, 4 and 12 and thereafter every 8 weeks (q8w) through Week 44 and 2 injections of Placebo on Week 1, 2, 3, and 8 and thereafter every q8w through Week 40. Subjects go under the follow-up phase from Week 44 through Week 56.	

Serious adverse events	Secukinumab 300 mg	Guselkumab 100 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	37 / 511 (7.24%)	33 / 534 (6.18%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Small Cell Lung Cancer			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arteriosclerosis			

subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
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 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Finger Amputation			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise Tolerance Decreased			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Immune system disorders			
Anaphylactoid Reaction			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Bartholin's Cyst			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Interstitial Lung Disease			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Cyst			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal Polyps			

subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all			

subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot Fracture			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Rupture			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
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 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull Fracture			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Rupture			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Limb Fracture			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial Fibrillation			

subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Complete			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure Congestive			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Occlusion			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wolff-Parkinson-White Syndrome			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Macular Fibrosis			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's Disease			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia Oral			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
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	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cholelithiasis			
subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-Induced Liver Injury			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Chronic Cutaneous Lupus Erythematosus			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Eruption			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash Morbilliform			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Intervertebral Disc Protrusion			
subjects affected / exposed	2 / 511 (0.39%)	0 / 534 (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	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Column Stenosis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Osteoarthritis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess Limb			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Labyrinthitis			
subjects affected / exposed	0 / 511 (0.00%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroborreliosis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 511 (0.20%)	1 / 534 (0.19%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 511 (0.20%)	0 / 534 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Secukinumab 300 mg	Guselkumab 100 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	254 / 511 (49.71%)	249 / 534 (46.63%)	
Nervous system disorders			
Headache			
subjects affected / exposed	48 / 511 (9.39%)	48 / 534 (8.99%)	
occurrences (all)	65	59	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	20 / 511 (3.91%)	27 / 534 (5.06%)	
occurrences (all)	21	31	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	25 / 511 (4.89%)	30 / 534 (5.62%)	
occurrences (all)	37	37	
Back Pain			

subjects affected / exposed	18 / 511 (3.52%)	29 / 534 (5.43%)	
occurrences (all)	19	35	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	125 / 511 (24.46%)	118 / 534 (22.10%)	
occurrences (all)	194	200	
Upper Respiratory Tract Infection			
subjects affected / exposed	92 / 511 (18.00%)	83 / 534 (15.54%)	
occurrences (all)	129	110	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 April 2017	To add information regarding the benefit-risk assessment for subjects who participated in this study. To be consistent with the European Union (EU) definitions of highly effective contraception by removing examples of contraceptives (including barrier methods which are not considered highly effective) from the relevant inclusion criterion; a unique number was assigned to the modified criterion. To update the inclusion criteria for consistency with the secukinumab EU Summary of Product Characteristics (SmPC) requiring subjects to wait 20 weeks rather than 16 weeks after their last treatment with secukinumab before donating eggs or sperm; and to require men who are sexually active with a woman of childbearing potential, and who have not had a vasectomy, to use a barrier method of birth control during the study for 20 rather than 16 weeks after the last administration of secukinumab (unique numbers were assigned to each modified criterion). To update the exclusion criteria for consistency with the secukinumab EU SmPC to exclude enrollment of subjects who are pregnant, nursing, or planning a pregnancy during the study or within 20 weeks after the last administration of secukinumab or within 12 weeks after receiving the last administration of guselkumab (a unique number was assigned to the modified criterion). To update the time frame for prohibitions and restrictions for contraception and sperm/egg donation to be consistent with the secukinumab EU SmPC (20 weeks rather than 16 weeks) after the last administration of secukinumab. To add the statement that discontinuation of study treatment should be considered if the subject does not show a response to treatment by Week 16.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported