Clinical trial results:
A Phase 3b, Multicenter, Interventional, Randomized, Placebo-controlled Study Investigating the Efficacy and Safety of Guselkumab for the Treatment of Palmoplantar non-Pustular Psoriasis

Summary

EudraCT number	2018-003206-58
Trial protocol	FR DE ES GB IT
Global end of trial date	30 November 2021

Results information

Result version number	v1 (current)
This version publication date	16 December 2022
First version publication date	16 December 2022

Trial information

Trial identification

Sponsor protocol code	CNTO1959PSO3013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03998683
WHO universal trial number (UTN)	-
Other trial identifiers	G-PLUS: CR108611

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International N.V
Sponsor organisation address	30, Turnhoutseweg, Belgium, 2340
Public contact	Clinical Registry Group, Janssen-Cilag International N.V, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International N.V, 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	30 November 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the efficacy of guselkumab for the treatment of palmoplantar non-pustular 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.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2019
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	Germany: 66
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	France: 10
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	Italy: 17
Worldwide total number of subjects	117
EEA total number of subjects	109

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)	104

From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 146 subjects were screened, of whom 29 subjects were screen failures. A total of 117 subjects were enrolled and treated in this study.

Period 1

Period 1 title	PHASE IIIB TRIAL (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received a single subcutaneous (SC) injection of placebo matched to guselkumab at Weeks 0, 4, and 12, and guselkumab 100 milligrams (mg) SC injections at Weeks 16, 20, 28, 36, and 44.

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

Dosage and administration details:

Single SC injection of guselkumab 100 mg at Weeks 16, 20, 28, 36 and 44.

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

Dosage and administration details:

Single SC injection of placebo matched to guselkumab at Weeks 0, 4 and 12.

Arm title	Guselkumab

Arm description:

Subjects received a single subcutaneous (SC) injection of guselkumab 100 milligrams (mg) at Weeks 0, 4, 12, 20, 28, 36, and 44 and placebo injection matched to guselkumab at Week 16.

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:

Single SC injection of placebo matched to guselkumab at Week 16.

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

Dosage and administration details:

Single SC injection of guselkumab 100 mg at Weeks 0, 4, 12, 20, 28, 36 and 44.

Number of subjects in period 1	Placebo	Guselkumab
Started	39	78
Completed	31	66
Not completed	8	12
Consent withdrawn by subject	3	3
Initiated prohibited medication	2	-
Adverse event, non-fatal	-	2
Adverse event, serious non-fatal	-	1
Unspecified	-	2
Lost to follow-up	1	2
Initiated rescue medication	1	-
Lack of efficacy	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received a single subcutaneous (SC) injection of placebo matched to guselkumab at Weeks 0, 4, and 12, and guselkumab 100 milligrams (mg) SC injections at Weeks 16, 20, 28, 36, and 44.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects received a single subcutaneous (SC) injection of guselkumab 100 milligrams (mg) at Weeks 0, 4, 12, 20, 28, 36, and 44 and placebo injection matched to guselkumab at Week 16.	

Reporting group values	Placebo	Guselkumab	Total
Number of subjects	39	78	117
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	35	69	104
From 65 to 84 years	4	9	13
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	47.8	51.6	
standard deviation	± 13.14	± 13.27	-
Title for Gender Units: subjects			
Female	15	42	57
Male	24	36	60

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received a single subcutaneous (SC) injection of placebo matched to guselkumab at Weeks 0, 4, and 12, and guselkumab 100 milligrams (mg) SC injections at Weeks 16, 20, 28, 36, and 44.	
Reporting group title	Guselkumab
Reporting group description:	
Subjects received a single subcutaneous (SC) injection of guselkumab 100 milligrams (mg) at Weeks 0, 4, 12, 20, 28, 36, and 44 and placebo injection matched to guselkumab at Week 16.	

Primary: Percentage of Subjects who Achieved Palmoplantar Psoriasis Area and Severity Index (ppPASI75) Response at Week 16

End point title	Percentage of Subjects who Achieved Palmoplantar Psoriasis Area and Severity Index (ppPASI75) Response at Week 16
End point description:	
ppPASI75 response was defined as improvement of greater than or equal to (>=) 75 percent (%) in ppPASI score from baseline. ppPASI: assessment tool based on PASI to assess severity of 3 symptoms - erythema, pustules/ induration, desquamation/ scale on palms or soles, each on a scale from 0 (none) to 4 (very severe), where higher score indicated more severe disease. Considering non-pustular palmoplantar disease, the score of pustules was set to '0' and thus the ppPASI75 total score was sum of sub-scores (erythema and desquamation) which ranged from 0 to 48, where higher score indicated more severe disease. Full analysis set included all randomised subjects who received at least 1 dose of study intervention and were analysed according to randomised treatment group, regardless of intervention they actually received.	
End point type	Primary
End point timeframe:	
From baseline up to Week 16	

End point values	Placebo	Guselkumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	78		
Units: percentage of subjects				
number (not applicable)	28.2	35.9		

Statistical analyses

Statistical analysis title	Guselkumab versus Placebo
Statistical analysis description:	
Difference in rates between guselkumab and placebo	
Comparison groups	Placebo v Guselkumab

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.533 [1]
Method	Fisher exact
Parameter estimate	Guselkumab&placebo:Percentage difference
Point estimate	7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.5
upper limit	24.7

Notes:

[1] - The threshold for statistical significance was 0.05 level.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 56

Adverse event reporting additional description:

The safety analysis set included all subjects who received one dose of study intervention and completed at least 1 follow-up safety assessment. Subjects were analysed according to the intervention they actually received.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Guselkumab

Reporting group description:

Subjects received Guselkumab 100 mg subcutaneous (SC) injections at Weeks 0, 4, 12, 20, 28, 36, and 44 and placebo injection at Week 16.

Reporting group title	Placebo

Reporting group description:

Subjects received placebo subcutaneous (SC) injections at Weeks 0, 4 and 12, and guselkumab 100 mg SC injections at Weeks 16, 20, 28, 36, and 44

Serious adverse events	Guselkumab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 78 (6.41%)	2 / 39 (5.13%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Humerus Fracture			
subjects affected / exposed	1 / 78 (1.28%)	0 / 39 (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			
Pyrexia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Duodenal Ulcer Haemorrhage			

subjects affected / exposed	0 / 78 (0.00%)	1 / 39 (2.56%)	
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			
Organising Pneumonia			
subjects affected / exposed	1 / 78 (1.28%)	0 / 39 (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			
Osteoarthritis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 39 (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			
Viral Pharyngitis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	1 / 78 (1.28%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 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	Guselkumab	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 78 (50.00%)	10 / 39 (25.64%)	
Investigations			
C-Reactive Protein Increased			
subjects affected / exposed	0 / 78 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	2	
Vascular disorders			

Hypertension			
subjects affected / exposed	5 / 78 (6.41%)	0 / 39 (0.00%)	
occurrences (all)	5	0	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 78 (7.69%)	4 / 39 (10.26%)	
occurrences (all)	8	5	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 78 (6.41%)	0 / 39 (0.00%)	
occurrences (all)	5	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 78 (7.69%)	1 / 39 (2.56%)	
occurrences (all)	8	1	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	4 / 78 (5.13%)	0 / 39 (0.00%)	
occurrences (all)	4	0	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	3 / 78 (3.85%)	3 / 39 (7.69%)	
occurrences (all)	5	4	
Arthralgia			
subjects affected / exposed	7 / 78 (8.97%)	0 / 39 (0.00%)	
occurrences (all)	8	0	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	15 / 78 (19.23%)	3 / 39 (7.69%)	
occurrences (all)	21	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 July 2019	This amendment was created to provide further clarification on the inclusion, exclusion and withdrawal criteria to provide specificity on the subjects to be included in this study. The frequency of visits for tests and data collection was changed.
22 April 2020	This amendment was created to incorporate the following changes: The Coronavirus Disease 2019 (COVID-19) pandemic might have an impact on the conduct of this clinical study. In alignment with recent health authority guidance, the sponsor was providing options for study-related subject management in the event of disruption to the conduct of the study.
18 June 2020	This amendment was created to incorporate the following changes: to revise the sample size of the study. In addition, a COVID-19 pandemic-related exclusion criterion was added, and the guidance for the reporting of adverse events was updated to include combination products.
16 July 2020	This amendment was created to clarify that subjects who received prior systemic treatment with JAK inhibitors would be excluded from the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported