Clinical trial results:
A Phase 2b Multicenter, Long-Term Extension, Dose-ranging Study to Evaluate the Efficacy and Safety of JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis

Summary

EudraCT number	2021-004320-16
Trial protocol	DE ES PL
Global end of trial date	29 September 2023

Results information

Result version number	v1 (current)
This version publication date	11 October 2024
First version publication date	11 October 2024

Trial information

Trial identification

Sponsor protocol code	77242113PSO2002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05364554
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 US Highway, Raritan, 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	29 September 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 September 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 long-term clinical response of JNJ-77242113 treatment 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 Practice and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 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: 34
Country: Number of subjects enrolled	Germany: 38
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Japan: 19
Country: Number of subjects enrolled	Korea, Republic of: 11
Country: Number of subjects enrolled	Poland: 57
Country: Number of subjects enrolled	Taiwan: 13
Country: Number of subjects enrolled	United States: 39
Worldwide total number of subjects	227
EEA total number of subjects	108

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)	212
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 227 subjects entered study 77242113PSO2002 (long-term extension, LTE) after completing originating study 77242113PSO2001 (EudraCT: 2021-003700-41) Week (W) 16. Pre protocol, data collected from W0 (originating study) through W52 (LTE W36) and from W16 (LTE W0) through W56 (LTE W40) were analysed for efficacy and safety, respectively.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Then JNJ-77242113 100 mg QD

Arm description:

Subjects originally randomised to placebo in originating study (77242113PSO2001) received orally once daily (QD) dose of JNJ-77242113 100 milligrams (mg) tablet in the morning from Week 0 through Week 36 in this LTE study.

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 originally randomised to placebo in originating study (77242113PSO2001) received JNJ-77242113 100 mg tablet QD from Week 0 through Week 36 in this LTE study.

Arm title	JNJ-77242113 25 mg QD

Arm description:

Subjects received orally QD dose of JNJ-77242113 25 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

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 25 mg QD in the morning from Week 0 through Week 36.

Arm title	JNJ-77242113 50 mg QD

Arm description:

Subjects received orally QD dose of JNJ-77242113 50 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

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 (2 tablets of 25 mg) QD in the morning from Week 0 through Week 36.

Arm title	JNJ-77242113 25 mg BID

Arm description:

Subjects received orally twice daily (BID; morning and evening) dose of JNJ-77242113 25 mg tablet from Week 0 through Week 36 in this LTE study.

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 25 mg BID (morning and evening) from Week 0 through Week 36.

Arm title	JNJ-77242113 100 mg QD

Arm description:

Subjects received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

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 100 mg QD in the morning from Week 0 through Week 36.

Arm title	JNJ-77242113 100 mg BID

Arm description:

Subjects received orally BID (morning and evening) dose of JNJ-77242113 100 mg tablet from Week 0 through Week 36 in this LTE study.

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 100 mg BID (morning and evening) from Week 0 through Week 36.

Number of subjects in period 1	Placebo Then JNJ-77242113 100 mg QD	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD
Started	35	35	39
Completed	29	27	33
Not completed	6	8	6
Unspecified	1	2	2
Lost to follow-up	-	2	1
Withdrawal by subject	5	4	3

Number of subjects in period 1	JNJ-77242113 25 mg BID	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID
Started	40	40	38
Completed	30	33	35
Not completed	10	7	3
Unspecified	1	2	1
Lost to follow-up	2	1	1
Withdrawal by subject	7	4	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo Then JNJ-77242113 100 mg QD
Reporting group description:	
Subjects originally randomised to placebo in originating study (77242113PSO2001) received orally once daily (QD) dose of JNJ-77242113 100 milligrams (mg) tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 25 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 25 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 50 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 50 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 25 mg BID
Reporting group description:	
Subjects received orally twice daily (BID; morning and evening) dose of JNJ-77242113 25 mg tablet from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 100 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 100 mg BID
Reporting group description:	
Subjects received orally BID (morning and evening) dose of JNJ-77242113 100 mg tablet from Week 0 through Week 36 in this LTE study.	

Reporting group values	Placebo Then JNJ-77242113 100 mg QD	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD
Number of subjects	35	35	39
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	31	34	38
From 65 to 84 years	4	1	1
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	44.3	45.1	44.6
standard deviation	± 13.96	± 12.43	± 9.51
Title for Gender Units: subjects			
Female	15	9	15
Male	20	26	24

Reporting group values	JNJ-77242113 25 mg BID	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID
Number of subjects	40	40	38

Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	36	37	36
From 65 to 84 years	4	3	2
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	46.1	43.8	41.6
standard deviation	± 11.75	± 14.03	± 11.71
Title for Gender Units: subjects			
Female	11	10	11
Male	29	30	27

Reporting group values	Total		
Number of subjects	227		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	212		
From 65 to 84 years	15		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	71		
Male	156		

End points

End points reporting groups

Reporting group title	Placebo Then JNJ-77242113 100 mg QD
Reporting group description:	
Subjects originally randomised to placebo in originating study (77242113PSO2001) received orally once daily (QD) dose of JNJ-77242113 100 milligrams (mg) tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 25 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 25 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 50 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 50 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 25 mg BID
Reporting group description:	
Subjects received orally twice daily (BID; morning and evening) dose of JNJ-77242113 25 mg tablet from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 100 mg QD
Reporting group description:	
Subjects received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Reporting group title	JNJ-77242113 100 mg BID
Reporting group description:	
Subjects received orally BID (morning and evening) dose of JNJ-77242113 100 mg tablet from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects originally randomised to placebo in originating study (77242113PSO2001) received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	JNJ-77242113 25 mg QD
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects received orally QD dose of JNJ-77242113 25 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	JNJ-77242113 50 mg QD
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects received orally QD dose of JNJ-77242113 50 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	JNJ-77242113 25 mg Twice Daily (BID)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects received orally twice daily (BID; morning and evening) dose of JNJ-77242113 25 mg tablet from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	JNJ-77242113 100 mg QD
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.	
Subject analysis set title	JNJ-77242113 100 mg BID

Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received orally BID (morning and evening) dose of JNJ-77242113 100 mg tablet from Week 0 through Week 36 in this LTE study.

Primary: Percentage of Subjects Who Achieved Greater Than or Equal to (>=) 75 Percent (%) Improvement From Baseline in Psoriasis Area Severity Index (PASI) Score (PASI-75) at LTE Week 36

End point title	Percentage of Subjects Who Achieved Greater Than or Equal to (>=) 75 Percent (%) Improvement From Baseline in Psoriasis Area Severity Index (PASI) Score (PASI-75) at LTE Week 36[1]

End point description:

The 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: 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 scale of 0 to 4 (0=none, 1 = slight, 2 = moderate, 3 = severe and 4 = very severe) and extent of involvement on scale of 0 (no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric score that could range from 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated more severe disease. Full analysis set (FAS) included randomised subjects who received at least one dose of study intervention in the originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113, and subjects who crossed over and received JNJ-77242113 for subjects initially randomised to placebo.

End point type	Primary

End point timeframe:

LTE Week 36

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	43	41
Units: Percentage of subjects				
number (not applicable)	65.7	48.8	69.8	58.5

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	65.1	76.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved at Least 90% Improvement From

Baseline in PASI Score (PASI-90) at LTE Week 36

End point title	Percentage of Subjects Who Achieved at Least 90% Improvement From Baseline in PASI Score (PASI-90) at LTE Week 36

End point description:

The 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: 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 (indicated no involvement) to 6 (90% - 100% involvement). The PASI produced a numeric total score that could range on a scale of 0 (no psoriasis) to 72 (maximum psoriasis). Higher score indicated more severe disease. FAS: subjects who received at least one dose of study intervention in the originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo.

End point type	Secondary

End point timeframe:

LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	43	41
Units: Percentage of subjects				
number (not applicable)	57.1	27.9	41.9	36.6

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	51.2	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved 100% Improvement From Baseline in PASI Score (PASI-100) at LTE Week 36

End point title	Percentage of Subjects Who Achieved 100% Improvement From Baseline in PASI Score (PASI-100) at LTE Week 36

End point description:

The 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 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 on a scale of 0 (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. The PASI produces a numeric score that can range from 0 (no psoriasis) to 72. Subjects with 100% improvement in PASI from baseline were considered PASI 100 responders. Higher score indicated more severe disease. FAS: subjects who received at least one dose of study intervention in the originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo.

End point type	Secondary

End point timeframe:

LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	43	41
Units: Percentage of subjects				
number (not applicable)	34.3	14.0	20.9	17.1

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	25.6	40.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PASI Total Score at LTE Week 36

End point title	Change From Baseline in PASI Total Score at LTE Week 36

End point description:

The 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, trunk, upper extremities, and lower extremities. Each of these areas were assessed and scored separately for erythema, induration, and scaling, which were 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 (indicated 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 more severe disease. FAS: who received at least one dose of study intervention in the originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo. N (number of subjects analysed) referred to the number of subjects evaluable for this endpoint

End point type	Secondary

End point timeframe:

Baseline (Week 0 of originating study), LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34	34	40	36
Units: Units on a scale				
arithmetic mean (standard deviation)	-14.15 (± 8.068)	-13.55 (± 8.232)	-14.45 (± 6.878)	-13.24 (± 8.981)

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	35		
Units: Units on a scale				
arithmetic mean (standard deviation)	-15.81 (± 8.908)	-18.46 (± 7.892)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at LTE Week 36

End point title	Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) at LTE Week 36

End point description:

Percentage of subjects who achieved an IGA score of cleared (0) or minimal (1) at LTE Week 36 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. FAS: who received at least one dose of study intervention in the originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and subjects who crossed over and received JNJ-77242113 initially randomised to placebo.

End point type	Secondary

End point timeframe:

LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	43	41
Units: Percentage of subjects				
number (not applicable)	65.7	37.2	60.5	46.3

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	60.5	73.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at LTE Week 36

End point title	Change From Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores at LTE Week 36

End point description:

PSSD, patient-reported outcome questionnaire aimed to measure severity of psoriasis symptoms and signs for treatment benefit assessment. PSSD questionnaire included 11 items:symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding/flaking, redness and bleeding) using 0 to 10 numerical ratings. Each item severity was rated on 11-point numeric scale ranged from 0(absent) to 10(worst imaginable). Symptom score:by averaging 5 questions and multiplying by 10. PSSD symptom score ranged from 0 to 100, derived from average of symptom scores, where 0=least severe symptom; 100=most severe disease. Higher score=more severe symptom. FAS:who received at least 1 dose of study intervention in originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo. N (number of subjects analysed)=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of originating study), LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34	34	40	36
Units: Units on a scale				
arithmetic mean (standard deviation)	-29.5 (±	-30.1 (±	-35.2 (±	-31.2 (±

	25.59)	28.09)	30.81)	28.48)

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	36		
Units: Units on a scale				
arithmetic mean (standard deviation)	-29.4 (± 27.41)	-47.7 (± 28.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in PSSD Signs Score at LTE Week 36

End point title	Change From Baseline in PSSD Signs Score at LTE Week 36

End point description:

PSSD, patient-reported outcome questionnaire aimed to measure severity of psoriasis symptoms and signs for treatment benefit assessment. PSSD questionnaire included 11 items:symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding/flaking, redness and bleeding) using 0 to 10 numerical ratings. Each item severity was rated on 11-point numeric scale ranged from 0(absent) to 10(worst imaginable). Symptom score:by averaging 5 questions and multiplying by 10. PSSD symptom score ranged from 0 to 100, derived from average of symptom scores, where 0=least severe symptom; 100=most severe disease. Higher score=more severe symptom. FAS:who received at least 1 dose of study intervention in originating study (77242113PSO2001) for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo. N (number of subjects analysed)=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of originating study), LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34	34	40	36
Units: Units on a scale				
arithmetic mean (standard deviation)	-42.8 (± 28.65)	-35.2 (± 29.02)	-39.2 (± 31.64)	-36.6 (± 29.16)

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	35	36		
Units: Units on a scale				
arithmetic mean (standard deviation)	-43.1 (± 26.87)	-53.1 (± 22.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PSSD Symptoms Score Equal (=)0 at LTE Week 36 Among Subjects With a Baseline (Week 0 of the Originating Study) Symptoms Score >=1

End point title	Percentage of Subjects Who Achieved PSSD Symptoms Score Equal (=)0 at LTE Week 36 Among Subjects With a Baseline (Week 0 of the Originating Study) Symptoms Score >=1

End point description:

PSSD, patient-reported outcome questionnaire aimed to measure severity of psoriasis symptoms and signs for treatment benefit assessment. PSSD questionnaire included 11 items:symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding/flaking, redness and bleeding) using 0 to 10 numerical ratings. Each item severity was rated on 11-point numeric scale: 0(absent) to 10(worst imaginable). Symptom score:by averaging 5 questions and multiplying by 10. PSSD symptom score ranged from 0 to 100,(0=least severe symptom; 100=most severe disease). Higher score=more severe symptom. Analysis population included subjects with baseline PSSD symptom score >=1. FAS:who received at least 1 dose of study intervention in originating study for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo.N (number of subjects analysed)=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of the Originating Study), LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	42	41
Units: Percentage of subjects				
number (not applicable)	34.3	18.6	21.4	17.1

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	30.2	26.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving PSSD Signs Score=0 at Week 36 Among Subjects With a Baseline (Week 0 of the Originating Study) Signs Score >=1

End point title	Percentage of Subjects Achieving PSSD Signs Score=0 at Week 36 Among Subjects With a Baseline (Week 0 of the Originating Study) Signs Score >=1

End point description:

PSSD, patient-reported outcome questionnaire aimed to measure severity of psoriasis symptoms and signs for treatment benefit assessment. PSSD questionnaire included 11 items:symptoms (itch, pain, stinging, burning and skin tightness) and subject observable signs (skin dryness, cracking, scaling, shedding/flaking, redness and bleeding) using 0 to 10 numerical ratings. Each item severity was rated on 11-point numeric scale: 0(absent) to 10(worst imaginable). Symptom score:by averaging 5 questions and multiplying by 10. PSSD symptom score ranged from 0 to 100,(0=least severe symptom; 100=most severe disease). Higher score=more severe symptom. Analysis population included subjects with baseline PSSD sign score >=1. FAS:who received at least 1 dose of study intervention in originating study for subjects initially randomised to JNJ-77242113 and who crossed over and received JNJ-77242113 initially randomised to placebo. N (number of subjects analysed)=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline (Week 0 of the Originating Study), LTE Week 36

End point values	Placebo - JNJ-77242113 100 Milligrams (mg) Once Daily (QD)	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg Twice Daily (BID)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	35	43	43	41
Units: Percentage of subjects				
number (not applicable)	22.9	16.3	11.6	12.2

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	42		
Units: Percentage of subjects				
number (not applicable)	14.0	16.7		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE was any untoward medical occurrence in a clinical investigation where subjects administered a product or medical device; the event needed not necessarily have a causal relationship with the treatment or usage. A SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, or resulted in congenital anomaly/birth defect. TEAE was defined as any AE that occurs after receiving the treatment in originating study (77242113PSO2001) and analysed from Week 16 (LTE Week 0) up to Week 56 (LTE Week 40) in this LTE study (77242113PSO2002). Long-term extension (LTE) safety analysis set included randomised subjects in study 77242113PSO2001 who entered the LTE study 77242113PSO2002 and received at least one dose of study intervention (including a partial dose) during the 77242113PSO2002 study period.

End point type	Secondary

End point timeframe:

From Week 16 (LTE Week 0) up to Week 56 (LTE Week 40)

End point values	Placebo Then JNJ-77242113 100 mg QD	JNJ-77242113 25 mg QD	JNJ-77242113 50 mg QD	JNJ-77242113 25 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	35	39	40
Units: Subjects				
TEAE	23	18	19	27
TESAE	1	0	2	3

End point values	JNJ-77242113 100 mg QD	JNJ-77242113 100 mg BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	38		
Units: Subjects				
TEAE	27	19		
TESAE	2	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Week 16 (LTE Week 0) up to Week 56 (LTE Week 40)

Adverse event reporting additional description:

Safety analysis were based on LTE safety analysis set which included randomised subjects in study 77242113PSO2001 who entered the LTE study 77242113PSO2002 and received at least one dose of study intervention (including a partial dose) during the 77242113PSO2002 study period.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Placebo Then JNJ-77242113 100 mg QD

Reporting group description:

Subjects originally randomised to placebo in originating study (77242113PSO2001) received orally once daily (QD) dose of JNJ-77242113 100 milligrams (mg) tablet in the morning from Week 0 through Week 36 in this LTE study.

Reporting group title	JNJ-77242113 25 mg QD

Reporting group description:

Subjects received orally QD dose of JNJ-77242113 25 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

Reporting group title	JNJ-77242113 100 mg QD

Reporting group description:

Subjects received orally QD dose of JNJ-77242113 100 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

Reporting group title	JNJ-77242113 25 mg BID

Reporting group description:

Subjects received orally twice daily (BID; morning and evening) dose of JNJ-77242113 25 mg tablet from Week 0 through Week 36 in this LTE study.

Reporting group title	JNJ-77242113 100 mg BID

Reporting group description:

Subjects received orally BID (morning and evening) dose of JNJ-77242113 100 mg tablet from Week 0 through Week 36 in this LTE study.

Reporting group title	JNJ-77242113 50 mg QD

Reporting group description:

Subjects received orally QD dose of JNJ-77242113 50 mg tablet in the morning from Week 0 through Week 36 in this LTE study.

Serious adverse events	Placebo Then JNJ-77242113 100 mg QD	JNJ-77242113 25 mg QD	JNJ-77242113 100 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 35 (2.86%)	0 / 35 (0.00%)	2 / 40 (5.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Uterine Leiomyoma			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ligament Injury			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary Artery Disease			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Dysfunction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	1 / 35 (2.86%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	JNJ-77242113 25 mg BID	JNJ-77242113 100 mg BID	JNJ-77242113 50 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 40 (7.50%)	1 / 38 (2.63%)	2 / 39 (5.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 38 (2.63%)	0 / 39 (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
Injury, poisoning and procedural complications			
Ligament Injury			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary Artery Disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Dysfunction			

subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar Hypertrophy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo Then JNJ-77242113 100 mg QD	JNJ-77242113 25 mg QD	JNJ-77242113 100 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 35 (40.00%)	13 / 35 (37.14%)	20 / 40 (50.00%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	2 / 35 (5.71%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 35 (2.86%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Injury, poisoning and procedural complications			
Meniscus Injury			
subjects affected / exposed	0 / 35 (0.00%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 35 (2.86%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 35 (0.00%)	2 / 35 (5.71%)	3 / 40 (7.50%)
occurrences (all)	0	2	3
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 35 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Infections and infestations			
Covid-19			

subjects affected / exposed	2 / 35 (5.71%)	1 / 35 (2.86%)	2 / 40 (5.00%)
occurrences (all)	2	1	2
Bronchitis			
subjects affected / exposed	1 / 35 (2.86%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Sinusitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 35 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	9 / 35 (25.71%)	3 / 35 (8.57%)	11 / 40 (27.50%)
occurrences (all)	11	3	11
Influenza			
subjects affected / exposed	1 / 35 (2.86%)	0 / 35 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 35 (11.43%)	6 / 35 (17.14%)	2 / 40 (5.00%)
occurrences (all)	4	10	2
Urinary Tract Infection			
subjects affected / exposed	2 / 35 (5.71%)	1 / 35 (2.86%)	0 / 40 (0.00%)
occurrences (all)	3	2	0

Non-serious adverse events	JNJ-77242113 25 mg BID	JNJ-77242113 100 mg BID	JNJ-77242113 50 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 40 (42.50%)	15 / 38 (39.47%)	15 / 39 (38.46%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 40 (0.00%)	2 / 38 (5.26%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Meniscus Injury			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	2 / 40 (5.00%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	2	1	1
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 40 (7.50%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Infections and infestations			
Covid-19			
subjects affected / exposed	1 / 40 (2.50%)	3 / 38 (7.89%)	3 / 39 (7.69%)
occurrences (all)	1	3	3
Bronchitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 38 (0.00%)	3 / 39 (7.69%)
occurrences (all)	1	0	3
Sinusitis			
subjects affected / exposed	2 / 40 (5.00%)	0 / 38 (0.00%)	1 / 39 (2.56%)
occurrences (all)	2	0	1
Nasopharyngitis			
subjects affected / exposed	6 / 40 (15.00%)	5 / 38 (13.16%)	7 / 39 (17.95%)
occurrences (all)	8	7	9
Influenza			
subjects affected / exposed	3 / 40 (7.50%)	1 / 38 (2.63%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 40 (7.50%)	4 / 38 (10.53%)	3 / 39 (7.69%)
occurrences (all)	4	4	3
Urinary Tract Infection			

subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	2 / 38 (5.26%) 2	1 / 39 (2.56%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 April 2022	The purpose of this amendment was to include toxicology data, updates to the study intervention dosing instructions to include a fasting requirement, and updates to the analysis strategy regarding discontinuations due to Corona Virus disease-2019 (COVID-19) (intercurrent event number 3) to a Treatment Policy strategy.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported