Clinical trial results:
A Phase 2a, Multicenter, Randomized, Double-blind Study Evaluating the Efficacy and Safety of Subcutaneously Administered Guselkumab and Golimumab Combination Therapy in Participants with Active Psoriatic Arthritis

Summary

EudraCT number	2021-002012-31
Trial protocol	ES IT DK HU FR
Global end of trial date	06 August 2024

Results information

Result version number	v1 (current)
This version publication date	16 August 2025
First version publication date	16 August 2025

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSA2003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05071664
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development LLC
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the efficacy of combination therapy with guselkumab plus golimumab versus guselkumab monotherapy in subjects with active psoriatic arthritis (PsA) and inadequate response (IR) to prior anti-tumor necrosis factor-alpha (anti-TNF-alpha) therapies by assessing clinical response.

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.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 October 2021
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	Denmark: 12
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Russian Federation: 4
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	Ukraine: 3
Country: Number of subjects enrolled	United States: 31
Worldwide total number of subjects	91
EEA total number of subjects	53

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)	91
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 91 adult subjects were randomised (2:1 ratio) and treated either in Group 1 (guselkumab plus golimumab) or Group 2 (guselkumab plus placebo). Out of which 76 subjects completed the study.

Period 1

Period 1 title	Overall Study Period (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	Group 1 : Guselkumab Plus Golimumab

Arm description:

Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

Arm type	Experimental
Investigational medicinal product name	Golimumab
Investigational medicinal product code	
Other name	SIMPONI, CNTO148
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received golimumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

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

Dosage and administration details:

Subjects received guselkumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

Arm title	Group 2: Guselkumab Plus Placebo

Arm description:

Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

Arm type	Active comparator
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:

Subjects received placebo (matched golimumab) SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

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

Dosage and administration details:

Subjects received guselkumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

Number of subjects in period 1	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo
Started	59	32
Completed	48	28
Not completed	11	4
Consent withdrawn by subject	3	3
Unspecified	5	1
Lost to follow-up	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1 : Guselkumab Plus Golimumab
Reporting group description:	
Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).	
Reporting group title	Group 2: Guselkumab Plus Placebo
Reporting group description:	
Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).	

Reporting group values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo	Total
Number of subjects	59	32	91
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	50.2	47.7	
standard deviation	± 10.53	± 10.34	-
Gender categorical Units: Subjects			
Male	23	12	35
Female	36	20	56
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	57	32	89
Multiple	0	0	0
Not Reported	1	0	1
Unknown	1	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	18	5	23
Not Hispanic or Latino	38	26	64
Not Reported	2	1	3
Unknown	1	0	1

End points

End points reporting groups

Reporting group title	Group 1 : Guselkumab Plus Golimumab
Reporting group description:	
Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).	
Reporting group title	Group 2: Guselkumab Plus Placebo
Reporting group description:	
Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).	

Primary: Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 24

End point title	Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 24
End point description:	
MDA: measured to indicate disease remission based on composite score of 7 domains. Subjects achieved MDA if fulfilled at least 5 of the 7 criteria: tender joint count (0 to 68 joints) less than or equal to (<=) 1, swollen joint count (0-66 joints) <=1, psoriasis area and severity index (PASI) <=1 (scale 0 [no] to 72 [maximal disease]) or body surface area (BSA) <=3 percent (%); Patient's Global Assessment of Pain <=15 scale 0 (no) to100 (severe pain); Patient's Global Assessment of Disease Activity <=20 scale 0 (very well) to 100 (very poor); Disability Index of the Health Assessment Questionnaire (HAQ-DI) score <=0.5, HAQ-DI score ranged 0 (no difficulty) to 3 (maximum difficulty); Leeds Enthesitis Index score <=1 for subjects with enthesitis at baseline. Full analysis set (FAS) included all subjects who were randomised in this study.	
End point type	Primary
End point timeframe:	
Week 24	

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	28.8	21.9		

Statistical analyses

Statistical analysis title	Statistical Analysis -1
Comparison groups	Group 2: Guselkumab Plus Placebo v Group 1 : Guselkumab Plus Golimumab

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.557
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.6
upper limit	3.3

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

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

End point description:

ACR 50 response, defined as greater than or equal to (>=) 50% improvement from baseline in both swollen joint (66 joints) and tender joint counts (68 joints) and >=50% improvement from baseline in 3 of 5 (>=3) assessments: Physician global assessment of disease activity (0 to 100 millimetres [mm] visual analog scale [VAS; 0 = no; 100 = severe symptoms]), Patient global assessment of disease activity (arthritis) (100 mm VAS [0 = no limitation of normal activities; 100 = very poor]), Patient's global assessment of pain (100 mm VAS [0 = no pain; 100 = most severe pain]), HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), total score (0 to 3) computed from item scores, lower scores indicated less disability and high-sensitivity C-reactive protein (hsCRP). FAS included all subjects who were randomised in study.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	44.1	21.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 16

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

End point description:

MDA: measured to indicate disease remission based on composite score of 7 domains. Subjects achieved MDA if fulfilled at least 5 of the 7 criteria: tender joint count (0 to 68 joints) <= 1, swollen joint count (0-66 joints) <=1, psoriasis area and severity index (PASI) <=1 (scale 0 [no] to 72 [maximal disease]) or body surface area (BSA) <=3 percent (%); Patient's Global Assessment of Pain <=15 scale 0 (no) to100 (severe pain); Patient's Global Assessment of Disease Activity <=20 scale 0 (very well) to 100 (very poor); Disability Index of the Health Assessment Questionnaire (HAQ-DI) score <=0.5, HAQ-DI score ranged 0 (no difficulty) to 3 (maximum difficulty); Leeds Enthesitis Index score <=1 for subjects with enthesitis at baseline. FAS included all subjects who were randomised in this study.

End point type	Secondary

End point timeframe:

Week 16

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	32.2	12.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24 Among the Subjects with >= 3% Body Surface Area (BSA) Psoriatic Involvement and an Investigator Global Assessment (IGA) Score of >=2 (Mild) at Baseline

End point title	Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24 Among the Subjects with >= 3% Body Surface Area (BSA) Psoriatic Involvement and an Investigator Global Assessment (IGA) Score of >=2 (Mild) at Baseline

End point description:

PASI 90 response was defined as at least a 90% reduction in PASI relative to baseline. PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: head and neck, trunk (including axillae and groin), upper extremities, and lower extremities (included buttocks). Each of these areas was 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 erythema, induration and scaling, each rated on a scale of 0 to 4. The PASI produces a numeric score range from 0 (no psoriasis) to 72 (worst condition). Higher scores indicated more severe disease. Population included all subjects with >=3% BSA and IGA >=2 at baseline.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	13		
Units: Percentage of Subjects				
number (not applicable)	54.5	38.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved PASI 100 Response at Week 24 Among the Subjects with >=3% BSA Psoriatic involvement and an IGA Score of >=2 (Mild) at Baseline

End point title	Percentage of Subjects who Achieved PASI 100 Response at Week 24 Among the Subjects with >=3% BSA Psoriatic involvement and an IGA Score of >=2 (Mild) at Baseline

End point description:

PASI 100 response was defined as at least a 100% reduction in PASI relative to baseline. PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: head and neck, trunk (including axillae and groin), upper extremities, and lower extremities (included buttocks). Each of these areas was 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 erythema, induration and scaling, each rated on a scale of 0 to 4. The PASI produces a numeric score range from 0 (no psoriasis) to 72 (worst condition). Higher scores indicate more severe disease. Population included all subjects with >=3% BSA and IGA >=2 at baseline.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	13		
Units: Percentage of Subjects				
number (not applicable)	31.8	30.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with an IGA-psoriasis Response at Week 24 Among Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (Mild) at Baseline

End point title	Percentage of Subjects with an IGA-psoriasis Response at Week 24 Among Subjects with >=3% BSA Psoriatic Involvement and an IGA Score of >=2 (Mild) at Baseline

End point description:

IGA psoriasis response is defined as an IGA psoriasis score of 0 (cleared) or 1 (minimal) and >=2 grade reduction from baseline in the IGA psoriasis score. The IGA documents the investigator's assessment of the subject’s psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as clear (0), minimal (1), mild (2), moderate (3), and severe (4) scale. The IGA score of psoriasis is based upon the average of induration, erythema, and scaling scores. The subject’s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). The IGA response was defined as a score of 0 (clear) or 1 (almost clear) with at least a 2-category improvement relative to baseline. Population included all subjects with >=3% BSA and IGA >=2 at baseline.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	13		
Units: Percentage of Subjects				
number (not applicable)	54.5	61.5		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Mean change from baseline in HAQ-DI score was a measure of the change in the physical function. It consists of a 20-questions instrument that assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0 = no difficulty to 3= inability to perform a task. Scores on each task are summed and averaged to provide an overall HAQ-DI total score ranging from 0 (least difficulty) to 3 (extreme difficulty). Lower scores were indicated of better functioning. Negative change from baseline indicates improvement of physical function. FAS included all subjects who were randomised in study.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Units on a scale				
least squares mean (confidence interval 90%)	-0.39 (-0.51 to -0.28)	-0.26 (-0.42 to -0.10)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Enthesitis was an important feature of psoriatic arthritis and other spondyloarthropathies. Enthesitis assessed using the Leeds Enthesitis Index (LEI), a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score was a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). A LEI score of 0 at a post baseline visit indicates resolution of enthesitis when baseline LEI >0. Population included all subjects with Enthesitis (LEI>0) at baseline.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	21		
Units: Percentage of Subjects				
number (not applicable)	48.6	52.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Resolution of Dactylitis Response at Week 24 Among the Subjects with Dactylitis at Baseline

End point title	Percentage of Subjects who Achieved Resolution of Dactylitis Response at Week 24 Among the Subjects with Dactylitis at Baseline

End point description:

Dactylitis was characterised by swelling in both hands and feet. The severity of dactylitis is scored on a scale from 0 to 3 (0-no dactylitis, 1-mild dactylitis, 2-moderate dactylitis, and 3-severe dactylitis) for each digit. The results for each digit summed to produce final dactylitis score which is from 0 to 60. Higher score indicates more severe dactylitis. Dactylitis count was derived based on dactylitis score, each score was recorded to 0 or 1 from 0 to 3, where any score >0 was recorded as 1. For resolution of dactylitis, it was defined as subjects who had a dactylitis score greater than 0 at baseline and a score of 0 at the analysis visit. Population included all subjects with Dactylitis at baseline.

End point type	Secondary

End point timeframe:

Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	8		
Units: Percentage of Subjects				
number (not applicable)	61.5	87.5		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SF-36 was a multi-domain instrument with 36 items to evaluate health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health). The scores for the 8 domains were combined into two summary scores: the physical component summary (PCS) score and the mental component summary (MCS) score. Domains 1 to 4 primarily contribute to the PCS score of the SF-36. Domains 5-8 primarily contributes to the MCS score of the SF-36. Each of the 8 domain scores and the component summary score range from 0=worst to 100=best. Higher scores represent better health status. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. FAS included all subjects who were randomised in study.

End point type	Secondary

End point timeframe:

Baseline (Week 0), Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Score on a scale				
least squares mean (confidence interval 90%)	8.84 (6.88 to 10.80)	3.59 (0.92 to 6.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Serious Adverse Events (TESAEs)

End point title	Percentage of Subjects with Treatment-emergent Serious Adverse Events (TESAEs)

End point description:

SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, led to a congenital anomaly/birth defect in the offspring of a subject, or was an important medical event. TESAEs were any SAE occurred at or after the initial administration of study intervention through the day of last dose plus 16 weeks. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	6.8	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point title	Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. TEAEs were any AE occurred at or after the initial administration of study intervention through the day of last dose plus 16 weeks. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	71.2	56.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Reasonably Related Adverse Events (AEs)

End point title	Percentage of Subjects with Reasonably Related Adverse Events (AEs)

End point description:

Percentage of subjects with reasonably related AEs were reported. An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. AE reasonably related to guselkumab or golimumab are AEs classified by the investigator as related to study agent. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	35.6	21.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Infections

End point title	Percentage of Subjects With Infections

End point description:

Percentage of subjects with infections were reported. Investigators evaluate subjects for any signs or symptoms of infection at every scheduled visit. An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	32.2	40.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With AEs Leading to Discontinuation of Study Intervention

End point title	Percentage of Subjects With AEs Leading to Discontinuation of Study Intervention

End point description:

Percentage of subjects with AEs leading to discontinuation of study intervention were reported. AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) to Week 24

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	3.4	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Injection-site Reactions

End point title	Percentage of Subjects With Injection-site Reactions

End point description:

Percentage of subjects with injection-site reaction were reported. A study intervention injection-site reaction was any adverse reaction at a subcutaneous study intervention injection-site. The injection sites were evaluated for reactions, and any injection-site reaction was recorded as an AE. Injection site reactions were significant bruising, erythema, hemorrhage, irritation, pain, and pruritus. The safety analysis set included all subjects who received at least one dose of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	10.2	3.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Golimumab

End point title	Serum Concentration of Golimumab[1]

End point description:

Serum concentration of golimumab was reported. Pharmacokinetics (PK) analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study

intervention and had at least one valid post-injection blood sample drawn for PK analysis. Here, 'n' (number analysed) signifies number of subjects evaluable for specified time points. Result was planned to be reported for the specified arm only.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 12, 16, 20, 24, and 36

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: This endpoint was planned to be analysed for specified arms only.

End point values	Group 1 : Guselkumab Plus Golimumab			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: Micrograms per millilitre				
arithmetic mean (standard deviation)				
Week 0 (n=59)	0.02 (± 0.136)			
Week 4 (n=49)	0.78 (± 1.749)			
Week 8 (n=47)	0.68 (± 0.670)			
Week 12 (n=38)	0.97 (± 2.316)			
Week 16 (n=33)	0.73 (± 0.646)			
Week 20 (n=27)	0.57 (± 0.399)			
Week 24 (n=25)	0.56 (± 0.424)			
Week 36 (n=23)	0.06 (± 0.250)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Guselkumab

End point title	Serum Concentration of Guselkumab

End point description:

Serum concentration of guselkumab was reported. The PK analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had at least one valid post-injection blood sample drawn for PK analysis. Here, 'n' (number analysed) signifies number of subjects evaluable for specified time points.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 12, 16, 20, 24, and 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Micrograms per milliliter				
arithmetic mean (standard deviation)				
Week 0 (n=59, 32)	0.05 (± 0.288)	0.00 (± 0.000)		
Week 4 (n=49, 28)	2.34 (± 1.338)	2.41 (± 1.527)		
Week 8 (n=47, 24)	3.36 (± 2.266)	3.56 (± 2.370)		
Week 12 (n=38, 21)	3.62 (± 2.342)	4.04 (± 2.785)		
Week 16 (n=33, 20)	3.95 (± 2.188)	4.19 (± 2.963)		
Week 20 (n=27, 18)	3.85 (± 2.214)	4.13 (± 2.954)		
Week 24 (n=26,16)	3.96 (± 2.297)	3.64 (± 2.850)		
Week 36 (n=23, 16)	0.95 (± 1.587)	1.00 (± 1.764)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-Guselkumab Antibodies

End point title	Percentage of Subjects with Anti-Guselkumab Antibodies

End point description:

Percentage of subjects with anti-guselkumab antibodies were reported. The immunogenicity analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had appropriate samples for antibodies to guselkumab and golimumab detection.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

End point values	Group 1 : Guselkumab Plus Golimumab	Group 2: Guselkumab Plus Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	32		
Units: Percentage of Subjects				
number (not applicable)	11.9	15.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-Golimumab Antibodies

End point title	Percentage of Subjects with Anti-Golimumab Antibodies[2]

End point description:

Percentage of subjects with anti-golimumab antibodies were reported. The immunogenicity analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had appropriate samples for antibodies to guselkumab and golimumab detection. As planned, results data were analysed and reported for the specified arm for this endpoint.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to Week 36

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: This endpoint was planned to be analysed for specified arms only.

End point values	Group 1 : Guselkumab Plus Golimumab			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: Percentage of Subjects				
number (not applicable)	67.8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: From screening (Week -6) up to Week 36; SAE and non-serious AEs: From baseline (Week 0) up to Week 36

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least one dose of study intervention.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Group 2: Guselkumab Plus Placebo

Reporting group description:

Subjects received SC injection of guselkumab 100 mg and placebo (matched to golimumab) using usingle-use prefilled syringe, once q4w (at Weeks 0, 4, 8, 12, 16, and 20).

Reporting group title	Group 1 : Guselkumab Plus Golimumab

Reporting group description:

Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

Serious adverse events	Group 2: Guselkumab Plus Placebo	Group 1 : Guselkumab Plus Golimumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)	4 / 59 (6.78%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neuroendocrine Tumour			
subjects affected / exposed	0 / 32 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 32 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Covid-19			

subjects affected / exposed	0 / 32 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Mycoplasmal			
subjects affected / exposed	0 / 32 (0.00%)	1 / 59 (1.69%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 2: Guselkumab Plus Placebo	Group 1 : Guselkumab Plus Golimumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 32 (31.25%)	25 / 59 (42.37%)	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 32 (3.13%)	7 / 59 (11.86%)	
occurrences (all)	1	7	
General disorders and administration site conditions			
Injection Site Reaction			
subjects affected / exposed	0 / 32 (0.00%)	3 / 59 (5.08%)	
occurrences (all)	0	4	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 32 (0.00%)	4 / 59 (6.78%)	
occurrences (all)	0	4	
Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)	7 / 59 (11.86%)	
occurrences (all)	0	10	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 32 (0.00%)	4 / 59 (6.78%)	
occurrences (all)	0	4	
Psoriatic Arthropathy			

subjects affected / exposed	0 / 32 (0.00%)	5 / 59 (8.47%)	
occurrences (all)	0	5	
Infections and infestations			
Oral Candidiasis			
subjects affected / exposed	2 / 32 (6.25%)	0 / 59 (0.00%)	
occurrences (all)	2	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 32 (6.25%)	3 / 59 (5.08%)	
occurrences (all)	2	3	
Urinary Tract Infection			
subjects affected / exposed	2 / 32 (6.25%)	0 / 59 (0.00%)	
occurrences (all)	2	0	
Influenza			
subjects affected / exposed	2 / 32 (6.25%)	2 / 59 (3.39%)	
occurrences (all)	2	2	
Covid-19			
subjects affected / exposed	2 / 32 (6.25%)	5 / 59 (8.47%)	
occurrences (all)	2	5	
Nasopharyngitis			
subjects affected / exposed	3 / 32 (9.38%)	5 / 59 (8.47%)	
occurrences (all)	3	7	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 October 2021	The purpose of this amendment was to address health authority feedback regarding washout periods for prohibited medications, provide further clarification on recurrent or chronic serious infections, testing for antibodies to both golimumab and guselkumab, and gadolinium administration.
19 August 2022	The purpose of this amendment was to proposed changes to the protocol, including changes to inclusion and exclusion criteria to facilitate recruitment of subjects and to ensure a broader and more representative population was included in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported