Clinical trial results:
A Phase 2, Multicenter, Open-Label Study of INCB050465, a PI3K Inhibitor, in Relapsed or Refractory Follicular Lymphoma

Summary

EudraCT number	2017-001624-22
Trial protocol	GB CZ DK SE DE HU ES IT
Global end of trial date	07 June 2024

Results information

Result version number	v1
This version publication date	26 February 2025
First version publication date	26 February 2025

Trial information

Trial identification

Sponsor protocol code	INCB 50465-203 (CITADEL-203)

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 Drive, 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	07 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to assess the efficacy of INCB050465 in terms of objective response rate (ORR) in participants with relapsed or refractory follicular lymphoma (FL).

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, Good Clinical Practices as defined in Title 21 of the United States Code of Federal Regulations Parts 11, 50, 54, 56, and 312, as well as International Council on Harmonisation Good Clinical Practice consolidated guidelines (E6) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2018
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: 1
Country: Number of subjects enrolled	Czechia: 17
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Denmark: 3
Country: Number of subjects enrolled	Spain: 18
Country: Number of subjects enrolled	United Kingdom: 17
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Israel: 10
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United States: 29
Worldwide total number of subjects	126
EEA total number of subjects	69

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)	50
From 65 to 84 years	72
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 44 investigative sites in the United States, Italy, Spain, Great Britain, Czech Republic, Hungary, Canada, Denmark, Germany, Israel, Poland, and Sweden

Pre-assignment

Screening details:

A total of 126 participants with relapsed or refractory follicular lymphoma were enrolled in the study and assigned to one of two treatment groups: Treatment A or Treatment B to receive parsaclisib.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW

Arm description:

Participants received parsaclisib 20 milligrams (mg) once daily (QD) for 8 weeks followed by 20 mg once weekly (QW) for up to approximately 52 weeks.

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

Dosage and administration details:

1 mg, 2.5 mg, 5 mg, and 20 mg tablets taken orally

Arm title	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD

Arm description:

Participants received parsaclisib 20 mg QD for 8 weeks followed by 2.5 mg QD for up to approximately 52 weeks.

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

Dosage and administration details:

1 mg, 2.5 mg, 5 mg, and 20 mg tablets taken orally

Number of subjects in period 1	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD
Started	23	103
Completed	14	50
Not completed	9	53
Consent withdrawn by subject	1	9
Physician decision	1	-
Site Closed	-	1
Death	5	27
Did Not Return to Site for Care	-	1
Lost to follow-up	2	4
Transitioned to Rollover Study	-	11

Baseline characteristics

Reporting groups	
Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW
Reporting group description:	
Participants received parsaclisib 20 milligrams (mg) once daily (QD) for 8 weeks followed by 20 mg once weekly (QW) for up to approximately 52 weeks.	
Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD
Reporting group description:	
Participants received parsaclisib 20 mg QD for 8 weeks followed by 2.5 mg QD for up to approximately 52 weeks.	

Reporting group values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD	Total
Number of subjects	23	103	126
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)	11	39	50
From 65-84 years	12	60	72
85 years and over	0	4	4
Age Continuous Units: years			
arithmetic mean	64.1	67.0	
standard deviation	± 11.56	± 10.68	-
Sex: Female, Male Units: participants			
Female	11	45	56
Male	12	58	70
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	6	7
Not Hispanic or Latino	19	90	109
Unknown or Not Reported	3	7	10
Race Customized Units: Subjects			
Asian	0	1	1
Black/ African- American	1	6	7
White/ Caucasian	21	92	113
Unavailable or Unknown	1	4	5

End points

End points reporting groups

Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW
Reporting group description:	
Participants received parsaclisib 20 milligrams (mg) once daily (QD) for 8 weeks followed by 20 mg once weekly (QW) for up to approximately 52 weeks.	
Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD
Reporting group description:	
Participants received parsaclisib 20 mg QD for 8 weeks followed by 2.5 mg QD for up to approximately 52 weeks.	

Primary: Objective Response Rate With Parsaclisib Based on Lugano Classification Response Criteria

End point title	Objective Response Rate With Parsaclisib Based on Lugano Classification Response Criteria[1]
End point description:	
ORR=percentage of participants with complete response(CR) or partial response(PR) per revised response criteria for lymphomas,determined by independent review committee(IRC).Criteria for CR:1.Target nodes/nodal masses of lymph nodes,extralymphatic sites regressed to≤1.5cm in longest dimension transverse diameter of lesion(LDi);2.Absence of non-measured lesion;3.Organ enlargement regressed to normal;4.No new lesions;5.Normal bone marrow morphology;if indeterminate,immunohistochemistry negative.Criteria for PR:1.Lymph nodes,extralymphatic sites-≥50%decrease in sum of product of perpendicular diameters for multiple lesions(SPD)of up to 6 target measurable nodes,extranodal sites;if lesion is too small to measure on computed tomography(CT),assign5mm×5mm as default;if no longer visible,0×0mm.Node>5mm×5mm but smaller than normal,use actual measurement.2.Absent/regressed non-measured lesions,no increase.3.Organ enlargement-Spleen regressed by>50%in length beyond normal.4.No new lesions.	
End point type	Primary
End point timeframe:	
Up to 1193 days	

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: Statistical analysis was not conducted for this endpoint.

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[2]	103[3]		
Units: percentage of participants				
number (confidence interval 95%)	65.2 (42.7 to 83.6)	78.6 (69.5 to 86.1)		

Notes:

[2] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

[3] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response Rate With Parsaclisib Based on Lugano Classification

Response Criteria

End point title	Complete Response Rate With Parsaclisib Based on Lugano Classification Response Criteria

End point description:

CRR was defined as the percentage of participants with a CR as defined by revised response criteria for lymphomas as determined by an IRC. The criteria for CR included: 1. Target nodes/nodal masses of lymph nodes and extralymphatic sites must regress to ≤ 1.5 cm in LDi; 2. Absence of non-measured lesion; 3. Organ enlargement regressed to normal; 4. No new lesions; 5. Bone marrow must be normal by morphology; if indeterminate, immunohistochemistry negative.

End point type	Secondary

End point timeframe:

Up to 1193 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[4]	103[5]		
Units: percentage of participants				
number (confidence interval 95%)	17.4 (5.0 to 38.8)	22.3 (14.7 to 31.6)		

Notes:

[4] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

[5] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) With Parsaclisib

End point title	Progression-free Survival (PFS) With Parsaclisib

End point description:

PFS was defined as the time from the date of the first dose of study treatment until the earliest date of disease progression, as determined by radiographic disease assessment provided by an IRC, or death from any cause.

End point type	Secondary

End point timeframe:

Up to 1193 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[6]	103[7]		
Units: months				
median (confidence interval 95%)	19.32 (8.31 to 33.15)	14.03 (11.07 to 20.07)		

Notes:

[6] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

[7] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR=time from first documented CR or PR until disease progression/death from any cause among participants who achieve an objective response as determined by IRC. CR: 1.Target nodes/nodal masses of lymph nodes and extralymphatic sites must regress to ≤1.5 cm in LDi; 2. Absence of non-measured lesion; 3.Organ enlargement regressed to normal; 4.No new lesions; 5.Bone marrow normal by morphology; if indeterminate, immunohistochemistry negative. PR: 1.Lymph nodes/extralymphatic sites- a. ≥50% decrease in SPD of up to 6 target measurable nodes/extranodal sites; b. when a lesion is too small to measure on CT, assign 5 mm×5 mm as the default; c.when no longer visible, 0×0 mm. For a node >5 mm×5 mm but smaller than normal, use actual measurement. 2.Non-measured lesions-Absent/regressed, but no increase. 3. Organ enlargement-Spleen regressed by >50% in length beyond normal. 4.No new lesions. 9999=The upper limit of the CI was not estimable due to the low number of participants with events.

End point type	Secondary

End point timeframe:

Up to 1193 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15[8]	81[9]		
Units: months				
median (confidence interval 95%)	14.06 (3.19 to 9999)	14.72 (11.76 to 25.72)		

Notes:

[8] - Only participants with an objective response were analyzed.

[9] - Only participants with an objective response were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) With Parsaclisib

End point title	Overall Survival (OS) With Parsaclisib

End point description:

OS was defined as the time from the date of the first dose of study treatment until death from any cause. -9999, 9999=The median and the lower and upper limits of the 95% CI were not estimable due to the low number of participants with events.

End point type	Secondary

End point timeframe:

Up to 1193 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[10]	103[11]		
Units: months				
median (confidence interval 95%)	9999 (35.48 to 9999)	9999 (-9999 to 9999)		

Notes:

[10] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

[11] - Full Analysis Set: all participants enrolled in the study who received ≥1 dose of parsaclisib

Statistical analyses

No statistical analyses for this end point

Secondary: Best Percent Change From Baseline in Target Lesion Size

End point title	Best Percent Change From Baseline in Target Lesion Size

End point description:

Target lesion size is measured by the sum of the product of diameters of all target lesion sizes and is determined by the IRC. The best percent change from Baseline is defined as the largest decrease, or smallest increase (if no decrease available), from Baseline in target lesion sizes on/before new (next-line) anti-lymphoma therapy during the study. Baseline is the last non-missing measurement obtained before the first administration of study drug. A negative percent change from Baseline indicates improvement.

End point type	Secondary

End point timeframe:

Up to 1193 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[12]	98[13]		
Units: percent change in lesion size				
arithmetic mean (standard deviation)	-72.90 (± 21.782)	-72.77 (± 31.972)		

Notes:

[12] - Full Analysis Set. Only participants with available data were analyzed.

[13] - Full Analysis Set. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

An adverse event (AE) is defined as any untoward medical occurrence associated with use of a drug in humans, whether or not considered drug related, that occurs after a participant provides informed consent. TEAE is any AE either reported for first time or worsening of a pre-existing event after first dose of study drug and within 30 days of last administration of study drug regardless of starting new anti-lymphoma therapy. SAE is any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, leads to a congenital anomaly/birth defect or is considered to be an important medical event that may not result in death, be immediately life-threatening, or require hospitalization but may be considered serious when, based on appropriate medical judgment, the event may jeopardize the participant or may require medical or surgical intervention.

End point type	Secondary

End point timeframe:

From the first dose of study drug up to approximately 2004 days

End point values	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23[14]	103[15]		
Units: percentage of participants				
number (not applicable)				
TEAEs	100.0	99.0		
SAEs	52.2	53.4		

Notes:

[14] - Safety Population: all participants enrolled in the study who received ≥1 dose of parsaclisib

[15] - Safety Population: all participants enrolled in the study who received ≥1 dose of parsaclisib

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to approximately 2004 days

Adverse event reporting additional description:

Adverse events have been reported for members of the Safety Population, comprised of all participants enrolled in the study who received at least 1 dose of parsaclisib.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD

Reporting group description:

Participants received parsaclisib 20 mg QD for 8 weeks followed by 2.5 mg QD for up to approximately 52 weeks.

Reporting group title	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW

Reporting group description:

Participants received parsaclisib 20 milligrams (mg) once daily (QD) for 8 weeks followed by 20 mg once weekly (QW) for up to approximately 52 weeks.

Serious adverse events	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	
Total subjects affected by serious adverse events			
subjects affected / exposed	55 / 103 (53.40%)	12 / 23 (52.17%)	
number of deaths (all causes)	27	5	
number of deaths resulting from adverse events	4	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Desmoplastic mesothelioma			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			

subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

General physical health deterioration			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	3 / 103 (2.91%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	3 / 103 (2.91%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	2 / 103 (1.94%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumothorax			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
C-reactive protein increased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body temperature increased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hip fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomal hernia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Cerebrovascular accident			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	2 / 103 (1.94%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis erosive			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	8 / 103 (7.77%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	8 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	10 / 103 (9.71%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	9 / 11	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated enterocolitis			

subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotid gland enlargement			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			

subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Rash			
subjects affected / exposed	2 / 103 (1.94%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 103 (2.91%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune arthritis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal chest pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Campylobacter colitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			

subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	3 / 103 (2.91%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	2 / 4	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 103 (0.97%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 103 (1.94%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 103 (0.97%)	2 / 23 (8.70%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			

subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 103 (0.97%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	2 / 103 (1.94%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Parsaclisib 20 mg QD for 8 Weeks followed by 2.5 mg QD	Parsaclisib 20 mg QD for 8 Weeks followed by 20 mg QW	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 103 (91.26%)	22 / 23 (95.65%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Infected neoplasm			

subjects affected / exposed	0 / 103 (0.00%)	2 / 23 (8.70%)	
occurrences (all)	0	2	
Vascular disorders			
Hypertension			
subjects affected / exposed	12 / 103 (11.65%)	0 / 23 (0.00%)	
occurrences (all)	13	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	21 / 103 (20.39%)	3 / 23 (13.04%)	
occurrences (all)	23	3	
Asthenia			
subjects affected / exposed	14 / 103 (13.59%)	2 / 23 (8.70%)	
occurrences (all)	17	2	
Oedema peripheral			
subjects affected / exposed	10 / 103 (9.71%)	1 / 23 (4.35%)	
occurrences (all)	10	1	
Peripheral swelling			
subjects affected / exposed	2 / 103 (1.94%)	2 / 23 (8.70%)	
occurrences (all)	2	2	
Pyrexia			
subjects affected / exposed	20 / 103 (19.42%)	2 / 23 (8.70%)	
occurrences (all)	26	2	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	28 / 103 (27.18%)	3 / 23 (13.04%)	
occurrences (all)	30	3	
Dyspnoea			
subjects affected / exposed	8 / 103 (7.77%)	0 / 23 (0.00%)	
occurrences (all)	10	0	
Oropharyngeal pain			
subjects affected / exposed	5 / 103 (4.85%)	2 / 23 (8.70%)	
occurrences (all)	7	2	
Wheezing			
subjects affected / exposed	0 / 103 (0.00%)	2 / 23 (8.70%)	
occurrences (all)	0	2	
Psychiatric disorders			

Insomnia			
subjects affected / exposed	6 / 103 (5.83%)	0 / 23 (0.00%)	
occurrences (all)	6	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	7 / 103 (6.80%)	1 / 23 (4.35%)	
occurrences (all)	11	1	
C-reactive protein increased			
subjects affected / exposed	2 / 103 (1.94%)	2 / 23 (8.70%)	
occurrences (all)	2	2	
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 103 (7.77%)	1 / 23 (4.35%)	
occurrences (all)	9	1	
Weight decreased			
subjects affected / exposed	6 / 103 (5.83%)	0 / 23 (0.00%)	
occurrences (all)	6	0	
Cardiac disorders			
Extrasystoles			
subjects affected / exposed	0 / 103 (0.00%)	2 / 23 (8.70%)	
occurrences (all)	0	2	
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 103 (6.80%)	1 / 23 (4.35%)	
occurrences (all)	7	1	
Headache			
subjects affected / exposed	14 / 103 (13.59%)	1 / 23 (4.35%)	
occurrences (all)	14	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 103 (6.80%)	2 / 23 (8.70%)	
occurrences (all)	8	2	
Neutropenia			
subjects affected / exposed	16 / 103 (15.53%)	2 / 23 (8.70%)	
occurrences (all)	21	4	
Thrombocytopenia			

subjects affected / exposed	7 / 103 (6.80%)	1 / 23 (4.35%)	
occurrences (all)	7	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	9 / 103 (8.74%)	0 / 23 (0.00%)	
occurrences (all)	12	0	
Constipation			
subjects affected / exposed	11 / 103 (10.68%)	1 / 23 (4.35%)	
occurrences (all)	11	1	
Diarrhoea			
subjects affected / exposed	45 / 103 (43.69%)	3 / 23 (13.04%)	
occurrences (all)	75	5	
Nausea			
subjects affected / exposed	28 / 103 (27.18%)	8 / 23 (34.78%)	
occurrences (all)	34	8	
Vomiting			
subjects affected / exposed	9 / 103 (8.74%)	3 / 23 (13.04%)	
occurrences (all)	10	4	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 103 (2.91%)	4 / 23 (17.39%)	
occurrences (all)	5	6	
Rash maculo-papular			
subjects affected / exposed	7 / 103 (6.80%)	1 / 23 (4.35%)	
occurrences (all)	7	1	
Rash			
subjects affected / exposed	15 / 103 (14.56%)	6 / 23 (26.09%)	
occurrences (all)	18	8	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	16 / 103 (15.53%)	2 / 23 (8.70%)	
occurrences (all)	17	2	
Back pain			
subjects affected / exposed	9 / 103 (8.74%)	1 / 23 (4.35%)	
occurrences (all)	9	1	
Myalgia			

subjects affected / exposed	5 / 103 (4.85%)	2 / 23 (8.70%)	
occurrences (all)	5	2	
Pain in extremity			
subjects affected / exposed	8 / 103 (7.77%)	1 / 23 (4.35%)	
occurrences (all)	8	1	
Infections and infestations			
COVID-19			
subjects affected / exposed	10 / 103 (9.71%)	1 / 23 (4.35%)	
occurrences (all)	12	1	
Urinary tract infection			
subjects affected / exposed	6 / 103 (5.83%)	3 / 23 (13.04%)	
occurrences (all)	6	3	
Upper respiratory tract infection			
subjects affected / exposed	7 / 103 (6.80%)	3 / 23 (13.04%)	
occurrences (all)	8	4	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	12 / 103 (11.65%)	2 / 23 (8.70%)	
occurrences (all)	13	2	
Hyperglycaemia			
subjects affected / exposed	7 / 103 (6.80%)	2 / 23 (8.70%)	
occurrences (all)	8	3	
Hypokalaemia			
subjects affected / exposed	13 / 103 (12.62%)	1 / 23 (4.35%)	
occurrences (all)	16	1	
Hypomagnesaemia			
subjects affected / exposed	10 / 103 (9.71%)	0 / 23 (0.00%)	
occurrences (all)	12	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2017	The primary purpose of this amendment was to align the visit schedule nomenclature with other CITADEL protocols.
15 August 2017	The primary purpose of this amendment was to address changes requested by the European Regulatory Agency.
11 September 2017	The primary purpose of this amendment was to address changes requested by the European Regulatory Agency.
25 October 2017	The primary purpose of this amendment was to remove the comparator arm (idelalisib) from the study.
11 July 2018	The primary purpose of this amendment was to modify the dose reduction schedules.
04 September 2018	The primary purpose of this amendment was to provide a list of CYP3A inhibitors and inducers.
06 December 2018	The primary purpose of the amendment was to stop the 1:1 allocation of participants after the 50th participant was enrolled and to enroll the remaining 50 participants to only 1 of the 2 treatment regimens being evaluated.
23 December 2019	The primary purpose of this amendment was to provide additional guidance on dose modification in the event of diarrhea and colitis and to define the end of the study, including the option to receive continued treatment with INCB050465 in a rollover protocol.
07 September 2022	The primary purpose of this amendment was to describe risks associated with COVID-19.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported