



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled Study of the PI3K Inhibitor Parsaclisib Plus Ruxolitinib in Participants With Myelofibrosis Who Have Suboptimal Response to Ruxolitinib

Summary

EudraCT number	2020-003415-98
Trial protocol	HU FR BE DE NO FI IT
Global end of trial date	21 August 2024

Results information

Result version number	v1
This version publication date	23 August 2025
First version publication date	23 August 2025

Trial information

Trial identification

Sponsor protocol code	INCB 50465-304/LIMBER-304
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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	21 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 August 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to evaluate and compare the efficacy of parsacalisib plus ruxolitinib versus placebo plus ruxolitinib on spleen volume at Week 24.

Protection of trial subjects:

This study was performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, applicable Good Clinical Practices, and applicable laws and country-specific regulations in which the study was being conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 May 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	Austria: 2
Country: Number of subjects enrolled	China: 41
Country: Number of subjects enrolled	Finland: 3
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Italy: 45
Country: Number of subjects enrolled	Japan: 19
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Norway: 7
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	Türkiye: 6
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 20
Country: Number of subjects enrolled	Hungary: 1
Worldwide total number of subjects	177
EEA total number of subjects	86

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)	90
From 65 to 84 years	87
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted across sites in Austria, China, Finland, France, Germany, Hungary, Italy, Japan, South Korea, Norway, Poland, Spain, Turkey, the United Kingdom, and the United States.

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, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Parsaclisib plus ruxolitinib

Arm description:

Participants were randomized to receive parsaclisib plus ruxolitinib beginning on Day 1. Participants received parsaclisib at a dose of 5 milligrams (mg) once daily (QD). Participants also received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. Treatment with parsaclisib plus ruxolitinib continued for as long as the participant tolerated the regimen and did not meet any discontinuation criteria.

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

Dosage and administration details:

5-mg to 25-mg tablets (all tablet strengths may not be available in all countries), administered orally per labelling instructions

Investigational medicinal product name	parsaclisib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5-mg tablets, 2.5-mg tablets, and 1-mg tablets, administered orally

Arm title	Placebo plus ruxolitinib
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Arm description:

Participants were randomized to receive placebo plus ruxolitinib beginning on Day 1 and continuing until Week 24. Participants received matching placebo at a dose of 5 mg QD and received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. After 24 weeks, participants randomized to receive placebo plus ruxolitinib had to switch to treatment with parsaclisib plus ruxolitinib or discontinue treatment. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.

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

Dosage and administration details:

5-mg to 25-mg tablets (all tablet strengths may not be available in all countries), administered orally per labelling instructions

Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

matching placebo tablets, administered orally

Number of subjects in period 1	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib
Started	90	87
Completed	0	0
Not completed	90	87
Consent withdrawn by subject	12	5
Adverse event, non-fatal	2	-
Death	10	9
Medical Decision	1	1
Study Terminated by Sponsor	57	65
Splenapendectomi	1	-
Lost to follow-up	-	2
Lack of efficacy	2	1
Transitioned to Rollover per Protocol	5	4

Baseline characteristics

Reporting groups

Reporting group title	Parsaclisib plus ruxolitinib
Reporting group description:	
Participants were randomized to receive parsaclisib plus ruxolitinib beginning on Day 1. Participants received parsaclisib at a dose of 5 milligrams (mg) once daily (QD). Participants also received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. Treatment with parsaclisib plus ruxolitinib continued for as long as the participant tolerated the regimen and did not meet any discontinuation criteria.	
Reporting group title	Placebo plus ruxolitinib
Reporting group description:	
Participants were randomized to receive placebo plus ruxolitinib beginning on Day 1 and continuing until Week 24. Participants received matching placebo at a dose of 5 mg QD and received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. After 24 weeks, participants randomized to receive placebo plus ruxolitinib had to switch to treatment with parsaclisib plus ruxolitinib or discontinue treatment. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.	

Reporting group values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib	Total
Number of subjects	90	87	177
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	43	47	90
From 65-84 years	47	40	87
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	64.0	62.3	-
standard deviation	± 9.88	± 9.92	-
Sex: Female, Male Units: participants			
Female	37	38	75
Male	53	49	102
Race, Customized Units: Subjects			
White or Caucasian	45	52	97
Black or African American	1	1	2
Asian	37	26	63
Not Reported	7	8	15
Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	10	12

Not Hispanic or Latino	70	57	127
Not Reported	7	4	11
Unknown	2	4	6
Captured as "Other" in Database	9	12	21

End points

End points reporting groups

Reporting group title	Parsaclisib plus ruxolitinib
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Reporting group description:

Participants were randomized to receive parsaclisib plus ruxolitinib beginning on Day 1. Participants received parsaclisib at a dose of 5 milligrams (mg) once daily (QD). Participants also received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. Treatment with parsaclisib plus ruxolitinib continued for as long as the participant tolerated the regimen and did not meet any discontinuation criteria.

Reporting group title	Placebo plus ruxolitinib
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Reporting group description:

Participants were randomized to receive placebo plus ruxolitinib beginning on Day 1 and continuing until Week 24. Participants received matching placebo at a dose of 5 mg QD and received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. After 24 weeks, participants randomized to receive placebo plus ruxolitinib had to switch to treatment with parsaclisib plus ruxolitinib or discontinue treatment. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.

Subject analysis set title	Placebo switch to parsaclisib
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

After 24 weeks, participants randomized to receive placebo plus ruxolitinib from Day 1 to Week 24 could have switched to treatment with parsaclisib plus ruxolitinib per the regimen received during the first 24 weeks of the study. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.

Primary: Percentage of participants achieving $\geq 25\%$ reduction in spleen volume from Baseline to Week 24 as measured by magnetic resonance imaging (MRI) (or computed tomography [CT] scan in applicable participants)

End point title	Percentage of participants achieving $\geq 25\%$ reduction in spleen volume from Baseline to Week 24 as measured by magnetic resonance imaging (MRI) (or computed tomography [CT] scan in applicable participants)
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End point description:

Participants had an MRI of the upper and lower abdomen and pelvis to determine the spleen volume. A CT scan was substituted for participants who were not candidates for MRI or when MRI was not readily available. Intent-to-Treat (ITT) Population: all randomized participants. Participants were analyzed if they had both Baseline and Week 24 measurements, or discontinued treatment before 03MAR2023 or switched treatment before Week 24, or reached Week 24 before 03MAR2023 but were missing Week 24 assessments. For participants who switched to parsaclisib plus ruxolitinib treatment early, data was truncated at the time of switch.

End point type	Primary
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End point timeframe:

Baseline; Week 24

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72 ^[1]	72 ^[2]		
Units: percentage of participants				
number (not applicable)	16.7	9.7		

Notes:

[1] - ITT Population

[2] - ITT Population

Statistical analyses

Statistical analysis title	Cochran Mantel-Haenszel (CMH) test
Comparison groups	Parsaclisib plus ruxolitinib v Placebo plus ruxolitinib
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	= 0.2567 ^[4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	5.02

Notes:

[3] - p-value for superiority is half of the CMH p-value.

[4] - CMH test for un-equality stratified by Dynamic International Prognostic Scoring System (DIPSS) category (intermediate 1 versus intermediate 2 and high) and Baseline platelet count ($\geq 100 \times 10^9/\text{Liters}$ [L] versus 50 to $< 100 \times 10^9/\text{L}$ inclusive)

Secondary: Percentage of participants who have a $\geq 50\%$ reduction in Total Symptom Score (TSS) from Baseline to Week 24 as measured by the Myelofibrosis Symptom Assessment Form v.4.0 (MFSAF v4.0) diary

End point title	Percentage of participants who have a $\geq 50\%$ reduction in Total Symptom Score (TSS) from Baseline to Week 24 as measured by the Myelofibrosis Symptom Assessment Form v.4.0 (MFSAF v4.0) diary
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End point description:

Symptoms of myelofibrosis were assessed using the MFSAF v4.0 diary. The MFSAF v4.0 is composed of 7 individual symptom scores (fatigue, night sweats, itchiness, abdominal discomfort, pain under left ribs, early satiety, bone pain), each collected daily using a 0- (no symptoms) to 10-point (worst imaginable symptoms) scale. The daily TSS (0 to 70) is the sum of the 7 individual symptom scores. A higher TSS corresponds to more severe symptoms. The Baseline/Week 24 total score was defined as the average of the daily total scores from the last 7 days before the first dose of parsaclisib, placebo, or ruxolitinib/the Week 24 visit. Participants were analyzed if they had both Baseline and Week 24 measurements, or discontinued treatment before 03MAR2023 or switched treatment before Week 24, or reached Week 24 before 03MAR2023 but were missing Week 24 assessments. For participants who switched to parsaclisib plus ruxolitinib treatment early, data was truncated at the time of switch.

End point type	Secondary
End point timeframe:	
Baseline; Week 24	

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70 ^[5]	71 ^[6]		
Units: percentage of participants				
number (not applicable)	17.1	14.1		

Notes:

[5] - ITT Population

[6] - ITT Population

Statistical analyses

Statistical analysis title	Reduction in TSS score
Comparison groups	Parsaclisib plus ruxolitinib v Placebo plus ruxolitinib
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	superiority ^[7]
P-value	= 0.5349 ^[8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	3.39

Notes:

[7] - p-value for superiority is half of the CMH p-value.

[8] - calculated from Cochran Mantel-Haenszel test for un-equality stratified by DIPSS category (intermediate 1 versus intermediate 2 and high) and Baseline platelet count ($\geq 100 \times 10^9/L$ versus 50 to $<100 \times 10^9/L$ inclusive)

Secondary: Change in TSS from Baseline to Week 24 as measured by the MFSAF v4.0 diary

End point title	Change in TSS from Baseline to Week 24 as measured by the MFSAF v4.0 diary
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End point description:

Symptoms of myelofibrosis were assessed using the MFSAF v4.0 diary. The MFSAF v4.0 is composed of 7 individual symptom scores (fatigue, night sweats, itchiness, abdominal discomfort, pain under left ribs, early satiety, bone pain), each collected daily using a 0- (no symptoms) to 10-point (worst imaginable symptoms) scale. The daily TSS (0 to 70) is the sum of the 7 individual symptom scores collected in a day. A higher TSS corresponds to more severe symptoms. The TSS was marked as missing if there were any missing individual scores. Observations with missing dates were excluded from the analysis. The Baseline/Week 24 total score was defined as the average of the daily total scores from the last 7 days before the first dose of parsaclisib, placebo, or ruxolitinib/the Week 24 visit. The Baseline/Week 24 total score was marked as missing if there were ≥ 4 out of the 7 daily TSSs missing. Change from Baseline was calculated as the Week 24 value minus the Baseline value.

End point type	Secondary
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End point timeframe:

Baseline; Week 24

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88 ^[9]	82 ^[10]		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline, n=88, 82	17.2 (± 11.61)	21.6 (± 14.28)		
Change from Baseline at Week 24, n=57, 61	-2.7 (± 8.67)	-2.7 (± 9.98)		

Notes:

[9] - ITT Population. Only participants with data available were analyzed.

[10] - ITT Population. Only participants with data available were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to the first ≥50% reduction in TSS as measured by the MFSAF v4.0 diary

End point title	Time to the first ≥50% reduction in TSS as measured by the MFSAF v4.0 diary
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End point description:

Symptoms were assessed using the MFSAF v4.0 diary. The MFSAF v4.0 is composed of 7 symptom scores (fatigue, night sweats, itchiness, abdominal discomfort, pain under left ribs, early satiety, bone pain), each collected daily using a 0- (no symptoms) to 10-point (worst imaginable symptoms) scale. The daily TSS (0 to 70) is the sum of the 7 individual symptom scores. A higher TSS corresponds to more severe symptoms. The TSS was marked as missing if there were any missing individual scores. Observations with missing dates were excluded from the analysis. The Baseline/Week 24 total score was defined as the average of the daily total scores from the last 7 days before the first dose of parsaclisib, placebo, or ruxolitinib/the Week 24 visit. The Baseline/Week 24 total scores was marked as missing if there were ≥4 out of the 7 daily TSSs missing. -9999, 9999=Values were not estimable because there were too few participants with a ≥50% reduction in TSS at the time of study termination.

End point type	Secondary
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End point timeframe:

Baseline; up to Week 24

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90 ^[11]	87 ^[12]		
Units: days				
median (confidence interval 95%)	9999 (160.0 to 9999)	9999 (-9999 to 9999)		

Notes:

[11] - ITT Population

[12] - ITT Population

Statistical analyses

Statistical analysis title	Time to the first ≥50% reduction in TSS
Comparison groups	Parsaclisib plus ruxolitinib v Placebo plus ruxolitinib

Number of subjects included in analysis	177
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2224 ^[13]
Method	Logrank

Notes:

[13] - calculated from log-rank test stratified by DIPSS category (intermediate 1 versus intermediate 2 and high) and Baseline platelet count ($\geq 100 \times 10^9/L$ versus 50 to $< 100 \times 10^9/L$ inclusive)

Secondary: Overall survival

End point title	Overall survival
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End point description:

Overall survival was defined as the interval between the randomization date and the date of death due to any cause. -9999, 9999=Due to study termination, the follow-up time was not long enough to estimate the median and the upper and lower limits of the confidence interval.

End point type	Secondary
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End point timeframe:

up to 917 days

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90 ^[14]	87 ^[15]		
Units: days				
median (confidence interval 95%)	9999 (-9999 to 9999)	9999 (-9999 to 9999)		

Notes:

[14] - ITT Population

[15] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any treatment-emergent adverse event (TEAE)

End point title	Number of participants with any treatment-emergent adverse event (TEAE)
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End point description:

An adverse event (AE) is defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. An AE could therefore be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A TEAE is defined as an AE reported for the first time or the worsening of a pre-existing event after the first dose of study treatment. Safety Population: all randomized participants who received at least 1 dose of parsaclisib, placebo, or ruxolitinib. Treatment groups for this population were determined according to the actual treatment the participant received regardless of assigned study drug treatment.

End point type	Secondary
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End point timeframe:

up to 917 days

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib	Placebo switch to parsaclisib	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	90 ^[16]	87 ^[17]	41 ^[18]	
Units: participants	81	76	33	

Notes:

[16] - Safety Population

[17] - Safety Population

[18] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any Grade 3 or higher TEAE

End point title	Number of participants with any Grade 3 or higher TEAE
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End point description:

An AE is defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not it is considered drug related. A TEAE is defined as an AE reported for the first time or the worsening of a pre-existing event after the first dose of study treatment. The severity of AEs was assessed using Common Terminology Criteria for Adverse Events (CTCAE) v5.0 Grades 1 through 5. Grade 1: mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2: moderate; minimal, local or noninvasive intervention indicated; limiting instrumental activities of daily living (ADL). Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL. Grade 4: life-threatening urgent intervention indicated. Grade 5: death related to AE.

End point type	Secondary
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End point timeframe:

up to 917 days

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib	Placebo switch to parsaclisib	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	90 ^[19]	87 ^[20]	41 ^[21]	
Units: participants	54	37	18	

Notes:

[19] - Safety Population

[20] - Safety Population

[21] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to the first ≥25% reduction in spleen volume

End point title	Time to the first ≥25% reduction in spleen volume
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End point description:

The time to the first ≥25% reduction in spleen volume is defined as the time from randomization to the first time participants had ≥25% reduction in spleen volume. Participants with a Baseline and post-

Baseline MRI or CT scan who did not have $\geq 25\%$ reduction in spleen volume at the time of analysis were censored at the time of the last MRI or CT scan. If the participants had no Baseline or post-Baseline MRI or CT scan, they were censored at the date of randomization. -9999, 9999=The median and the upper and lower limits of the confidence interval were not estimable because too few participants had a $\geq 25\%$ reduction in spleen volume.

End point type	Secondary
End point timeframe:	
up to 898 days	

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	90 ^[22]	87 ^[23]		
Units: days				
median (confidence interval 95%)	9999 (-9999 to 9999)	9999 (-9999 to 9999)		

Notes:

[22] - ITT Population

[23] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of maintenance of a $\geq 25\%$ reduction in spleen volume

End point title	Duration of maintenance of a $\geq 25\%$ reduction in spleen volume
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End point description:

The duration of $\geq 25\%$ reduction from Baseline in spleen volume was defined as the interval between the first spleen volume measurement that was a $\geq 25\%$ reduction from Baseline and the date of the first measurement that was no longer a $\geq 25\%$ reduction from Baseline. If the end date was not observed before the database cutoff, the duration was censored at the last assessment. Only those participants who had at least 1 measurement of $\geq 25\%$ reduction from Baseline were analyzed. -9999, 9999=The median and the upper and lower limits of the confidence interval were not estimable because too few participants had a $\geq 25\%$ reduction in spleen volume.

End point type	Secondary
End point timeframe:	
up to 898 days	

End point values	Parsaclisib plus ruxolitinib	Placebo plus ruxolitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12 ^[24]	7 ^[25]		
Units: days				
median (confidence interval 95%)	9999 (-9999 to 9999)	9999 (-9999 to 9999)		

Notes:

[24] - ITT Population

[25] - ITT Population

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to 917 days

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs), defined as adverse events reported for the first time or the worsening of pre-existing events after the first dose of study treatment, have been reported for members of the Safety Population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22
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Reporting groups

Reporting group title	Parsaclisib plus ruxolitinib
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Reporting group description:

Participants were randomized to receive parsaclisib plus ruxolitinib beginning on Day 1. Participants received parsaclisib at a dose of 5 milligrams (mg) once daily (QD). Participants also received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. Treatment with parsaclisib plus ruxolitinib continued for as long as the participant tolerated the regimen and did not meet any discontinuation criteria.

Reporting group title	Placebo switch to parsaclisib
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Reporting group description:

After 24 weeks, participants randomized to receive placebo plus ruxolitinib from Day 1 to Week 24 could have switched to treatment with parsaclisib plus ruxolitinib per the regimen received during the first 24 weeks of the study. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.

Reporting group title	Placebo plus ruxolitinib
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Reporting group description:

Participants were randomized to receive placebo plus ruxolitinib beginning on Day 1 and continuing until Week 24. Participants received matching placebo at a dose of 5 mg QD and received the stable dose of ruxolitinib they were taking for the 8 weeks prior to Day 1. After 24 weeks, participants randomized to receive placebo plus ruxolitinib had to switch to treatment with parsaclisib plus ruxolitinib or discontinue treatment. Treatment continued for as long as the regimen was tolerated and the participant did not meet any discontinuation criteria. Participants who demonstrated worsening symptomatic splenomegaly could have switched to treatment with parsaclisib plus ruxolitinib early.

Serious adverse events	Parsaclisib plus ruxolitinib	Placebo switch to parsaclisib	Placebo plus ruxolitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 90 (36.67%)	8 / 41 (19.51%)	15 / 87 (17.24%)
number of deaths (all causes)	10	2	7
number of deaths resulting from adverse events	6	2	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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

Breast neoplasm			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Basal cell carcinoma			
subjects affected / exposed	1 / 90 (1.11%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Skin squamous cell carcinoma metastatic			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transformation to acute myeloid leukaemia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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			
Chest pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malaise			

subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Pyrexia			
subjects affected / exposed	2 / 90 (2.22%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Haemoptysis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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
Lung disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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
Investigations			
Platelet count decreased			
subjects affected / exposed	2 / 90 (2.22%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial injury			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Subdural haematoma			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac disorders			
Atrioventricular block second degree			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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			
Dizziness			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Syncope			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 90 (2.22%)	0 / 41 (0.00%)	2 / 87 (2.30%)
occurrences causally related to treatment / all	1 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Febrile neutropenia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Splenic haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Subcapsular splenic haematoma			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Thrombocytopenia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faeces discoloured			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising colitis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Ulcerative gastritis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Skin and subcutaneous tissue disorders			
Pyoderma gangrenosum			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			

subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	5 / 90 (5.56%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	3 / 90 (3.33%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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
Enterocolitis bacterial			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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
Herpes zoster			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Pneumonia influenzal			
subjects affected / exposed	2 / 90 (2.22%)	0 / 41 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia escherichia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 41 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Pneumonia			
subjects affected / exposed	8 / 90 (8.89%)	2 / 41 (4.88%)	2 / 87 (2.30%)
occurrences causally related to treatment / all	5 / 11	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary tuberculosis			

subjects affected / exposed	1 / 90 (1.11%)	0 / 41 (0.00%)	0 / 87 (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
Urinary tract infection			
subjects affected / exposed	0 / 90 (0.00%)	1 / 41 (2.44%)	0 / 87 (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	Parsaclisib plus ruxolitinib	Placebo switch to parsaclisib	Placebo plus ruxolitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 90 (78.89%)	25 / 41 (60.98%)	58 / 87 (66.67%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	8 / 90 (8.89%)	4 / 41 (9.76%)	3 / 87 (3.45%)
occurrences (all)	9	4	4
Cytomegalovirus test positive			
subjects affected / exposed	4 / 90 (4.44%)	3 / 41 (7.32%)	0 / 87 (0.00%)
occurrences (all)	4	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 90 (7.78%)	4 / 41 (9.76%)	4 / 87 (4.60%)
occurrences (all)	8	5	5
Neutrophil count decreased			
subjects affected / exposed	5 / 90 (5.56%)	1 / 41 (2.44%)	3 / 87 (3.45%)
occurrences (all)	7	1	3
Platelet count decreased			
subjects affected / exposed	20 / 90 (22.22%)	5 / 41 (12.20%)	14 / 87 (16.09%)
occurrences (all)	33	5	23
White blood cell count decreased			
subjects affected / exposed	8 / 90 (8.89%)	0 / 41 (0.00%)	7 / 87 (8.05%)
occurrences (all)	12	0	17
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	7 / 90 (7.78%) 9	1 / 41 (2.44%) 1	2 / 87 (2.30%) 2
Headache subjects affected / exposed occurrences (all)	8 / 90 (8.89%) 8	1 / 41 (2.44%) 1	4 / 87 (4.60%) 4
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	26 / 90 (28.89%) 38	6 / 41 (14.63%) 6	20 / 87 (22.99%) 36
Neutropenia subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0	3 / 41 (7.32%) 3	1 / 87 (1.15%) 3
Thrombocytopenia subjects affected / exposed occurrences (all)	10 / 90 (11.11%) 11	8 / 41 (19.51%) 14	8 / 87 (9.20%) 10
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	7 / 90 (7.78%) 7	3 / 41 (7.32%) 3	4 / 87 (4.60%) 4
Fatigue subjects affected / exposed occurrences (all)	5 / 90 (5.56%) 6	0 / 41 (0.00%) 0	4 / 87 (4.60%) 4
Pyrexia subjects affected / exposed occurrences (all)	13 / 90 (14.44%) 20	1 / 41 (2.44%) 2	8 / 87 (9.20%) 14
Gastrointestinal disorders			
Abdominal pain upper subjects affected / exposed occurrences (all)	8 / 90 (8.89%) 9	0 / 41 (0.00%) 0	2 / 87 (2.30%) 2
Constipation subjects affected / exposed occurrences (all)	6 / 90 (6.67%) 7	0 / 41 (0.00%) 0	0 / 87 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	10 / 90 (11.11%) 10	1 / 41 (2.44%) 4	9 / 87 (10.34%) 10

Nausea subjects affected / exposed occurrences (all)	7 / 90 (7.78%) 8	2 / 41 (4.88%) 2	7 / 87 (8.05%) 8
Stomatitis subjects affected / exposed occurrences (all)	6 / 90 (6.67%) 8	1 / 41 (2.44%) 1	2 / 87 (2.30%) 2
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	8 / 90 (8.89%) 8	2 / 41 (4.88%) 2	4 / 87 (4.60%) 4
Dyspnoea subjects affected / exposed occurrences (all)	6 / 90 (6.67%) 6	0 / 41 (0.00%) 0	3 / 87 (3.45%) 3
Epistaxis subjects affected / exposed occurrences (all)	5 / 90 (5.56%) 6	0 / 41 (0.00%) 0	3 / 87 (3.45%) 5
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	5 / 90 (5.56%) 5	0 / 41 (0.00%) 0	6 / 87 (6.90%) 10
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	4 / 90 (4.44%) 4	0 / 41 (0.00%) 0	5 / 87 (5.75%) 5
Arthralgia subjects affected / exposed occurrences (all)	4 / 90 (4.44%) 4	3 / 41 (7.32%) 3	3 / 87 (3.45%) 3
Pain in extremity subjects affected / exposed occurrences (all)	5 / 90 (5.56%) 5	1 / 41 (2.44%) 1	3 / 87 (3.45%) 3
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	16 / 90 (17.78%) 16	6 / 41 (14.63%) 6	10 / 87 (11.49%) 10
Cytomegalovirus infection			

subjects affected / exposed occurrences (all)	10 / 90 (11.11%) 10	2 / 41 (4.88%) 2	0 / 87 (0.00%) 0
Metabolism and nutrition disorders Hyperuricaemia subjects affected / exposed occurrences (all)	7 / 90 (7.78%) 7	0 / 41 (0.00%) 0	4 / 87 (4.60%) 4

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 October 2021	The primary purpose of this amendment was to address changes requested by different national regulatory agencies and ethics committees.
20 October 2022	The primary purpose of this amendment was to update safety information for parsaclisib, including information regarding coronavirus disease 2019 (COVID-19), and the potential impact of parsaclisib therapy on infection risk, vaccine effectiveness, and severity of disease.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Following an interim analysis by an independent Data Monitoring Committee (DMC), the study was terminated early due to futility.

Notes: