Clinical trial results:
A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 2 Study of the Efficacy and the Safety and Tolerability of BMS-986278 in Participants with Pulmonary Fibrosis

Summary

EudraCT number	2019-003992-21
Trial protocol	BE DE IT
Global end of trial date	22 September 2023

Results information

Result version number	v1 (current)
This version publication date	09 October 2024
First version publication date	09 October 2024

Trial information

Trial identification

Sponsor protocol code	IM027-040

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	22 September 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the rate of change in ppFVC from baseline to Week 26 in IPF participants randomized to receive BMS-986278 at 30 mg or 60 mg BID compared to those randomized to receive placebo.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 July 2020
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: 16
Country: Number of subjects enrolled	Mexico: 16
Country: Number of subjects enrolled	United States: 53
Country: Number of subjects enrolled	Argentina: 26
Country: Number of subjects enrolled	Chile: 48
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Germany: 32
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	France: 25
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	Israel: 15
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Japan: 75
Country: Number of subjects enrolled	Korea, Republic of: 17
Country: Number of subjects enrolled	Taiwan: 5
Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	China: 12
Worldwide total number of subjects	399
EEA total number of subjects	82

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)	106
From 65 to 84 years	287
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

493 participants were randomized into this study, 399 received treatment, and 304 received treatment in an optional treatment extension phase.

Period 1

Period 1 title	Treatment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	IPF Cohort: Placebo

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.

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

Dosage and administration details:

Placebo tablet administered twice per day

Arm title	IPF Cohort: 30 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered once per day

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

Dosage and administration details:

Placebo tablet administered once per day

Arm title	IPF Cohort: 60 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered twice per day

Arm title	PF-ILD Cohort: Placebo

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.

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

Dosage and administration details:

Placebo tablet administered twice per day

Arm title	PF-ILD Cohort: 30 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered once per day

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

Dosage and administration details:

Placebo tablet administered once per day

Arm title	PF-ILD Cohort: 60 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
30 mg BMS-986278 tablet administered twice per day

Number of subjects in period 1	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278
Started	92	91	93
Completed	82	82	84
Not completed	10	9	9
Consent withdrawn by subject	2	1	1
Adverse event, non-fatal	6	5	5
Participant no longer meets study criteria	-	1	2
Adverse event unrelated to study drug	-	2	1
Other reasons	2	-	-

Number of subjects in period 1	PF-ILD Cohort: Placebo	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278
Started	41	40	42
Completed	33	37	40
Not completed	8	3	2
Consent withdrawn by subject	-	1	1
Adverse event, non-fatal	6	1	-
Participant no longer meets study criteria	1	-	1
Adverse event unrelated to study drug	-	-	-
Other reasons	1	1	-

Period 2	
Period 2 title	Optional Treatment Extension (OTE)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes

Arm title	IPF Cohort: Placebo

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.

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

Dosage and administration details:

Placebo tablet administered twice per day

Arm title	IPF Cohort: 30 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

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

Dosage and administration details:

Placebo tablet administered once per day

Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered once per day

Arm title	IPF Cohort: 60 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered twice per day

Arm title	IPF Cohort - OTE Phase: BMS-986278 10mg

Arm description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Arm type	Experimental

Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg BMS-986278 tablet administered once per day

Arm title	PF-ILD Cohort: Placebo

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.

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

Dosage and administration details:

Placebo tablet administered twice per day

Arm title	PF-ILD Cohort: 30 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered once per day

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

Dosage and administration details:

Placebo tablet administered once per day

Arm title	PF-ILD Cohort: 60 mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg BMS-986278 tablet administered twice per day

Arm title	PF-ILD Cohort - OTE Phase: 10mg BMS-986278

Arm description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Arm type	Experimental
Investigational medicinal product name	BMS-986278
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg BMS-986278 tablet administered once per day

Number of subjects in period 2[1]	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278
Started	67	67	68
PBO BMS-986278 30 mg	33 [2]	0 [3]	0 [4]
PBO BMS-986278 60 mg	34 [5]	0 [6]	0 [7]
Completed	62	64	59
Not completed	5	3	9
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	3	-	1
Adverse event, non-fatal	1	2	7
Adverse event unrelated to study drug	-	1	1

Number of subjects in period 2[1]	IPF Cohort - OTE Phase: BMS-986278 10mg	PF-ILD Cohort: Placebo	PF-ILD Cohort: 30 mg BMS-986278
Started	11	27	28
PBO BMS-986278 30 mg	0 [8]	13 [9]	0 [10]
PBO BMS-986278 60 mg	0 [11]	14 [12]	0 [13]
Completed	8	23	27
Not completed	3	4	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	3	2	1
Adverse event unrelated to study drug	-	1	-

Number of subjects in period 2[1]	PF-ILD Cohort: 60 mg BMS-986278	PF-ILD Cohort - OTE Phase: 10mg BMS-986278
Started	32	4
PBO BMS-986278 30 mg	0 [14]	0 [15]
PBO BMS-986278 60 mg	0 [16]	0 [17]
Completed	31	4
Not completed	1	0

Adverse event, serious fatal	1	-
Consent withdrawn by subject	-	-
Adverse event, non-fatal	-	-
Adverse event unrelated to study drug	-	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: This period is an Optional Treatment Extension which did not include all participants.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This period is an Optional Treatment Extension which did not include all participants.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This period is an Optional Treatment Extension which did not include all participants.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This period is an Optional Treatment Extension which did not include all participants.

[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This period is an Optional Treatment Extension which did not include all participants.

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This milestone reflects a sub-group of the arm based on the dose level received.

Baseline characteristics

Reporting groups	
Reporting group title	IPF Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	IPF Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	IPF Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	

Reporting group values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278
Number of subjects	92	91	93
Age categorical Units: Subjects			
Adults (18-64 years)	26	20	27
From 65-84 years	65	69	65
85 years and over	1	2	1
Age Continuous Units: Years			
arithmetic mean	69.0	69.5	68.8
standard deviation	± 6.70	± 7.31	± 7.85
Sex: Female, Male Units: Participants			
Female	16	14	24
Male	76	77	69
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	25	25	27
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	65	64	64

More than one race	0	0	0
Unknown or Not Reported	1	2	1

Reporting group values	PF-ILD Cohort: Placebo	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278
Number of subjects	41	40	42
Age categorical Units: Subjects			
Adults (18-64 years)	12	10	11
From 65-84 years	29	30	29
85 years and over	0	0	2
Age Continuous Units: Years			
arithmetic mean	68.8	71.4	67.9
standard deviation	± 8.06	± 7.92	± 8.41
Sex: Female, Male Units: Participants			
Female	21	17	20
Male	20	23	22
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	9	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	31	27	32
More than one race	0	0	0
Unknown or Not Reported	2	2	4

Reporting group values	Total		
Number of subjects	399		
Age categorical Units: Subjects			
Adults (18-64 years)	106		
From 65-84 years	287		
85 years and over	6		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	112		
Male	287		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1		
Asian	100		
Native Hawaiian or Other Pacific Islander	0		

Black or African American	3		
White	283		
More than one race	0		
Unknown or Not Reported	12		

End points

End points reporting groups

Reporting group title	IPF Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	IPF Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	IPF Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	
Reporting group title	IPF Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	IPF Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	IPF Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	
Reporting group title	IPF Cohort - OTE Phase: BMS-986278 10mg
Reporting group description:	
Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase	
Reporting group title	PF-ILD Cohort: Placebo
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 30 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.	
Reporting group title	PF-ILD Cohort: 60 mg BMS-986278
Reporting group description:	
Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.	

Reporting group title	PF-ILD Cohort - OTE Phase: 10mg BMS-986278

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Primary: Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC) in IPF Participants

End point title	Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC) in IPF Participants[1]

End point description:

Forced vital capacity (FVC) is defined as the maximum capacity of air that a participant can exhale after a maximum inspiration as measured by the volume of air exhaled in a spirometer. It is reported as the percentage of the predicted value for the participant. Rate of change from baseline in ppFVC (%) estimated from measurements taken over 26 weeks of treatment in IPF participants. The decrease in ppFVC (%) is assumed to be linear within each participant over the 26 weeks. Prespecified to be collected for IPF Cohort only.

End point type	Primary

End point timeframe:

At baseline and week 26

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: Summary statistics only were planned for this endpoint.

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	59	67	0[2]
Units: Percent change from baseline				
arithmetic mean (standard error)	-2.807 (± 0.7286)	-3.068 (± 0.7335)	-1.120 (± 0.6691)	()

Notes:

[2] - This endpoint was prespecified in the protocol to apply to the IPF cohort only.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	0[4]		
Units: Percent change from baseline				
arithmetic mean (standard error)	()	()		

Notes:

[3] - This endpoint was prespecified in the protocol to apply to the IPF cohort only.

[4] - This endpoint was prespecified in the protocol to apply to the IPF cohort only.

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Adverse Events (AEs)

End point title	The Number of Participants Experiencing Adverse Events (AEs)

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Adverse events are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after last dose during the main study treatment phase

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	74	69	69	32

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	33	28		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point title	The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point description:

The number of participants who discontinued study treatment due to adverse events (AEs)

End point type	Secondary

End point timeframe:

From first dose up to 30 days after last dose during the main study treatment phase

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	9	9	6	7

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	The Number of Participants Experiencing Serious Adverse Events (SAEs)

End point description:

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires inpatient hospitalization or causes prolongation of existing hospitalization.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after last dose during the main study treatment phase

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	16	10	10	13

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	4	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Concentration (Cmax)

End point title	Maximum Concentration (Cmax)

End point description:

Cmax is defined as the maximum concentration of the analyte recorded in the participants. Cmax of BMS-986278 and BMT-327319 was derived from plasma concentration versus time data.

End point type	Secondary

End point timeframe:

On Day 1 and Week 4 (Day 29)

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[5]	8	13	0[6]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Day 1; Analyte: BMS-986278	()	465.0 (± 36.23)	1089.8 (± 42.06)	()
Day 1; Analyte: BMT-323719	()	114.66 (± 32.147)	167.35 (± 39.538)	()
Day 29; Analyte: BMS-986278	()	641.0 (± 27.68)	1301.3 (± 20.80)	()
Day 29; Analyte: BMT-323719	()	169.30 (± 28.104)	275.82 (± 34.554)	()

Notes:

[5] - Zero participants in this arm had evaluable Cmax measurements.

[6] - Zero participants in this arm had evaluable Cmax measurements.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Day 1; Analyte: BMS-986278	715.4 (± 2.87)	1112.3 (± 77.45)		
Day 1; Analyte: BMT-323719	94.8 (± 10.39)	189.6 (± 86.07)		
Day 29; Analyte: BMS-986278	691.9 (± 2.04)	1247.80 (± 29.84)		

Day 29; Analyte: BMT-323719	161.9 (± 30.60)	433.5 (± 58.73)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Who Died Due to Adverse Events (AEs)

End point title	The Number of Participants Who Died Due to Adverse Events (AEs)

End point description:

The number of participants who died while receiving study treatment due to an adverse event

End point type	Secondary

End point timeframe:

From first dose up to 30 days after last dose during the main study treatment phase

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	2	3	4	3

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Concentration (Tmax)

End point title	Time to Maximum Concentration (Tmax)

End point description:

Tmax is defined as the amount of time until the maximum concentration of the analyte is recorded in the participants

End point type	Secondary

End point timeframe:

On Day 1 and Week 4 (Day 29)

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	8	13	0[8]
Units: Hours				
median (full range (min-max))				
Day 1; Analyte: BMS-986278	(to)	2.0170 (1.567 to 4.100)	1.6670 (1.283 to 5.917)	(to)
Day 1; Analyte: BMT-323719	(to)	4.0670 (1.867 to 7.900)	4.0330 (1.900 to 8.000)	(to)
Day 29; Analyte: BMS-986278	(to)	1.9080 (1.450 to 4.117)	1.6750 (1.317 to 4.000)	(to)
Day 29; Analyte: BMT-323719	(to)	4.0670 (2.083 to 6.000)	2.0085 (1.417 to 7.850)	(to)

Notes:

[7] - Zero participants in this arm had evaluable Tmax measurements.

[8] - Zero participants in this arm had evaluable Tmax measurements.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: Hours				
median (full range (min-max))				
Day 1; Analyte: BMS-986278	1.55 (1.50 to 1.60)	2.01 (1.83 to 2.18)		
Day 1; Analyte: BMT-323719	7.96 (7.92 to 8.00)	4.10 (3.98 to 4.22)		
Day 29; Analyte: BMS-986278	2.68 (1.533 to 3.82)	4.06 (3.98 to 4.13)		
Day 29; Analyte: BMT-323719	5.79 (4.10 to 7.48)	3.74 (1.48 to 6.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Curve (AUC0-8)

End point title	Area Under Curve (AUC0-8)

End point description:

Area under the plasma concentration-time curve (AUC) from the timepoint of 0 hours to 24 hours post dose as measured on Day 1 and Week 4.

"99999"=N/A

End point type	Secondary

End point timeframe:

On Day 1 and Week 4 (Day 29)

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[9]	7	12	0[10]
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Day 1; Analyte: BMS-986278	()	1990.4530 (± 20.78185)	4430.5891 (± 31.16188)	()
Day 1; Analyte: BMT-323719	()	686.2045 (± 32.95587)	913.4300 (± 50.72949)	()
Day 29; Analyte: BMS-986278	()	2853.9081 (± 21.72108)	5433.1662 (± 25.62819)	()
Day 29; Analyte: BMT-323719	()	1179.6486 (± 31.27987)	1784.7369 (± 30.32795)	()

Notes:

[9] - Zero participants in this arm had evaluable AUC0-8 measurements.

[10] - Zero participants in this arm had evaluable AUC0-8 measurements.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Day 1; Analyte: BMS-986278	3358 (± 8.7)	4347 (± 61.3)		
Day 1; Analyte: BMT-323719	532 (± 99999)	2081 (± 99999)		
Day 29; Analyte: BMS-986278	3591 (± 99999)	8107 (± 99999)		
Day 29; Analyte: BMT-323719	99999 (± 99999)	2839 (± 45.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration Trough (Ctrough)

End point title	Concentration Trough (Ctrough)

End point description:

Ctrough is defined as the lowest concentration of drug in the blood immediately before the next dose is administered

End point type	Secondary

End point timeframe:

On Week 4 (Day 29) and Week 12 (Day 85)

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	56	60	0[12]
Units: ng/mL				
median (full range (min-max))				
Day 29-BMS-986278	(to)	92.1 (13.5 to 433)	217 (32.4 to 1540)	(to)
Day 85-BMS-986278	(to)	84.2 (16.7 to 389)	199 (5.37 to 726)	(to)
Day 29-BMT-323719	(to)	60.3 (12.9 to 207)	141 (52.4 to 384)	(to)
Day 85-BMT-323719	(to)	64.2 (0.200 to 174)	132 (0.200 to 371)	(to)

Notes:

[11] - Zero participants in this arm had evaluable Ctrough measurements.

[12] - Zero participants in this arm had evaluable Ctrough measurements.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	31		
Units: ng/mL				
median (full range (min-max))				
Day 29-BMS-986278	116.0000 (26.300 to 392.000)	286.0000 (49.600 to 2659.000)		
Day 85-BMS-986278	88.7000 (20.100 to 380.000)	196.0000 (68.000 to 1773.000)		
Day 29-BMT-323719	75.5000 (0.200 to 121.000)	177.5000 (0.200 to 693.000)		
Day 85-BMT-323719	67.4500 (11.000 to 186.000)	156.0000 (0.200 to 326.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Electrocardiogram (ECG) Abnormalities

End point title	The Number of Participants Experiencing Electrocardiogram (ECG) Abnormalities

End point description:

A frequency summary of investigator clinical interpretation of ECG abnormal findings is listed.

End point type	Secondary

End point timeframe:
At Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	27	18	31	5

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	9	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Vital Sign Measurements

End point title	Change from Baseline in Vital Sign Measurements

End point description:
The change from baseline in select vital sign measurements

End point type	Secondary

End point timeframe:
At baseline and at Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Change from baseline in mmHg				
median (full range (min-max))				
Sitting Diastolic - 0 Hours Pre-Dose	0.0 (-20 to 19)	0.0 (-21 to 20)	1.0 (-16 to 24)	3.0 (-9 to 13)
Standing Diastolic - 0 Hours Pre-Dose	-2.0 (-18 to 15)	0.0 (-28 to 22)	1.0 (-24 to 30)	1.5 (-15 to 26)
Supine Diastolic - 0 Hours Pre-Dose	-1.0 (-12 to 18)	1.0 (-25 to 17)	1.0 (-23 to 19)	2.5 (-13 to 15)
Sitting Systolic - 0 Hours Pre-Dose	-1.0 (-29 to 37)	1.0 (-23 to 30)	3.0 (-22 to 34)	0.0 (-35 to 17)

Standing Systolic - 0 Hours Pre-Dose	-3.0 (-27 to 28)	-1.5 (-35 to 31)	3.0 (-28 to 36)	0.5 (-38 to 33)
Supine Systolic - 0 Hours Pre-Dose	0.0 (-24 to 34)	0.0 (-25 to 43)	3.0 (-24 to 24)	2.5 (-29 to 25)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Change from baseline in mmHg				
median (full range (min-max))				
Sitting Diastolic - 0 Hours Pre-Dose	1.0 (-18 to 17)	-1.0 (-27 to 15)		
Standing Diastolic - 0 Hours Pre-Dose	-0.5 (-14 to 20)	0.0 (-18 to 16)		
Supine Diastolic - 0 Hours Pre-Dose	0.0 (-8 to 17)	0.0 (-14 to 14)		
Sitting Systolic - 0 Hours Pre-Dose	1.0 (-22 to 37)	-1.0 (-49 to 34)		
Standing Systolic - 0 Hours Pre-Dose	0.5 (-23 to 28)	0.0 (-34 to 26)		
Supine Systolic - 0 Hours Pre-Dose	2.0 (-20 to 49)	-3.0 (-30 to 23)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with ≥ 10% Absolute Decline in ppFVC (%)

End point title	The Number of Participants with ≥ 10% Absolute Decline in ppFVC (%)

End point description:

The number of participants with ≥ 10% absolute decline in percent predicted forced vital capacity (ppFVC) at pre-specified timepoints.

ppFVC is the maximum capacity of air that a participant can exhale after a maximum inspiration. It measures the volume of air exhaled in a spirometer, after a maximal inspiration. It is reported as the percentage of the predicted value for the participants.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, 16, 20, and 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	75	75	35
Units: Participants				
Week 4	3	0	2	0
Week 8	4	4	3	2

Week 12	4	1	3	1
Week 16	3	2	2	2
Week 20	10	1	1	2
Week 26	7	7	4	3

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	36		
Units: Participants				
Week 4	0	0		
Week 8	0	0		
Week 12	0	0		
Week 16	0	0		
Week 20	1	0		
Week 26	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC) in PF-ILD Participants

End point title	Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC) in PF-ILD Participants

End point description:

Rate of change from baseline in ppFVC (%) estimated from measurements taken over 26 weeks of treatment in PF-ILD participants.

ppFVC is the maximum capacity of air that a patient can exhale after a maximum inspiration. It measures the volume of air exhaled in a spirometer, after a maximal inspiration. It is reported as the percentage of the predicted value for the patient. This endpoint was prespecified in the protocol to be collected for PF-ILD Cohort only.

End point type	Secondary

End point timeframe:

From first dose up to Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[13]	0[14]	0[15]	22
Units: Percent change from baseline				
arithmetic mean (standard error)	()	()	()	-2.681 (± 1.4730)

Notes:

[13] - This endpoint was prespecified in the protocol to apply to the PF-ILD cohort only.

[14] - This endpoint was prespecified in the protocol to apply to the PF-ILD cohort only.

[15] - This endpoint was prespecified in the protocol to apply to the PF-ILD cohort only.

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	31		
Units: Percent change from baseline				
arithmetic mean (standard error)	2.717 (± 0.9054)	-1.203 (± 0.8808)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants with 0% Change in ppFVC (%)

End point title	The Number of Participants with 0% Change in ppFVC (%)

End point description:

The number of participants with 0% change in percent predicted forced vital capacity (ppFVC) at pre-specified timepoints.

ppFVC is the maximum capacity of air that a participant can exhale after a maximum inspiration. It measures the volume of air exhaled in a spirometer, after a maximal inspiration. It is reported as the percentage of the predicted value for the participants.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, 16, 20, and 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	75	75	35
Units: Participants				
Week 4	48	41	33	14
Week 8	47	43	69	15
Week 12	46	43	39	17
Week 16	51	45	39	15
Week 20	51	40	33	18
Week 26	53	42	34	17

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	36		
Units: Participants				
Week 4	12	13		
Week 8	13	12		
Week 12	13	13		
Week 16	11	18		
Week 20	15	18		
Week 26	22	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence ≥ 10% Absolute Decline in ppFVC (%)

End point title	Time to First Occurrence ≥ 10% Absolute Decline in ppFVC (%)

End point description:

The amount of time in weeks to the participant's first occurrence ≥ 10% absolute decline in Percent Predicted Forced Vital Capacity (ppFVC). ppFVC is the maximum capacity of air that a participant can exhale after a maximum inspiration. It measures the volume of air exhaled in a spirometer, after a maximal inspiration. It is reported as the percentage of the predicted value for the participants. A participant’s time is censored at the last observed time prior to discontinuation if a participant discontinues study without event, or at week 26 if a participant does not experience the event until the end of week 26. Kaplan-Meier product limit method will be employed to estimate the survival curves.

"99999"=N/A

End point type	Secondary

End point timeframe:

From first dose to the first occurrence of ≥ 10% absolute decline in ppFVC

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	9	6	5
Units: Weeks				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (26.3 to 99999)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	1		
Units: Weeks				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC)

End point title	Absolute Change From Baseline in Percent Predicted Forced Vital Capacity (ppFVC)

End point description:

The absolute change in ppFVC (%) is measured from baseline up to the pre-specified timepoints of Weeks 4, 8, 12, 16, 20, and 26.

ppFVC is the maximum capacity of air that a participant can exhale after a maximum inspiration. It measures the volume of air exhaled in a spirometer, after a maximal inspiration. It is reported as the percentage of the predicted value for the participants.

End point type	Secondary

End point timeframe:

From baseline up to Weeks 4, 8, 12, 16, 20, and 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	75	75	35
Units: mL				
arithmetic mean (standard deviation)				
Absolute change from Baseline to Week 4	-1.491 (± 4.3773)	-0.482 (± 4.2499)	0.023 (± 5.4007)	1.119 (± 6.0123)
Absolute change from Baseline to Week 8	-1.783 (± 4.5234)	-1.046 (± 4.8192)	-1.079 (± 5.1294)	-0.334 (± 7.6326)
Absolute change from Baseline to Week 12	-1.974 (± 5.0324)	-0.589 (± 4.8575)	-1.109 (± 5.9152)	-2.012 (± 5.5436)
Absolute change from Baseline to Week 16	-2.422 (± 5.0040)	-1.042 (± 5.1644)	-1.220 (± 4.3475)	-1.180 (± 7.6897)
Absolute change from Baseline to Week 20	-2.625 (± 4.8978)	-1.717 (± 3.9049)	-0.387 (± 4.2802)	-2.650 (± 4.2813)
Absolute change from Baseline to Week 26	-2.807 (± 6.0959)	-3.068 (± 5.6339)	-1.120 (± 5.4768)	-2.681 (± 6.9089)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	36		
Units: mL				

arithmetic mean (standard deviation)				
Absolute change from Baseline to Week 4	0.327 (± 3.1862)	0.217 (± 3.5946)		
Absolute change from Baseline to Week 8	0.966 (± 3.2631)	0.475 (± 3.2802)		
Absolute change from Baseline to Week 12	0.114 (± 4.2490)	0.196 (± 3.7168)		
Absolute change from Baseline to Week 16	-0.197 (± 4.5490)	-0.394 (± 4.3439)		
Absolute change from Baseline to Week 20	-0.382 (± 4.6328)	-0.272 (± 6.0198)		
Absolute change from Baseline to Week 26	-2.717 (± 4.8758)	-1.203 (± 4.9043)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Forced Vital Capacity (FVC)

End point title	Absolute Change From Baseline in Forced Vital Capacity (FVC)

End point description:

Forced vital capacity (FVC) is defined as the amount of air that can be forcibly exhaled from your lungs after taking the deepest breath possible. The absolute change in FVC (mL) is measured from baseline up to Weeks 4, 8, 12, 16, 20, and 26.

End point type	Secondary

End point timeframe:

From baseline up to Weeks 4, 8, 12, 16, 20, and 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	78	75	75	35
Units: mL				
arithmetic mean (standard deviation)				
Absolute change from Baseline to Week 4	-54.7 (± 153.50)	-21.2 (± 142.25)	4.3 (± 181.75)	39.1 (± 152.57)
Absolute change from Baseline to Week 8	-62.7 (± 157.81)	-38.2 (± 173.96)	-36.1 (± 165.74)	-8.8 (± 180.10)
Absolute change from Baseline to Week 12	-75.5 (± 184.02)	-27.2 (± 173.23)	-35.4 (± 176.48)	-61.6 (± 177.42)
Absolute change from Baseline to Week 16	-88.2 (± 183.44)	-41.0 (± 184.89)	-45.8 (± 152.79)	-44.3 (± 222.44)
Absolute change from Baseline to Week 20	-95.6 (± 181.41)	-70.0 (± 142.70)	-21.1 (± 154.05)	-84.6 (± 134.01)
Absolute change from Baseline to Week 26	-106.4 (± 214.94)	-117.3 (± 207.60)	-48.8 (± 184.97)	-99.1 (± 212.04)

End point values	PF-ILD Cohort:	PF-ILD Cohort:		

	30 mg BMS-986278	60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	36		
Units: mL				
arithmetic mean (standard deviation)				
Absolute change from Baseline to Week 4	6.0 (± 107.11)	-0.30 (± 113.07)		
Absolute change from Baseline to Week 8	24.7 (± 92.87)	11.2 (± 106.11)		
Absolute change from Baseline to Week 12	-1.5 (± 129.64)	0.9 (± 128.40)		
Absolute change from Baseline to Week 16	-22.8 (± 146.75)	-12.1 (± 140.79)		
Absolute change from Baseline to Week 20	-15.2 (± 168.21)	-3.9 (± 222.29)		
Absolute change from Baseline to Week 26	-100.0 (± 166.30)	-37.7 (± 179.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Single Breath Diffusing Capacity of Carbon Monoxide (DLCO SB)

End point title	Absolute Change From Baseline in Single Breath Diffusing Capacity of Carbon Monoxide (DLCO SB)

End point description:

The absolute change in single breath diffusing capacity of carbon monoxide (DLCO SB) (mL/min/mmHg) (corrected for hemoglobin) from baseline to Week 26. DLCO is defined as a measurement of the extent to which oxygen passes from the alveoli into the blood. Baseline is defined as first dose.

End point type	Secondary

End point timeframe:

From first dose up to Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	40	44	20
Units: mL/min/mmHg				
median (full range (min-max))	-0.4664 (-17.023 to 5.725)	-0.3418 (-14.024 to 3.190)	-0.4518 (-5.449 to 3.888)	-0.2352 (-15.031 to 9.564)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	32		
Units: mL/min/mmHg				
median (full range (min-max))	-0.3269 (-8.902 to 2.086)	-0.1829 (-12.766 to 7.063)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change from Baseline in Walking Endurance/Distance

End point title	Absolute Change from Baseline in Walking Endurance/Distance

End point description:

The absolute change in walking endurance/distance as determined by the 6-minute walk test (6MWT) from baseline to Week 26. The 6-Minute Walk Test (6MWT) is a submaximal exercise test used to assess aerobic capacity and endurance. Baseline is defined as first dose.

End point type	Secondary

End point timeframe:

From first dose up to Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	62	70	25
Units: Meters				
median (full range (min-max))	0.0 (-495 to 119)	3.0 (-260 to 138)	6.0 (-370 to 92)	11.0000 (-315.833 to 175.000)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	37		
Units: Meters				
median (full range (min-max))	0.0000 (-220.000 to 188.400)	-14.0000 (-173.000 to 242.857)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in Percent Predicted Single Breath Diffusing Capacity of Carbon Monoxide (ppDLCO SB)

End point title	Absolute Change From Baseline in Percent Predicted Single Breath Diffusing Capacity of Carbon Monoxide (ppDLCO SB)

End point description:

The absolute change in percent predicted single breath diffusing capacity of carbon monoxide (DLCO SB) (mL/min/mmHg) (corrected for hemoglobin) from baseline to Week 26. DLCO is defined as a measurement of the extent to which oxygen passes from the alveoli into the blood. Baseline is defined as first dose.

End point type	Secondary

End point timeframe:

From first dose up to Week 26

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	40	44	21
Units: mL/min/mmHg				
median (full range (min-max))	-1.4634 (-38.133 to 64.451)	-0.3470 (-26.548 to 51.300)	-3.2455 (-48.939 to 35.463)	-1.000 (-22.176 to 11.587)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	34		
Units: mL/min/mmHg				
median (full range (min-max))	-1.4683 (-62.971 to 13.767)	-1.4609 (-13.016 to 20.997)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Acute Exacerbation

End point title	Time to First Acute Exacerbation

End point description:

Time to first acute exacerbations of lung fibrosis was measured from the day of first dose up to the day of first acute exacerbation. Participants who discontinued the study treatment prior to the end of the main study without experiencing the event were excluded from the analysis. A participant's time was censored at the last observed time prior to discontinuation if a participant discontinued study without event, or at week 26 if a participant did not experience the event until the end of week 26.

Acute exacerbations were defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new
widespread alveolar abnormality, as follows:
1) Acute worsening or development of dyspnea (< 1 month duration)

2) Imaging with new bilateral ground-glass opacity and/or consolidation superimposed on a background pattern consistent with usual interstitial pneumonia
3) Respiratory deterioration not fully explained by cardiac failure or fluid overload

"99999"=N/A

End point type	Secondary

End point timeframe:

From the first dose up to the day of the first acute exacerbation or Week 26, whichever comes first

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	1	3
Units: Weeks				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[16]	1		
Units: Weeks				
median (confidence interval 95%)	(to)	99999 (99999 to 99999)		

Notes:

[16] - Zero participants in this arm experienced acute exacerbation.

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Acute Exacerbation

End point title	The Number of Participants Experiencing Acute Exacerbation

End point description:

The number of participants experiencing acute exacerbations of lung fibrosis.

Acute exacerbations were defined as an acute, clinically significant, respiratory deterioration characterized by evidence of new
widespread alveolar abnormality, as follows:
1) Acute worsening or development of dyspnea (< 1 month duration)
2) Imaging with new bilateral ground-glass opacity and/or consolidation superimposed on a background pattern consistent with usual interstitial pneumonia
3) Respiratory deterioration not fully explained by cardiac failure or fluid overload

End point type	Secondary

End point timeframe:

From the first dose up to the day of the first acute exacerbation or Week 26, whichever comes first

End point values	IPF Cohort: Placebo	IPF Cohort: 30 mg BMS-986278	IPF Cohort: 60 mg BMS-986278	PF-ILD Cohort: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	91	93	41
Units: Participants	2	3	1	3

End point values	PF-ILD Cohort: 30 mg BMS-986278	PF-ILD Cohort: 60 mg BMS-986278		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: Participants	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for all-cause mortality from their randomization to study completion, (up to approximately 2 years). SAEs and Other AEs were assessed from first dose to 30 days following last dose (up to approximately 58 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	IPF Cohort - Main Study - BMS 30mg

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

Reporting group title	IPF Cohort - Main Study - BMS 60mg

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Reporting group title	IPF Cohort - Main Study - Placebo

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received placebo twice a day for up to 26 weeks.

Reporting group title	IPF Cohort - OTE - BMS 30mg

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Reporting group title	IPF Cohort - OTE - BMS 60mg

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day during the OTE phase.

Reporting group title	IPF Cohort - OTE - BMS 10mg

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Reporting group title	PF-ILD Cohort - OTE BMS 30mg

Reporting group description:

Participants in the Progressive Fibrotic Idiopathic Pulmonary Fibrosis (IPF) cohort who received 30 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Reporting group title	PF-ILD Cohort - Main Study - BMS 30mg

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received one 30 mg BMS-986278 and one placebo per day for up to 26 weeks.

Reporting group title	PF-ILD Cohort - Main Study - BMS 60mg

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 30 mg BMS-986278 twice a day for a total of 60 mg for up to 26 weeks.

Reporting group title	PF-ILD Cohort - Main Study - Placebo

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received placebo twice a day for up to 26 weeks.

Reporting group title	PF-ILD Cohort - OTE BMS 60mg

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 60 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Reporting group title	PF-ILD Cohort - OTE BMS 10mg

Reporting group description:

Participants in the Progressive Fibrotic Interstitial Lung Disease (PF-ILD) cohort who received 10 mg of BMS-986278 during the Optional Treatment Extension (OTE) phase

Serious adverse events	IPF Cohort - Main Study - BMS 30mg	IPF Cohort - Main Study - BMS 60mg	IPF Cohort - Main Study - Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 91 (10.99%)	10 / 93 (10.75%)	16 / 92 (17.39%)
number of deaths (all causes)	4	5	4
number of deaths resulting from adverse events	3	4	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric adenoma			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Gastric cancer			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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 squamous cell carcinoma stage I			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Granulomatosis with polyangiitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 91 (1.10%)	1 / 93 (1.08%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypersensitivity pneumonitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	4 / 91 (4.40%)	0 / 93 (0.00%)	3 / 92 (3.26%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung opacity			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Pulmonary fibrosis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Pulmonary oedema			

subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Respiratory failure			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Investigations			
Forced vital capacity decreased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Acute myocardial infarction			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Atrial fibrillation			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Myocardial infarction			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Pericarditis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Nervous system disorders			

Cerebrovascular accident			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatic nerve palsy			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ischaemic			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
Cholangitis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Biliary dyskinesia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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 retention			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (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
COVID-19			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Clostridium difficile infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	2 / 92 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lower respiratory tract infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 91 (1.10%)	1 / 93 (1.08%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (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
Fluid retention			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	IPF Cohort - OTE - BMS 30mg	IPF Cohort - OTE - BMS 60mg	IPF Cohort - OTE - BMS 10mg
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 100 (19.00%)	23 / 102 (22.55%)	4 / 11 (36.36%)
number of deaths (all causes)	4	6	3
number of deaths resulting from adverse events	3	5	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Bladder cancer			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Gastric adenoma			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 100 (0.00%)	3 / 102 (2.94%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung squamous cell carcinoma stage I			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Vascular disorders			
Granulomatosis with polyangiitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Vasculitis			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Dyspnoea			
subjects affected / exposed	0 / 100 (0.00%)	2 / 102 (1.96%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity pneumonitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic interstitial pneumonia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	8 / 100 (8.00%)	7 / 102 (6.86%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 9	1 / 7	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 1
Interstitial lung disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung opacity			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Pneumothorax			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Pulmonary embolism			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			

subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Investigations			
Forced vital capacity decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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

Fall			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Pericardial effusion			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Sciatic nerve palsy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Iron deficiency anaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Ear and labyrinth disorders			

Vertigo positional			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ischaemic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Diarrhoea			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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			
Bile duct stone			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Cholangitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dyskinesia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary retention			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Spinal stenosis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Herpes zoster			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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

Diabetic foot infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 100 (1.00%)	2 / 102 (1.96%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 11 (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
Pneumonia legionella			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (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

Serious adverse events	PF-ILD Cohort - OTE BMS 30mg	PF-ILD Cohort - Main Study - BMS 30mg	PF-ILD Cohort - Main Study - BMS 60mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 41 (19.51%)	4 / 40 (10.00%)	6 / 42 (14.29%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric adenoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung squamous cell carcinoma stage I			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Granulomatosis with polyangiitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity pneumonitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Hypoxia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Interstitial lung disease			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung opacity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Forced vital capacity decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (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

Animal bite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Atrial fibrillation			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatic nerve palsy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ischaemic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (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
Haematemesis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hiatus hernia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dyskinesia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Calculus urinary			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Herpes zoster			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (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
Pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (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
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-ILD Cohort - Main Study - Placebo	PF-ILD Cohort - OTE BMS 60mg	PF-ILD Cohort - OTE BMS 10mg
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 41 (31.71%)	7 / 46 (15.22%)	0 / 4 (0.00%)
number of deaths (all causes)	4	3	0
number of deaths resulting from adverse events	3	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric adenoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung squamous cell carcinoma stage I			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic syndrome			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Granulomatosis with polyangiitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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			
Asthenia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Dyspnoea			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity pneumonitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Interstitial lung disease			
subjects affected / exposed	2 / 41 (4.88%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung opacity			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Pleurisy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Pulmonary fibrosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			
Forced vital capacity decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Femur fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Atrial flutter			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Sciatic nerve palsy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ischaemic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Inguinal hernia			

subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Hiatus hernia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dyskinesia			

subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Cholecystitis acute			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (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
Spinal stenosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (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
Urinary tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	IPF Cohort - Main Study - BMS 30mg	IPF Cohort - Main Study - BMS 60mg	IPF Cohort - Main Study - Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 91 (59.34%)	51 / 93 (54.84%)	57 / 92 (61.96%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	3 / 91 (3.30%)	7 / 93 (7.53%)	1 / 92 (1.09%)
occurrences (all)	3	7	1
Hypotension			
subjects affected / exposed	2 / 91 (2.20%)	4 / 93 (4.30%)	1 / 92 (1.09%)
occurrences (all)	2	4	1
Orthostatic hypotension			
subjects affected / exposed	7 / 91 (7.69%)	5 / 93 (5.38%)	9 / 92 (9.78%)
occurrences (all)	7	5	10
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 91 (2.20%)	0 / 93 (0.00%)	2 / 92 (2.17%)
occurrences (all)	2	0	2
Fatigue			
subjects affected / exposed	5 / 91 (5.49%)	1 / 93 (1.08%)	4 / 92 (4.35%)
occurrences (all)	5	1	5
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 91 (6.59%)	10 / 93 (10.75%)	5 / 92 (5.43%)
occurrences (all)	8	10	6
Dyspnoea			

subjects affected / exposed	4 / 91 (4.40%)	4 / 93 (4.30%)	8 / 92 (8.70%)
occurrences (all)	4	4	9
Idiopathic pulmonary fibrosis			
subjects affected / exposed	3 / 91 (3.30%)	2 / 93 (2.15%)	2 / 92 (2.17%)
occurrences (all)	3	2	2
Oropharyngeal pain			
subjects affected / exposed	2 / 91 (2.20%)	1 / 93 (1.08%)	1 / 92 (1.09%)
occurrences (all)	2	1	1
Pulmonary hypertension			
subjects affected / exposed	1 / 91 (1.10%)	2 / 93 (2.15%)	1 / 92 (1.09%)
occurrences (all)	1	2	1
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Tooth fracture			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 91 (2.20%)	2 / 93 (2.15%)	3 / 92 (3.26%)
occurrences (all)	2	2	3
Dizziness exertional			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	6 / 91 (6.59%)	5 / 93 (5.38%)	3 / 92 (3.26%)
occurrences (all)	7	6	4
Eye disorders			
Cataract			

subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 91 (0.00%)	5 / 93 (5.38%)	5 / 92 (5.43%)
occurrences (all)	0	5	5
Dental caries			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	10 / 91 (10.99%)	11 / 93 (11.83%)	12 / 92 (13.04%)
occurrences (all)	11	12	14
Vomiting			
subjects affected / exposed	0 / 91 (0.00%)	2 / 93 (2.15%)	4 / 92 (4.35%)
occurrences (all)	0	2	5
Nausea			
subjects affected / exposed	5 / 91 (5.49%)	4 / 93 (4.30%)	3 / 92 (3.26%)
occurrences (all)	5	7	3
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	1 / 91 (1.10%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	2 / 91 (2.20%)	2 / 93 (2.15%)	1 / 92 (1.09%)
occurrences (all)	2	2	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 91 (4.40%)	3 / 93 (3.23%)	1 / 92 (1.09%)
occurrences (all)	4	3	1
Arthralgia			
subjects affected / exposed	4 / 91 (4.40%)	4 / 93 (4.30%)	5 / 92 (5.43%)
occurrences (all)	5	4	5
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2

COVID-19			
subjects affected / exposed	3 / 91 (3.30%)	9 / 93 (9.68%)	7 / 92 (7.61%)
occurrences (all)	3	9	7
Bronchitis			
subjects affected / exposed	4 / 91 (4.40%)	1 / 93 (1.08%)	1 / 92 (1.09%)
occurrences (all)	4	1	2
Influenza			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
Laryngitis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 93 (1.08%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 91 (3.30%)	1 / 93 (1.08%)	1 / 92 (1.09%)
occurrences (all)	3	2	2
Nasopharyngitis			
subjects affected / exposed	6 / 91 (6.59%)	3 / 93 (3.23%)	2 / 92 (2.17%)
occurrences (all)	6	3	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 91 (1.10%)	4 / 93 (4.30%)	1 / 92 (1.09%)
occurrences (all)	1	4	1
Hyperglycaemia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 93 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	IPF Cohort - OTE - BMS 30mg	IPF Cohort - OTE - BMS 60mg	IPF Cohort - OTE - BMS 10mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 100 (40.00%)	43 / 102 (42.16%)	8 / 11 (72.73%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	3 / 100 (3.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
Hypotension			
subjects affected / exposed	0 / 100 (0.00%)	3 / 102 (2.94%)	1 / 11 (9.09%)
occurrences (all)	0	3	1
Orthostatic hypotension			
subjects affected / exposed	3 / 100 (3.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	3	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	2 / 100 (2.00%)	4 / 102 (3.92%)	0 / 11 (0.00%)
occurrences (all)	2	4	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 100 (3.00%)	7 / 102 (6.86%)	1 / 11 (9.09%)
occurrences (all)	3	8	1
Dyspnoea			
subjects affected / exposed	3 / 100 (3.00%)	6 / 102 (5.88%)	0 / 11 (0.00%)
occurrences (all)	3	6	0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	3 / 100 (3.00%)	6 / 102 (5.88%)	1 / 11 (9.09%)
occurrences (all)	3	8	1
Oropharyngeal pain			

subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Pulmonary hypertension			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Tooth fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Dizziness exertional			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	3 / 100 (3.00%)	4 / 102 (3.92%)	0 / 11 (0.00%)
occurrences (all)	3	4	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 100 (2.00%)	2 / 102 (1.96%)	1 / 11 (9.09%)
occurrences (all)	3	2	1
Dental caries			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	4 / 100 (4.00%)	8 / 102 (7.84%)	1 / 11 (9.09%)
occurrences (all)	4	9	1
Vomiting			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 100 (1.00%)	3 / 102 (2.94%)	1 / 11 (9.09%)
occurrences (all)	1	3	1
Arthralgia			
subjects affected / exposed	3 / 100 (3.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	5	0	0
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
COVID-19			
subjects affected / exposed	12 / 100 (12.00%)	8 / 102 (7.84%)	1 / 11 (9.09%)
occurrences (all)	12	8	1
Bronchitis			
subjects affected / exposed	4 / 100 (4.00%)	5 / 102 (4.90%)	1 / 11 (9.09%)
occurrences (all)	4	5	1
Influenza			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 100 (1.00%)	3 / 102 (2.94%)	0 / 11 (0.00%)
occurrences (all)	1	3	0
Nasopharyngitis			
subjects affected / exposed	3 / 100 (3.00%)	1 / 102 (0.98%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	1 / 11 (9.09%)
occurrences (all)	0	1	1

Non-serious adverse events	PF-ILD Cohort - OTE BMS 30mg	PF-ILD Cohort - Main Study - BMS 30mg	PF-ILD Cohort - Main Study - BMS 60mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 41 (43.90%)	23 / 40 (57.50%)	24 / 42 (57.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 42 (2.38%)
occurrences (all)	0	0	1

Hypotension			
subjects affected / exposed	0 / 41 (0.00%)	4 / 40 (10.00%)	3 / 42 (7.14%)
occurrences (all)	0	4	3
Orthostatic hypotension			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	4 / 42 (9.52%)
occurrences (all)	2	2	4
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	3 / 42 (7.14%)
occurrences (all)	1	0	3
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 41 (7.32%)	3 / 40 (7.50%)	5 / 42 (11.90%)
occurrences (all)	3	3	5
Dyspnoea			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	0 / 42 (0.00%)
occurrences (all)	2	2	0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	3
Pulmonary hypertension			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Investigations			

Blood bilirubin increased			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	0 / 42 (0.00%)
occurrences (all)	1	1	0
Injury, poisoning and procedural complications			
Tooth fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	4 / 42 (9.52%)
occurrences (all)	0	0	4
Dizziness exertional			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 41 (4.88%)	1 / 40 (2.50%)	2 / 42 (4.76%)
occurrences (all)	2	1	2
Eye disorders			
Cataract			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	2 / 42 (4.76%)
occurrences (all)	1	1	2
Dental caries			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 41 (4.88%)	6 / 40 (15.00%)	3 / 42 (7.14%)
occurrences (all)	2	8	3
Vomiting			

subjects affected / exposed	0 / 41 (0.00%)	3 / 40 (7.50%)	0 / 42 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	0 / 41 (0.00%)	4 / 40 (10.00%)	1 / 42 (2.38%)
occurrences (all)	0	4	1
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 41 (0.00%)	3 / 40 (7.50%)	0 / 42 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	2 / 42 (4.76%)
occurrences (all)	0	0	2
Arthralgia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	2 / 42 (4.76%)
occurrences (all)	1	0	2
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 41 (0.00%)	2 / 40 (5.00%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	7 / 41 (17.07%)	5 / 40 (12.50%)	6 / 42 (14.29%)
occurrences (all)	8	5	6
Bronchitis			
subjects affected / exposed	2 / 41 (4.88%)	1 / 40 (2.50%)	0 / 42 (0.00%)
occurrences (all)	3	3	0
Influenza			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 41 (0.00%)	2 / 40 (5.00%)	0 / 42 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	3 / 42 (7.14%)
occurrences (all)	1	0	3
Nasopharyngitis			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	3 / 42 (7.14%)
occurrences (all)	1	1	5
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 42 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	PF-ILD Cohort - Main Study - Placebo	PF-ILD Cohort - OTE BMS 60mg	PF-ILD Cohort - OTE BMS 10mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 41 (46.34%)	23 / 46 (50.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	2	1	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 41 (2.44%)	2 / 46 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Fatigue			
subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 41 (9.76%)	2 / 46 (4.35%)	1 / 4 (25.00%)
occurrences (all)	5	2	1
Dyspnoea			
subjects affected / exposed	6 / 41 (14.63%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	6	1	0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Tooth fracture			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Supraventricular extrasystoles			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 41 (9.76%)	2 / 46 (4.35%)	0 / 4 (0.00%)
occurrences (all)	4	5	0
Dizziness exertional			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 41 (7.32%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	6	1	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 41 (2.44%)	3 / 46 (6.52%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 41 (2.44%)	2 / 46 (4.35%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Dental caries			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	6 / 41 (14.63%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	10	2	0
Vomiting			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	3 / 41 (7.32%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	1 / 41 (2.44%)	2 / 46 (4.35%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	2 / 41 (4.88%)	6 / 46 (13.04%)	1 / 4 (25.00%)
occurrences (all)	2	6	1
Bronchitis			
subjects affected / exposed	2 / 41 (4.88%)	3 / 46 (6.52%)	1 / 4 (25.00%)
occurrences (all)	6	3	1
Influenza			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Laryngitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)	1 / 46 (2.17%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Nasopharyngitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	0 / 41 (0.00%)	0 / 46 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 46 (2.17%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 February 2020	Added Medical Monitor; Added eligibility check; Added pregnancy testing for women; < 55 years of age (per IRB request); Removed Study Acknowledgement/Disclosure page; Clarified drug dispensing frequency and treatment compliance check; Clarified when vital signs and orthostatic BP and HR will be measured; Removed approximate blood; volumes to be collected throughout the study; Clarified when to withhold study treatment; Clarified "progression" definition for PF-ILD inclusion criteria; Lowered age limit for PF-ILD cohort; Broadened language about excluding significant lung disease from both cohorts; Permitted stable DMARD use for PF-ILD participants; Added HBcAb and pregnancy test, and removed cannabinoids from Laboratory Assessments
25 June 2020	Changed Medical Monitor; Added an optional treatment extension for IPF and PF-ILD participants who complete the main study; Extended intensive PK substudy participation to the PF-ILD cohort and adjusted the number of participants to be included; Clarified the posttreatment HRCT requirement for the main study; Added spirometry measurements to Week 20 in the main study; Removed the FEF25-75 test from spirometry parameters; Added a sparse PK sample collection at the Week 4 visit in the main study; Modified the secondary and exploratory endpoints; Added a statistical analysis for the PF-ILD cohort once the cohort completes the main study; Incorporated changes requested by Health Authority and Ethics Committee; Added "end of study" definition; Excluded participants with total bilirubin greater than 1.5 x ULN and specified the range permitted for those with Gilbert's syndrome; Excluded participants with history of allergy to BMS-986278 or history of significant drug allergy; Clarified additional ECG assessments to be performed as clinically indicated; Added a caption title to create Table 10
14 January 2021	Updated sections throughout protocol to allow participants with PF-ILD to remain on stable background therapies; Clarified restriction on concomitant use of anti-fibrotics during the main study; Updated screening period from 28 to 42 days; Updated several inclusion and exclusion criteria; Added COVID-19-related risk assessment; Added language for collecting AEs and SAEs related to COVID-19; Added serum collections for possible assessments of SARS-CoV-2 serologic status and related exploratory objective and endpoint; Added clinical laboratory sampling on Day 1 of the OTE; Updated study treatment discontinuation criteria; Added requirement to record date and time of last study treatment administration prior to PK study visits; Modified language referring to number of participants enrolled per treatment arm in the PK substudy; Revised language throughout protocol to provide sites more flexibility regarding order and timing of study procedures; Clarified definitions for orthostatic hypotension and orthostatic tachycardia; Clarified the Hepatitis B virus DNA serology testing; Added AE intensity definitions; Updated definitions for Full Analysis Set and Safety populations; Clarified requirement for review of dosing diaries; Added section for OTE rationale; Revised language on nintedanib nonclinical toxicology; Updated contact information for Clinical Trial Physician/Medical Monitor; Added Clinical Scientist name and contact info to title page.
21 December 2021	Revised the PET tracer substudy to allow incorporation of participants with PF-ILD; Clarified phrasing in inclusion and exclusion criteria; Added 2 secondary endpoints evaluating the effect of BMS-986278 treatment
22 September 2022	Updated BMS Japan address; Added clarifying sentence in Section 5.1 and 7.3.1; Updated header and footnote c in Table 7; Added clarifying text in Section 10.4.4.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported