Clinical trial results:
A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Oral Tablet Formulation of JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2021-005987-23
Trial protocol	FR ES
Global end of trial date	11 April 2023

Results information

Result version number	v1 (current)
This version publication date	25 April 2024
First version publication date	25 April 2024

Trial information

Trial identification

Sponsor protocol code	77242113PSO2003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05357755
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202, South Raritan, New Jersey, United States, 08869
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	18 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 April 2023
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 an oral tablet formulation of JNJ-77242113 compared with placebo in subjects with moderate-to-severe plaque 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	13 June 2022
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	Canada: 13
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Poland: 21
Country: Number of subjects enrolled	United States: 34
Worldwide total number of subjects	89
EEA total number of subjects	42

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)	84
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 118 subjects were screened, out of which 28 subjects were screen failure. A total of 90 subjects were randomised, out of which 1 subject was inadvertently randomised but never treated. Hence, 89 subjects started the study and received study treatment.

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	Placebo

Arm description:

Subjects with moderate to severe plaque psoriasis, received placebo delayed release tablet orally matching to JNJ-77242113 to maintain the blind once daily (QD) from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

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

Dosage and administration details:

Subjects received placebo delayed release tablet once daily.

Arm title	JNJ-77242113 10 mg QD

Arm description:

Subjects with moderate to severe plaque psoriasis, received 10 milligrams (mg) of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

Arm type	Experimental
Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 10 mg delayed release tablet once daily.

Arm title	JNJ-77242113 50 mg QD

Arm description:

Subjects with moderate to severe plaque psoriasis, received 50 mg of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

Arm type	Experimental

Investigational medicinal product name	JNJ-77242113
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received JNJ-77242113 50 mg delayed release tablet once daily.

Number of subjects in period 1	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD
Started	24	31	34
Completed	15	22	32
Not completed	9	9	2
Consent withdrawn by subject	7	6	1
Unspecified	1	2	-
Lost to follow-up	1	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received placebo delayed release tablet orally matching to JNJ-77242113 to maintain the blind once daily (QD) from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	
Reporting group title	JNJ-77242113 10 mg QD
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received 10 milligrams (mg) of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	
Reporting group title	JNJ-77242113 50 mg QD
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received 50 mg of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	

Reporting group values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD
Number of subjects	24	31	34
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	30	31
From 65 to 84 years	1	1	3
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	41.2	41.2	42.2
standard deviation	± 12.78	± 12.36	± 15.06
Title for Gender Units: subjects			
Female	8	8	12
Male	16	23	22
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	2
Black or African American	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	21	27	30
More than one race	0	0	1
Unknown or Not Reported	2	2	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	1	5
Not Hispanic or Latino	20	29	29
Unknown or Not Reported	0	1	0

Region of Enrollment Units: Subjects			
Canada	2	4	7
France	1	2	2
Germany	5	3	4
Poland	5	11	5
Spain	1	1	2
United States	10	10	14

Reporting group values	Total		
Number of subjects	89		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	84		
From 65 to 84 years	5		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	28		
Male	61		
Race Units: Subjects			
American Indian or Alaska Native	0		
Asian	4		
Black or African American	2		
Native Hawaiian or Other Pacific Islander	0		
White	78		
More than one race	1		
Unknown or Not Reported	4		
Ethnicity Units: Subjects			
Hispanic or Latino	10		
Not Hispanic or Latino	78		
Unknown or Not Reported	1		
Region of Enrollment Units: Subjects			
Canada	13		
France	5		
Germany	12		
Poland	21		
Spain	4		
United States	34		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received placebo delayed release tablet orally matching to JNJ-77242113 to maintain the blind once daily (QD) from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	
Reporting group title	JNJ-77242113 10 mg QD
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received 10 milligrams (mg) of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	
Reporting group title	JNJ-77242113 50 mg QD
Reporting group description:	
Subjects with moderate to severe plaque psoriasis, received 50 mg of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.	

Primary: Percentages of Subjects who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index Score (PASI 75) at Week 16

End point title	Percentages of Subjects who Achieved at Least 75 Percent (%) Improvement From Baseline in Psoriasis Area and Severity Index Score (PASI 75) at Week 16
End point description:	
Percentages of subjects who achieved PASI 75 (greater than or equal to [>=] 75% improvement from baseline in PASI) at Week 16 were reported. PASI score: used for assessing and grading the severity of psoriatic lesions and their response to therapy. To calculate PASI scores, the body was divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1=slight, 2=moderate, 3=severe, 4=very severe) and extent of involvement from 0 (no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. Baseline: the closest measurement taken prior to or at the time of first study intervention administration date. Full analysis set (FAS): all randomised subjects who took at least 1 dose of study intervention.	
End point type	Primary
End point timeframe:	
Baseline, Week 16	

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Percentage of subjects				
number (not applicable)	4.2	41.9	73.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 1
Comparison groups	JNJ-77242113 10 mg QD v Placebo
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Secondary: Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) is 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. TEAE was defined as any adverse event that occurs at or after the initial administration of study intervention. The baseline measurement was defined as the closest measurement taken prior to or at the time of the first study intervention administration date. Data included all TEAEs (both serious and non-serious). The safety analysis set included all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Subjects	14	13	20	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects who Achieved at Least 90% Improvement From Baseline in PASI Score (PASI 90) at Week 16

End point title	Percentages of Subjects who Achieved at Least 90% Improvement From Baseline in PASI Score (PASI 90) at Week 16

End point description:

Percentages of subjects who achieved PASI 90 (>=90% improvement from baseline in PASI) at Week 16 were reported. The PASI score used for assessing and grading the severity of psoriatic lesions and their response to therapy. To calculate PASI scores, the body was divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1=slight, 2=moderate, 3=severe and 4=very severe) and extent of involvement from 0 (no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. The baseline was defined as the closest measurement taken prior to or at the time of first study intervention administration date. FAS: all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Percentage of subjects				
number (not applicable)	0	25.8	52.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 6
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 5
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Cochran-Mantel-Haenszel

Secondary: Number of Subjects With Serious TEAEs

End point title	Number of Subjects With Serious TEAEs

End point description:

An AE is 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. A serious adverse event (SAE) is any untoward medical occurrence at any dose that: results in death, is life threatening, require inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or results in congenital anomaly/birth defect. TEAE was defined as any adverse event that occurs at or after the initial administration of study intervention. The baseline measurement was defined as the closest measurement taken prior to or at the time of the first study intervention administration date. The safety analysis set included all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

From baseline (Week 0) up to 4 weeks after last dose of study drug (up to 20 weeks)

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Subjects	0	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Total Score at Week 16

End point title	Change From Baseline in PASI Total Score at Week 16

End point description:

Change from baseline in PASI total score at Week 16 was reported. PASI score: used for assessing and grading the severity of psoriatic lesions and their response to therapy. In PASI scores, the body was divided into 4 regions: head, trunk, upper extremities and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1=slight, 2=moderate, 3=severe, 4=very severe) and extent of involvement from 0 (no involvement) to 6 (90% - 100% involvement). PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. Baseline was defined as the closest measurement taken prior to or at the time of first study agent administration date. FAS: all randomised subjects who took at least 1 dose of study intervention. Here, 'N' (number of subjects analysed)= number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	25	33	
Units: Units on a score				
arithmetic mean (standard deviation)	-4.30 (± 6.105)	-11.56 (± 9.425)	-16.84 (± 8.278)	

Statistical analyses

Statistical analysis title	Statistical Analysis 4
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	Statistical Analysis 3
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis

Secondary: Percentages of Subjects who Achieved 100% Improvement From Baseline in PASI Score (PASI 100) at Week 16

End point title	Percentages of Subjects who Achieved 100% Improvement From Baseline in PASI Score (PASI 100) at Week 16

End point description:

Percentages of subjects who achieved PASI 100 (100% improvement from baseline in PASI) at Week 16 were reported. The PASI score, used for assessing and grading the severity of psoriatic lesions and their response to therapy. To calculate PASI scores, the body was divided into 4 regions: head, trunk, upper extremities, and lower extremities. Each of these areas was assessed and scored separately for erythema, induration, and scaling, which were each rated on a scale of 0 to 4 (0=none, 1=slight, 2=moderate, 3=severe and 4=very severe) and extent of involvement from 0 (no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated greater severity of psoriasis. The baseline was defined as the closest measurement taken prior to or at the time of first study intervention administration date. FAS included all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Percentage of subjects				
number (not applicable)	0	9.7	23.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 8
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.011
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 7
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.125
Method	Cochran-Mantel-Haenszel

Secondary: Percentages of Subjects who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

End point title	Percentages of Subjects who Achieved an Investigator Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at Week 16

End point description:

Percentages of subjects who achieved an IGA score of cleared (0) or minimal (1) at Week 16 was reported. The IGA documented 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 cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. The FAS included all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Percentage of subjects				
number (not applicable)	4.2	41.9	73.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 10
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 9
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Cochran-Mantel-Haenszel

Secondary: Percent Change From Baseline in Psoriasis-Affected Body Surface Area (BSA) at Week 16

End point title	Percent Change From Baseline in Psoriasis-Affected Body Surface Area (BSA) at Week 16

End point description:

Percent change from baseline in psoriasis-affected BSA at Week 16 was reported. BSA was commonly used measure of severity of skin disease. It was defined as the percentage of surface area of the body involved with the condition being assessed, (that is, plaque psoriasis). BSA was assessed using handprint method where the surface area of the subject’s hand including the palm and all 5 digits was used as a guide to estimate 1% BSA. Psoriasis affected BSA under 5% suggests mild psoriasis, a BSA of 5% to 10% is considered moderate, and an involved BSA of over 10% indicates severe psoriasis. The baseline measurement was defined as the closest measurement taken prior to or at the time of the first study intervention administration date. The FAS included all randomised subjects who took at least 1 dose of study intervention. Here, 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	21	25	33	
Units: Percent change				
arithmetic mean (standard deviation)	-0.9 (± 8.26)	-14.9 (± 15.09)	-20.1 (± 12.63)	

Statistical analyses

Statistical analysis title	Statistical Analysis 14
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Statistical analysis title	Statistical Analysis 13
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Percentages of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16

End point title	Percentages of Subjects Who Achieved an IGA Score of Cleared (0) at Week 16

End point description:

Percentages of subjects who achieved an IGA score of cleared (0) at Week 16 was reported. The IGA documented 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 cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Higher score indicated more severe disease. The FAS included all randomised subjects who took at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	JNJ-77242113 10 mg QD	JNJ-77242113 50 mg QD	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	31	34	
Units: Percentage of subjects				
number (not applicable)	0	12.9	29.4	

Statistical analyses

Statistical analysis title	Statistical Analysis 12
Comparison groups	Placebo v JNJ-77242113 50 mg QD
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical Analysis 11
Comparison groups	Placebo v JNJ-77242113 10 mg QD
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.071
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All cause mortality: From screening up to 4 weeks after last dose of study drug (up to Week 24); Serious AEs and non-serious AEs: From baseline (Week 0) up to 4 weeks after last dose of study drug (up to Week 20)

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who took at least 1 dose of study intervention.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects with moderate to severe plaque psoriasis, received placebo delayed release tablet orally matching to JNJ-77242113 to maintain the blind once daily (QD) from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

Reporting group title	JNJ-77242113 50 mg QD

Reporting group description:

Subjects with moderate to severe plaque psoriasis, received 50 mg of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

Reporting group title	JNJ-77242113 10 mg QD

Reporting group description:

Subjects with moderate to severe plaque psoriasis, received 10 milligrams (mg) of JNJ-77242113 delayed release tablet, orally QD from Week 0 through Week 16. Subjects were then followed up for safety up to 4 weeks after the last dose.

Serious adverse events	Placebo	JNJ-77242113 50 mg QD	JNJ-77242113 10 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	2 / 34 (5.88%)	0 / 31 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Radius Fracture			
subjects affected / exposed	0 / 24 (0.00%)	1 / 34 (2.94%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	0 / 24 (0.00%)	1 / 34 (2.94%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	JNJ-77242113 50 mg QD	JNJ-77242113 10 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 24 (41.67%)	11 / 34 (32.35%)	7 / 31 (22.58%)
Investigations			
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 34 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	3
Blood Glucose Increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 34 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 34 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 24 (0.00%)	2 / 34 (5.88%)	0 / 31 (0.00%)
occurrences (all)	0	3	0
General disorders and administration site conditions			
Influenza Like Illness			
subjects affected / exposed	0 / 24 (0.00%)	2 / 34 (5.88%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	2 / 24 (8.33%)	1 / 34 (2.94%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 24 (0.00%)	2 / 34 (5.88%)	0 / 31 (0.00%)
occurrences (all)	0	2	0

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 24 (8.33%)	1 / 34 (2.94%)	1 / 31 (3.23%)
occurrences (all)	2	1	1
Covid-19			
subjects affected / exposed	0 / 24 (0.00%)	3 / 34 (8.82%)	0 / 31 (0.00%)
occurrences (all)	0	3	0
Urinary Tract Infection			
subjects affected / exposed	2 / 24 (8.33%)	0 / 34 (0.00%)	1 / 31 (3.23%)
occurrences (all)	2	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 24 (16.67%)	2 / 34 (5.88%)	1 / 31 (3.23%)
occurrences (all)	5	5	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported