Clinical trial results:
A PHASE 2, 24-WEEK, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED,
MULTICENTER STUDY, WITH AN 80-WEEK ACTIVE TREATMENT EXTENSION,
TO EVALUATE THE EFFICACY AND SAFETY OF CC-90001 IN SUBJECTS WITH
IDIOPATHIC PULMONARY FIBROSIS

Summary

EudraCT number	2016-003473-17
Trial protocol	GB GR
Global end of trial date	24 December 2021

Results information

Result version number	v1 (current)
This version publication date	07 January 2023
First version publication date	07 January 2023

Trial information

Trial identification

Sponsor protocol code	CC-90001-IPF-001

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	15 December 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of CC-90001, 200 mg and 400 mg, when orally administered (PO) once daily (QD), compared with placebo, on percent of predicted forced vital capacity (FVC) after 24 weeks of treatment in subjects with idiopathic pulmonary fibrosis (IPF).

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 subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 July 2017
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	Australia: 15
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	United Kingdom: 23
Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Turkey: 5
Country: Number of subjects enrolled	Ukraine: 23
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	United States: 20
Country: Number of subjects enrolled	Brazil: 8
Country: Number of subjects enrolled	Colombia: 2
Worldwide total number of subjects	135
EEA total number of subjects	10

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)	36
From 65 to 84 years	98
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants in the placebo arm during treatment period were re-randomized during the active treatment period to receive either CC-90001 200mg or CC-90001 400mg.

1 participant in the active treatment period did not have the end of study form filled out and therefore was listed in the missing row.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CC-90001 200mg (IPF Study)

Arm description:

CC-90001 200mg PO QD

Arm type	Experimental
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200mg PO QD (One 200mg tablet)

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

Dosage and administration details:

one placebo tablet PO QD

Arm title	CC-90001 400mg (IPF Study)

Arm description:

CC-90001 400mg PO QD

Arm type	Experimental
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

400mg PO QD (Two 200mg tablet)

Arm title	Placebo (IPF Study)

Arm description: Placebo	
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: two placebo tablets PO QD	
Arm title	CC-90001 400mg (PPF Sub-Study)
Arm description: CC-90001 400mg PO QD	
Arm type	Experimental
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 200mg PO QD (Two 200mg tablet)	
Arm title	Placebo (PPF Sub-Study)
Arm description: Placebo	
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: two placebo tablets PO QD	

Number of subjects in period 1	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)
Started	39	37	36
Completed	32	28	31
Not completed	7	9	5
Adverse event, serious fatal	-	1	1
Adverse event, non-fatal	4	5	1
Other Reasons	1	-	-
Progressive Disease	1	-	1
Withdrawal by participant	1	3	2

Number of subjects in period 1	CC-90001 400mg (PPF Sub-Study)	Placebo (PPF Sub-Study)
Started	15	8

Completed	15	7
Not completed	0	1
Adverse event, serious fatal	-	-
Adverse event, non-fatal	-	-
Other Reasons	-	-
Progressive Disease	-	-
Withdrawal by participant	-	1

Period 2

Period 2 title	Active Treatment Extension Period
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	CC-90001 200mg (IPF Study)

Arm description:
CC-90001 200mg PO QD

Arm type	Experimental
Investigational medicinal product name	CC-90001 and placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
200mg of CC-90001 (One 200mg Tablet PO QD) and One placebo tablet

Arm title	CC-90001 400mg (IPF Study)

Arm description:
CC-90001 400mg PO QD

Arm type	Experimental
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
400mg (Two 200mg Tablet PO QD)

Arm title	Placebo (IPF Study)

Arm description:
Placebo

Arm type	Placebo

Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
400mg (two 200mg Tablet PO QD)

Investigational medicinal product name	CC-90001 and placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
200mg of CC-90001 (One 200mg Tablet PO QD) and One placebo tablet

Arm title	CC-90001 400mg (PPF Sub-Study)

Arm description:
CC-90001 400mg PO QD

Arm type	Experimental
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
400mg (Two 200mg Tablet PO QD)

Arm title	Placebo (PPF Sub-Study)

Arm description:
Placebo

Arm type	Placebo
Investigational medicinal product name	CC-90001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
400mg (Two 200mg Tablet PO QD)

Investigational medicinal product name	CC-90001 and placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
200mg of CC-90001 (One 200mg Tablet PO QD) and One placebo tablet

Number of subjects in period 2[1]	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)
Started	31	27	30
CC-90001 200mg	0 [2]	0 [3]	15
CC-90001 400mg	0 [4]	0 [5]	15
Completed	5	13	15
Not completed	26	14	15
Adverse event, serious fatal	2	1	1
Physician decision	2	-	-
Adverse event, non-fatal	6	5	4
Other Reasons	3	3	3
Progressive Disease	10	5	4
Withdrawal by participant	2	-	3
Unknown, participant missing	1	-	-

Number of subjects in period 2[1]	CC-90001 400mg (PPF Sub-Study)	Placebo (PPF Sub-Study)
Started	15	6
CC-90001 200mg	0 [6]	3
CC-90001 400mg	0 [7]	3
Completed	3	0
Not completed	12	6
Adverse event, serious fatal	1	-
Physician decision	-	-
Adverse event, non-fatal	1	-
Other Reasons	8	3
Progressive Disease	1	2
Withdrawal by participant	1	1
Unknown, participant missing	-	-

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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase
[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: Re-randomization occurred after placebo treatment phase going into active treatment extension treatment phase

Baseline characteristics

Reporting groups	
Reporting group title	CC-90001 200mg (IPF Study)
Reporting group description: CC-90001 200mg PO QD	
Reporting group title	CC-90001 400mg (IPF Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (IPF Study)
Reporting group description: Placebo	
Reporting group title	CC-90001 400mg (PPF Sub-Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (PPF Sub-Study)
Reporting group description: Placebo	

Reporting group values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)
Number of subjects	39	37	36
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	11	7	5
>=65 years	28	30	31
Sex: Female, Male Units: Participants			
Female	11	8	6
Male	28	29	30
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	38	35	35
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	4	3
Not Hispanic or Latino	35	33	32
Unknown or Not Reported	0	0	1

Reporting group values	CC-90001 400mg (PPF Sub-Study)	Placebo (PPF Sub-Study)	Total
Number of subjects	15	8	135

Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	8	5	36
>=65 years	7	3	99
Sex: Female, Male Units: Participants			
Female	6	4	35
Male	9	4	100
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	15	8	131
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	11
Not Hispanic or Latino	15	8	123
Unknown or Not Reported	0	0	1

End points

End points reporting groups

Reporting group title	CC-90001 200mg (IPF Study)
Reporting group description: CC-90001 200mg PO QD	
Reporting group title	CC-90001 400mg (IPF Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (IPF Study)
Reporting group description: Placebo	
Reporting group title	CC-90001 400mg (PPF Sub-Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (PPF Sub-Study)
Reporting group description: Placebo	
Reporting group title	CC-90001 200mg (IPF Study)
Reporting group description: CC-90001 200mg PO QD	
Reporting group title	CC-90001 400mg (IPF Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (IPF Study)
Reporting group description: Placebo	
Reporting group title	CC-90001 400mg (PPF Sub-Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (PPF Sub-Study)
Reporting group description: Placebo	
Subject analysis set title	Placebo/CC-90001 200mg (IPF Study)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants who received placebo in the placebo treatment phase and then CC-90001 200mg PO QD in the active treatment extension phase	
Subject analysis set title	Placebo/CC-90001 400mg (IPF Study)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants who received placebo in the placebo treatment phase and then CC-90001 400mg PO QD in the active treatment extension phase	
Subject analysis set title	Placebo/CC-90001 200mg (PPF Sub-study)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants who received placebo in the placebo treatment phase and then CC-90001 200mg PO QD in the active treatment extension phase	
Subject analysis set title	Placebo/CC-90001 400mg (PPF Sub-Study)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received placebo in the placebo treatment phase and then CC-90001 400mg PO QD in the active treatment extension phase

Subject analysis set title	Placebo/CC-90001 200mg (IPF Study)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received placebo in the placebo treatment phase and then CC-90001 200mg PO QD in the active treatment extension phase

Subject analysis set title	Placebo/CC-90001 400mg (PPF Sub-study)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received placebo in the placebo treatment phase and then CC-90001 400mg PO QD in the active treatment extension phase

Subject analysis set title	Placebo/CC-90001 200mg (PPF Sub-Study)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants who received placebo in the placebo treatment phase and then CC-90001 200mg PO QD in the active treatment extension phase

Primary: Percentage point difference in % predicted forced vital capacity (FVC).

End point title	Percentage point difference in % predicted forced vital capacity (FVC).[1][2]

End point description:

Mean change from baseline in percentage point difference in % predicted forced vital capacity (FVC)

FAS population is defined as all randomized participants who received at least one dose of the investigational product.

Baseline is defined as day 1 of treatment.

End point type	Primary

End point timeframe:

from baseline to week 24

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: No statistical analysis done for this endpoint

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	39	37	36	
Units: Percentage Point				
arithmetic mean (standard deviation)				
Week 1	0.5 (± 3.04)	0.6 (± 2.87)	-0.9 (± 3.51)	
Week 4	0.3 (± 4.65)	1.7 (± 3.90)	-1.4 (± 3.75)	
Week 8	0.5 (± 5.70)	2.4 (± 3.98)	-1.7 (± 3.75)	
Week 12	-0.6 (± 4.83)	2.0 (± 3.70)	-2.5 (± 4.57)	
Week 16	-1.7 (± 5.55)	1.0 (± 5.27)	-2.0 (± 4.43)	
Week 20	-1.2 (± 3.92)	0.6 (± 4.55)	-2.7 (± 6.60)	
Week 24	-2.3 (± 4.96)	-0.5 (± 4.77)	-2.5 (± 4.85)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in absolute forced vital capacity (FVC).

End point title	Mean change from baseline in absolute forced vital capacity (FVC).[3]

End point description:

Mean change from baseline in absolute FVC in the full analysis set (FAS) population.

FAS population is defined as all randomized participants who received at least one dose of the investigational product.

Baseline is defined as day 1 of treatment.

End point type	Secondary

End point timeframe:

from baseline to week 24

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	29	30	
Units: mL				
arithmetic mean (standard deviation)	-74.9 (± 162.58)	-6.8 (± 170.39)	-88.3 (± 176.80)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in dyspnea rating on Borg Scale

End point title	Mean change from baseline in dyspnea rating on Borg Scale[4]

End point description:

Mean change from baseline in dyspnea rating on Borg Scale after the 6MWT.

The Borg scale ranges from 0 to 10. Where 0 is no dyspnea and a 10 is extremely strong dyspnea. The lower the number the better.
Time points to be measured
From baseline to Week 24, extension week 52, extension week 76, extension week 104, week 24 to extension week 52 and Week 24 to extension week 104

here "9999" signifies NA

End point type	Secondary

End point timeframe:

From baseline to Week 108

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	36	15
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 24	0.4 (± 1.38)	0.1 (± 1.39)	0.0 (± 1.55)	9999 (± 9999)
Extension Week 52	0.9 (± 1.32)	1.3 (± 1.48)	9999 (± 9999)	0.1 (± 0.68)
Extension Week 76	-0.2 (± 1.53)	1.2 (± 1.30)	9999 (± 9999)	-0.7 (± 1.30)
Extension Week 104	1.0 (± 3.50)	0.6 (± 1.15)	9999 (± 9999)	1.3 (± 0.88)
Week 24 to ext Week 52	0.7 (± 1.71)	1.1 (± 1.53)	9999 (± 9999)	-0.1 (± 0.64)
Week 24 to ext Week 104	1.8 (± 2.57)	-0.1 (± 1.02)	9999 (± 9999)	0.3 (± 0.52)

End point values	Placebo/CC-90001 400mg (IPF Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 24	9999 (± 9999)			
Extension Week 52	1.0 (± 1.93)			
Extension Week 76	-0.5 (± 1.52)			
Extension Week 104	-0.5 (± 1.52)			
Week 24 to ext Week 52	1.5 (± 2.25)			
Week 24 to ext Week 104	0.2 (± 2.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who had disease progression

End point title	Percentage of participants who had disease progression[5]

End point description:

Disease progression is defined as one or more of the following:
-Death from respiratory failure,
-Absolute decrease of ≥ 10% from baseline in % predicted FVC at two consecutive evaluations at a minimum of 4 weeks between evaluations
-Decrease from baseline of ≥ 50 meters in 6MWT distance (in the absence of a readily explainable cause, such as injury or trauma).
-Unexplained worsening hypoxemia (an absolute decrease from baseline of 4% or more in arterial oxygen saturation by pulse oximetry [SpO2]).

FAS population is defined as all randomized participants who received at least one dose of the investigational product.

Baseline is defined as day 1 of treatment.

End point type	Secondary

End point timeframe:

From Baseline up to week 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	39	37	36	
Units: Percentage of participants				
number (not applicable)	23.1	27.0	25.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in total score and domains on the Saint George’s Respiratory Questionnaire (SGRQ)

End point title	Mean change from baseline in total score and domains on the Saint George’s Respiratory Questionnaire (SGRQ)[6]

End point description:

The SGRQ is a quality of life health questionnaire that has been validated in IPF. It consists of 76 items in three domains:
-Symptoms
-Activity
-Impact of disease on daily life

A total score is calculated from 0 (no health impairment) to 100 (maximum health impairment). In addition to the total score, there is also a score for each domain: symptoms, activity, and impact which are scored 0-100. Each component score is derived by dividing the summed weights, unique for all questions, by the maximum possible weight.

End point type	Secondary

End point timeframe:

From Baseline up to week 24

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	23	27	
Units: Score on a Scale				
arithmetic mean (standard deviation)				

Activity	2.1 (± 16.95)	-6.5 (± 12.72)	-4.5 (± 13.04)	
Impact of disease on daily life	-1.9 (± 19.31)	-8.6 (± 19.17)	-1.2 (± 20.59)	
Symptoms	2.0 (± 21.10)	-11.8 (± 17.57)	-8.3 (± 20.63)	
Total	-0.3 (± 16.84)	-8.6 (± 15.44)	-3.7 (± 15.99)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in The University of California San Diego Shortness of Breath Questionnaire (UCSD-SOBQ)

End point title	Mean change from baseline in The University of California San Diego Shortness of Breath Questionnaire (UCSD-SOBQ)[7]

End point description:

The UCSD-SOBQ is a 24-item dyspnea questionnaire that asks participants to rate themselves from 0 ("Not at all") to 5 ("Maximally or unable to do because of breathlessness") in two areas: 1) how short of breath they are while performing various activities (21 items); and 2) how much shortness of breath, fear of hurting themselves by overexerting, and fear of shortness of breath limit them in their daily lives (3 items). If the subject does not routinely perform the activity, they are asked to estimate the degree of shortness of breath anticipated. The UCSD-SOBQ is scored by summing responses across all 24 items to form a total score. Scores range from 0 to 120. The lower the score the better.

End point type	Secondary

End point timeframe:

From Baseline up to week 24

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	26	23	27	
Units: Score on a Scale				
arithmetic mean (standard deviation)	1.1 (± 17.28)	-3.3 (± 16.69)	-1.4 (± 16.19)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change in distance walked in the 6-minute Walk Test (6MWT)

End point title	Mean change in distance walked in the 6-minute Walk Test (6MWT)[8]

End point description:

Mean change in distance walked in the 6-minute Walk Test (6MWT)

The 6MWT measures the distance a participant is able to walk on a hard, flat surface, over a total of six minutes.

The time points which will be measured are from baseline to Week 24, Extension Week 52, Extension

Week 76, Extension Week 104, Week 24 to extension week 52 and Week 24 to extension week 104

FAS population is defined as all randomized participants who received at least one dose of the investigational product.

Baseline is defined as day 1 of treatment. Week 24 is the start of baseline of the active treatment extension period.

Here "9999" signifies NA

End point type	Secondary

End point timeframe:

From baseline up to week 104

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	36	15
Units: meters				
arithmetic mean (standard deviation)				
Week 24	6.9 (± 73.42)	-21.1 (± 45.80)	-8.1 (± 49.89)	9999 (± 9999)
Extension Week 52	-21.9 (± 82.57)	-15.9 (± 46.42)	9999 (± 9999)	-30.0 (± 56.69)
Extension Week 76	-9.7 (± 58.90)	3.7 (± 46.31)	9999 (± 9999)	14.4 (± 25.00)
Extension Week 104	-15.3 (± 95.13)	-25.4 (± 58.73)	9999 (± 9999)	-18.6 (± 56.24)
Week 24 to ext Week 52	0.2 (± 1.02)	0.7 (± 1.25)	9999 (± 9999)	-0.9 (± 0.88)
Week 24 to ext Week 104	0.0 (± 1.00)	-0.3 (± 0.42)	9999 (± 9999)	0.6 (± 1.24)

End point values	Placebo/CC-90001 400mg (IPF Study)			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: meters				
arithmetic mean (standard deviation)				
Week 24	9999 (± 9999)			
Extension Week 52	-29.1 (± 94.95)			
Extension Week 76	-42.7 (± 92.46)			
Extension Week 104	-38.7 (± 87.80)			
Week 24 to ext Week 52	0.7 (± 1.59)			
Week 24 to ext Week 104	-0.1 (± 1.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with Adverse events at the end of the active treatment phase

End point title	Number of participants with Adverse events at the end of the active treatment phase[9]

End point description:

Number of participants with Adverse events at the end of the active treatment phase

TEAE = Treatment emergent adverse event
tx = treatment

End point type	Secondary

End point timeframe:

From re-randomization to end of treatment (approximately 84 weeks)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	CC-90001 400mg (PPF Sub-Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	15	15
Units: Participants				
TEAE	25	23	11	11
TEAE related to study treatment	7	13	1	2
Serious TEAE	10	6	2	3
Serious TEAE related to study Drug	0	0	0	0
Severe TEAE	8	7	2	2
TEAE leading to Death	5	4	1	2
TEA leading to study treatment interruption	2	6	1	1
TEAE leading to permanent tx discontinuation	6	4	1	0

End point values	Placebo/CC-90001 400mg (IPF Study)	Placebo/CC-90001 200mg (PPF Sub-study)	Placebo/CC-90001 400mg (PPF Sub-Study)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	3	3	
Units: Participants				
TEAE	13	2	3	
TEAE related to study treatment	8	1	0	
Serious TEAE	4	0	0	
Serious TEAE related to study Drug	0	0	0	
Severe TEAE	4	0	0	
TEAE leading to Death	2	0	0	
TEA leading to study treatment interruption	2	0	0	
TEAE leading to permanent tx discontinuation	3	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with Adverse events in the placebo controlled period

End point title	Number of participants with Adverse events in the placebo controlled period

End point description:

Number of participants with Adverse events in the placebo controlled period.

TEAE = Treatment emergent adverse event
tx = treatment

End point type	Secondary

End point timeframe:

from baseline to re-randomization (approximately 56 weeks for the IPF cohort and 28 weeks for the PPF cohort)

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	CC-90001 400mg (PPF Sub-Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	36	15
Units: Participants				
TEAE	30	34	31	8
TEAE related to study treatment	14	21	14	3
Serious TEAE	6	4	2	1
Serious TEAE related to study Drug	1	1	0	0
Severe TEAE	4	8	3	0
TEAE leading to Death	0	1	2	0
TEA leading to study treatment interruption	6	3	5	0
TEAE leading to permanent study tx discontinuation	5	7	2	0

End point values	Placebo (PPF Sub-Study)			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Participants				
TEAE	5			
TEAE related to study treatment	1			
Serious TEAE	0			

Serious TEAE related to study Drug	0			
Severe TEAE	0			
TEAE leading to Death	0			
TEA leading to study treatment interruption	2			
TEAE leading to permanent study tx discontinuation	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with worst changes in hematology laboratory parameters during the active treatment extension period

End point title	Number of participants with worst changes in hematology laboratory parameters during the active treatment extension period[10]

End point description:

Number of participants with worst changes in hematology laboratory parameters including: basophils, hemoglobin, lymphocytes, neutrophils and platelets.

End point type	Secondary

End point timeframe:

From re-randomization to end of treatment (approximately 84 weeks)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	CC-90001 400mg (PPF Sub-Study)	Placebo/CC-90001 400mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	15	15
Units: Participants				
Basophils - Normal to low	0	0	0	0
Basophils - Normal to high	5	3	0	1
Hemoglobin - Normal to low	2	2	1	0
Hemoglobin - Normal to high	3	4	0	1
Lymphocytes - Normal to low	2	2	1	1
Lymphocytes - Normal to high	3	5	0	1
Neutrophils - Normal to low	1	1	0	0
Neutrophils - Normal to high	14	11	1	6
Platelets - Normal to low	0	1	0	2
Platelets - Normal to high	0	1	0	0

End point values	Placebo/CC-90001 200mg (IPF Study)	Placebo/CC-90001 400mg (PPF Sub-study)	Placebo/CC-90001 200mg (PPF Sub-Study)	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	3	3	
Units: Participants				
Basophils - Normal to low	0	0	0	
Basophils - Normal to high	1	0	0	
Hemoglobin - Normal to low	1	0	0	
Hemoglobin - Normal to high	2	0	0	
Lymphocytes - Normal to low	0	0	0	
Lymphocytes - Normal to high	2	1	1	
Neutrophils - Normal to low	0	0	0	
Neutrophils - Normal to high	11	0	0	
Platelets - Normal to low	0	0	0	
Platelets - Normal to high	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with worst changes in hematology laboratory parameters during the in the placebo controlled period

End point title	Number of participants with worst changes in hematology laboratory parameters during the in the placebo controlled period

End point description:

Number of participants with worst changes in hematology laboratory parameters including: basophils, hemoglobin, lymphocytes, neutrophils and platelets. in the placebo controlled period

End point type	Secondary

End point timeframe:

from baseline to re-randomization (approximately 56 weeks for the IPF cohort and 28 weeks for the PPF cohort)

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	CC-90001 400mg (PPF Sub-Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	36	15
Units: Participants				
Basophils - Normal to low	0	0	0	0
Basophils - Normal to high	3	0	1	3
Hemoglobin - Normal to low	4	2	1	0
Hemoglobin - Normal to high	2	2	3	0
Lymphocytes - Normal to low	1	2	2	3
Lymphocytes - Normal to high	4	4	2	3
Neutrophils - Normal to low	1	0	0	1
Neutrophils - Normal to high	6	10	7	3
Platelets - Normal to low	0	1	2	0
Platelets - Normal to high	4	0	0	0

End point values	Placebo (PPF Sub-Study)			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Participants				
Basophils - Normal to low	0			
Basophils - Normal to high	2			
Hemoglobin - Normal to low	0			
Hemoglobin - Normal to high	0			
Lymphocytes - Normal to low	0			
Lymphocytes - Normal to high	1			
Neutrophils - Normal to low	1			
Neutrophils - Normal to high	2			
Platelets - Normal to low	0			
Platelets - Normal to high	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with a worst change from worst post-baseline in urinalysis laboratory analysis in the active treatment extension period

End point title	Number of participants with a worst change from worst post-baseline in urinalysis laboratory analysis in the active treatment extension period[11]

End point description:

Number of subjects with worst change from baseline in urinalysis laboratory analysis for the following measures:

Erythrocytes, Leukocytes, Tubular Epithelial Cells

Here "9999" signifies NA

End point type	Secondary

End point timeframe:

From re-randomization to end of treatment (approximately 84 weeks)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	CC-90001 400mg (PPF Sub-Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	15	15
Units: Participants				
Erythrocytes - Normal to abnormal	0	0	0	0
Leukocytes - Normal to abnormal	2	1	2	0

Tubular Epithelial Cells - Normal abnormal	9999	9999	9999	9999

End point values	Placebo/CC-90001 400mg (IPF Study)	Placebo/CC-90001 400mg (PPF Sub-study)	Placebo/CC-90001 200mg (PPF Sub-Study)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	3	3	
Units: Participants				
Erythrocytes - Normal to abnormal	0	1	0	
Leukocytes - Normal to abnormal	0	1	0	
Tubular Epithelial Cells - Normal abnormal	9999	9999	9999	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with a worst change from worst post-baseline in urinalysis laboratory analysis in the placebo controlled period

End point title	Number of participants with a worst change from worst post-baseline in urinalysis laboratory analysis in the placebo controlled period

End point description:

Number of subjects with worst change from baseline in urinalysis laboratory analysis for the following measures:

Erythrocytes, Leukocytes, Tubular Epithelial Cells

Here "9999" signifies NA

End point type	Secondary

End point timeframe:

from baseline to re-randomization (approximately 56 weeks for the IPF cohort and 28 weeks for the PPF cohort)

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	CC-90001 400mg (PPF Sub-Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	36	15
Units: Participants				
Erythrocytes - Normal to Abnormal	3	0	0	1
Leukocytes - Normal to Abnormal	4	1	2	2
Tubular Epithelial Cells - Normal to Abnormal	9999	9999	9999	9999

End point values	Placebo (PPF Sub-Study)			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Participants				
Erythrocytes - Normal to Abnormal	0			
Leukocytes - Normal to Abnormal	0			
Tubular Epithelial Cells - Normal to Abnormal	9999			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Electrocardiogram measurements in the active treatment extension period

End point title	Mean change from baseline in Electrocardiogram measurements in the active treatment extension period[12]

End point description:

Mean change from baseline in Electrocardiogram readings for the following measures: QT interval, QTcF interval, QTcB interval, PR interval, QRS duration and RR interval

End point type	Secondary

End point timeframe:

From re-randomization to 4 week follow up after end of treatment (approximately 84 weeks)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	CC-90001 400mg (PPF Sub-Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	15	15
Units: msec				
arithmetic mean (standard deviation)				
QT Interval	-14.3 (± 29.70)	0.2 (± 23.85)	-3.0 (± 21.29)	-7.7 (± 22.23)
QTcF Interval	-3.9 (± 21.13)	2.2 (± 18.75)	5.6 (± 26.09)	-3.4 (± 15.02)
QTcB Interval	1.3 (± 21.06)	3.5 (± 25.53)	10.0 (± 37.36)	-0.7 (± 19.04)
PR Interval	-9.2 (± 17.07)	9.2 (± 18.63)	0.6 (± 16.27)	-12.8 (± 6.55)
QRS Duration	-1.8 (± 7.11)	5.1 (± 14.46)	2.1 (± 7.24)	1.0 (± 7.25)
RR Interval	-75.4 (± 129.46)	-14.0 (± 148.45)	-51.4 (± 167.76)	-25.7 (± 136.36)

End point values	Placebo/CC-90001 400mg (IPF Study)	Placebo/CC-90001 200mg (PPF Sub-study)	Placebo/CC-90001 400mg (PPF Sub-Study)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	3	3	
Units: msec				
arithmetic mean (standard deviation)				
QT Interval	-10.9 (± 22.53)	9.0 (± 28.28)	25.0 (± 26.87)	
QTcF Interval	-1.9 (± 4.94)	14.0 (± 11.31)	23.5 (± 4.95)	
QTcB Interval	2.9 (± 13.46)	17.5 (± 31.82)	22.5 (± 6.36)	
PR Interval	3.3 (± 15.27)	14.5 (± 28.99)	2.0 (± 7.07)	
QRS Duration	-3.8 (± 5.60)	2.5 (± 2.12)	14.5 (± 13.44)	
RR Interval	-77.9 (± 181.66)	-28.0 (± 272.94)	15.5 (± 135.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Electrocardiogram measurements in the placebo controlled period

End point title	Mean change from baseline in Electrocardiogram measurements in the placebo controlled period

End point description:

Mean change from baseline in Electrocardiogram readings for the following measures: QT interval, QTcF interval, QTcB interval, PR interval, QRS duration and RR interval

End point type	Secondary

End point timeframe:

from baseline to week 24

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	CC-90001 400mg (PPF Sub-Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	36	15
Units: msec				
arithmetic mean (standard deviation)				
QT Interval	-2.9 (± 22.37)	0.2 (± 22.76)	-1.8 (± 26.23)	-9.6 (± 30.52)
QTcF Interval	-0.3 (± 15.12)	-0.9 (± 13.23)	-2.2 (± 16.80)	1.5 (± 16.83)
QTcB Interval	0.5 (± 19.57)	-1.2 (± 16.57)	-2.4 (± 18.20)	7.6 (± 23.51)
PR Interval	-5.1 (± 13.89)	-0.3 (± 10.84)	-0.8 (± 12.02)	-5.3 (± 12.23)
QRS Duration	2.0 (± 8.86)	2.1 (± 9.65)	-0.5 (± 8.44)	-0.9 (± 6.74)
RR Interval	-20.9 (± 127.25)	6.5 (± 127.19)	13.0 (± 129.92)	-68.4 (± 173.55)

End point values	Placebo (PPF Sub-Study)			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: msec				
arithmetic mean (standard deviation)				
QT Interval	-15.0 (± 15.56)			
QTcF Interval	6.0 (± 1.41)			
QTcB Interval	19.0 (± 11.31)			
PR Interval	20.5 (± 20.51)			
QRS Duration	-3.0 (± 4.24)			
RR Interval	-110.5 (± 78.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with worst increase from baseline in Blood Pressure in the active extension period

End point title	Number of participants with worst increase from baseline in Blood Pressure in the active extension period[13]

End point description:

Number of participants with an increase from baseline in systolic and diastolic blood pressure.

Sys = systolic
Dys = dyastolic
inc = increase

End point type	Secondary

End point timeframe:

From re-randomization to end of treatment (approximately 84 weeks)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Different reporting arms for different periods.

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	CC-90001 400mg (PPF Sub-Study)	Placebo/CC-90001 200mg (IPF Study)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	39	37	15	15
Units: Participants				
Sys inc from baseline > 10 but ≤ 15 (mild)	5	4	1	3
Sys inc from baseline > 15 but ≤ 20 (moderate)	1	4	0	2
Sys inc from baseline > 20 (severe)	4	8	0	4
Dys inc from baseline > 5 but ≤ 10 (mild)	6	6	4	7
Dys inc from baseline > 10 but ≤ 15 (moderate)	5	3	1	2
Dys inc from baseline > 15 (severe)	5	6	0	5

End point values	Placebo/CC-90001 400mg (IPF Study)	Placebo/CC-90001 200mg (PPF Sub-study)	Placebo/CC-90001 400mg (PPF Sub-Study)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	3	3	
Units: Participants				
Sys inc from baseline > 10 but ≤ 15 (mild)	1	0	0	
Sys inc from baseline > 15 but ≤ 20 (moderate)	3	0	0	
Sys inc from baseline > 20 (severe)	4	0	1	
Dys inc from baseline > 5 but ≤ 10 (mild)	3	1	2	
Dys inc from baseline > 10 but ≤ 15 (moderate)	4	0	0	
Dys inc from baseline > 15 (severe)	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with worst increase from baseline in Blood Pressure in the placebo-controlled period

End point title	Number of participants with worst increase from baseline in Blood Pressure in the placebo-controlled period

End point description:

Number of participants with worst increase from baseline in systolic and diastolic blood pressure.

Sys = systolic
Dys = dyastolic
inc = increase

End point type	Secondary

End point timeframe:

from baseline to re-randomization (approximately 56 weeks for the IPF cohort and 28 weeks for the PPF cohort)

End point values	CC-90001 200mg (IPF Study)	CC-90001 400mg (IPF Study)	Placebo (IPF Study)	CC-90001 400mg (PPF Sub-Study)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	37	36	0[14]
Units: Participants				
Sys inc from baseline > 10 but ≤ 15 (mild)	2	0	2	
Sys inc from baseline > 15 but ≤ 20 (moderate)	3	2	3	
Sys inc from baseline > 20 (severe)	0	3	0	

Sys inc from baseline > 5 but ≤ 10 (mild)	4	2	1	
Dys inc from baseline > 10 but ≤ 15 (moderate)	3	2	1	
Dys inc from baseline > 15 (severe)	2	2	2	

Notes:

[14] - Not analyzed

End point values	Placebo (PPF Sub-Study)			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Participants				
Sys inc from baseline > 10 but ≤ 15 (mild)				
Sys inc from baseline > 15 but ≤ 20 (moderate)				
Sys inc from baseline > 20 (severe)				
Sys inc from baseline > 5 but ≤ 10 (mild)				
Dys inc from baseline > 10 but ≤ 15 (moderate)				
Dys inc from baseline > 15 (severe)				

Notes:

[15] - Not Analyzed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Adverse Events, Serious Adverse events and all cause mortality: approximately 108 weeks.	
Adverse event reporting additional description: AEs, SAEs and All cause mortality are calculated from first dose, to 4 weeks after last treatment.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	CC-90001 400 mg PO QD (IPF Study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	CC-90001 200 mg PO QD (IPF Study)
Reporting group description: CC-90001 200mg PO QD	
Reporting group title	CC-90001 400 mg PO QD (PPF Sub-study)
Reporting group description: CC-90001 400mg PO QD	
Reporting group title	Placebo (PPF Sub-study)
Reporting group description: Placebo	
Reporting group title	Placebo (IPF Study)
Reporting group description: Placebo	

Serious adverse events	CC-90001 400 mg PO QD (IPF Study)	CC-90001 200 mg PO QD (IPF Study)	CC-90001 400 mg PO QD (PPF Sub-study)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 37 (24.32%)	16 / 39 (41.03%)	3 / 15 (20.00%)
number of deaths (all causes)	5	5	1
number of deaths resulting from adverse events			
Investigations			
Troponin increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			

subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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 neoplasm malignant			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Transitional cell carcinoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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			
Acute coronary syndrome			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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

Angina pectoris			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	0 / 15 (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
Post herpetic neuralgia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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			
Obstructive pancreatitis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Pancreatitis acute			

subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Salivary hypersecretion			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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			
Drug-induced liver injury			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	2 / 37 (5.41%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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 spontaneous			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (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 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Respiratory failure			
subjects affected / exposed	2 / 37 (5.41%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Bronchitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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 / 37 (0.00%)	1 / 39 (2.56%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diverticulitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Haemophilus infection			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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
Lower respiratory tract infection			

subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	0 / 15 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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 bacterial			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (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
Suspected COVID-19			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (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

Serious adverse events	Placebo (PPF Sub-study)	Placebo (IPF Study)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	9 / 36 (25.00%)	
number of deaths (all causes)	0	6	
number of deaths resulting from adverse events			
Investigations			
Troponin increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			

subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Obstructive pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary hypersecretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 8 (0.00%)	3 / 36 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Interstitial lung disease			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CC-90001 400 mg PO QD (IPF Study)	CC-90001 200 mg PO QD (IPF Study)	CC-90001 400 mg PO QD (PPF Sub-study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 37 (86.49%)	32 / 39 (82.05%)	12 / 15 (80.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 37 (5.41%)	0 / 39 (0.00%)	2 / 15 (13.33%)
occurrences (all)	2	0	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 37 (8.11%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	3	4	0
Oedema peripheral			

subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Social circumstances			
Dependence on oxygen therapy			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 37 (18.92%)	12 / 39 (30.77%)	0 / 15 (0.00%)
occurrences (all)	10	13	0
Dyspnoea			
subjects affected / exposed	6 / 37 (16.22%)	7 / 39 (17.95%)	0 / 15 (0.00%)
occurrences (all)	6	8	0
Dyspnoea exertional			
subjects affected / exposed	2 / 37 (5.41%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 37 (0.00%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
Oropharyngeal pain			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Productive cough			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Pulmonary hypertension			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Sinus congestion			

subjects affected / exposed	3 / 37 (8.11%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	1 / 15 (6.67%)
occurrences (all)	2	2	15
Insomnia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	3	0
Blood glucose increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	3	0
Blood pressure increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	5
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	6	0
Blood triglycerides increased			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Low density lipoprotein decreased			

subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	3 / 37 (8.11%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	3	2	0
Fall			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Limb injury			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Skin laceration			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nervous system disorders			

Dizziness			
subjects affected / exposed	6 / 37 (16.22%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	7	5	0
Dysgeusia			
subjects affected / exposed	2 / 37 (5.41%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	7 / 37 (18.92%)	3 / 39 (7.69%)	3 / 15 (20.00%)
occurrences (all)	17	3	25
Paraesthesia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutrophilia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 37 (5.41%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Eye disorders			
Cataract			
subjects affected / exposed	2 / 37 (5.41%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Abdominal discomfort			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 37 (2.70%)	1 / 39 (2.56%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	3	0

Constipation			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	11 / 37 (29.73%)	10 / 39 (25.64%)	0 / 15 (0.00%)
occurrences (all)	19	14	0
Dyspepsia			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Flatulence			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 37 (5.41%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	2	3	0
Nausea			
subjects affected / exposed	16 / 37 (43.24%)	12 / 39 (30.77%)	4 / 15 (26.67%)
occurrences (all)	26	16	22
Toothache			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	7 / 37 (18.92%)	6 / 39 (15.38%)	0 / 15 (0.00%)
occurrences (all)	13	8	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 37 (8.11%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
Rash			
subjects affected / exposed	3 / 37 (8.11%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Skin exfoliation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			

subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	2 / 37 (5.41%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Renal cyst			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 37 (13.51%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences (all)	5	0	3
Back pain			
subjects affected / exposed	3 / 37 (8.11%)	1 / 39 (2.56%)	1 / 15 (6.67%)
occurrences (all)	3	1	1
Bursitis			
subjects affected / exposed	2 / 37 (5.41%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Muscle spasms			
subjects affected / exposed	4 / 37 (10.81%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	5	1	0
Myalgia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Neck pain			

subjects affected / exposed	2 / 37 (5.41%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
subjects affected / exposed	4 / 37 (10.81%)	0 / 39 (0.00%)	2 / 15 (13.33%)
occurrences (all)	4	0	3
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	3 / 15 (20.00%)
occurrences (all)	1	0	3
Bronchitis			
subjects affected / exposed	2 / 37 (5.41%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	2	3	0
Cystitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Influenza			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 37 (2.70%)	4 / 39 (10.26%)	0 / 15 (0.00%)
occurrences (all)	2	10	0
Nasopharyngitis			
subjects affected / exposed	5 / 37 (13.51%)	3 / 39 (7.69%)	1 / 15 (6.67%)
occurrences (all)	6	4	1
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Pyelonephritis acute			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis chronic			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2

Respiratory tract infection			
subjects affected / exposed	0 / 37 (0.00%)	3 / 39 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	4	0
Rhinitis			
subjects affected / exposed	2 / 37 (5.41%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	3	2	0
Sialoadenitis			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 37 (10.81%)	5 / 39 (12.82%)	0 / 15 (0.00%)
occurrences (all)	7	9	0
Urinary tract infection			
subjects affected / exposed	1 / 37 (2.70%)	4 / 39 (10.26%)	0 / 15 (0.00%)
occurrences (all)	1	6	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Gout			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vitamin D deficiency			
subjects affected / exposed	3 / 37 (8.11%)	1 / 39 (2.56%)	0 / 15 (0.00%)
occurrences (all)	3	1	0
Hyponatraemia			

subjects affected / exposed	3 / 37 (8.11%)	0 / 39 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Placebo (PPF Sub-study)	Placebo (IPF Study)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	32 / 36 (88.89%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Social circumstances			
Dependence on oxygen therapy			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 8 (0.00%)	12 / 36 (33.33%)	
occurrences (all)	0	16	
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	6 / 36 (16.67%)	
occurrences (all)	0	8	
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Idiopathic pulmonary fibrosis			

subjects affected / exposed	3 / 8 (37.50%)	1 / 36 (2.78%)	
occurrences (all)	4	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Pulmonary hypertension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Sinus congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 8 (25.00%)	2 / 36 (5.56%)	
occurrences (all)	3	2	
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Depression			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Blood glucose increased			

subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Blood pressure increased			
subjects affected / exposed	4 / 8 (50.00%)	0 / 36 (0.00%)	
occurrences (all)	6	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Blood triglycerides increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Low density lipoprotein decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Neutrophil count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Fall			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Limb injury			

subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Rib fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Atrial flutter			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	4 / 36 (11.11%)	
occurrences (all)	1	4	
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	3 / 8 (37.50%)	4 / 36 (11.11%)	
occurrences (all)	42	5	
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Neutrophilia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Eye disorders			

Cataract			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	3	
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	7	
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	2 / 36 (5.56%)	
occurrences (all)	1	5	
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	10 / 36 (27.78%)	
occurrences (all)	0	17	
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	5 / 36 (13.89%)	
occurrences (all)	0	7	
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	4 / 36 (11.11%)	
occurrences (all)	0	4	
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	11 / 36 (30.56%)	
occurrences (all)	3	19	
Toothache			

subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Rash			
subjects affected / exposed	0 / 8 (0.00%)	4 / 36 (11.11%)	
occurrences (all)	0	7	
Skin exfoliation			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Urticaria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Renal cyst			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Renal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 36 (2.78%)	
occurrences (all)	5	1	
Back pain			
subjects affected / exposed	2 / 8 (25.00%)	4 / 36 (11.11%)	
occurrences (all)	22	4	
Bursitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	2 / 8 (25.00%)	2 / 36 (5.56%)	
occurrences (all)	3	2	
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 8 (25.00%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Cystitis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Herpes zoster			
subjects affected / exposed	1 / 8 (12.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Influenza			

subjects affected / exposed	0 / 8 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	5 / 36 (13.89%)	
occurrences (all)	0	7	
Nasopharyngitis			
subjects affected / exposed	3 / 8 (37.50%)	5 / 36 (13.89%)	
occurrences (all)	5	5	
Post-acute COVID-19 syndrome			
subjects affected / exposed	1 / 8 (12.50%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Pyelonephritis acute			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pyelonephritis chronic			
subjects affected / exposed	1 / 8 (12.50%)	1 / 36 (2.78%)	
occurrences (all)	2	2	
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Sialoadenitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	2	
Suspected COVID-19			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	3 / 36 (8.33%)	
occurrences (all)	0	3	
Urinary tract infection			

subjects affected / exposed	0 / 8 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	3	
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	5 / 36 (13.89%)	
occurrences (all)	0	5	
Gout			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 August 2017	Added new inclusion criterion #4 regarding consideration of treatment options for idiopathic pulmonary fibrosis (IPF) Revised inclusion criterion #6 regarding the diagnosis of IPF via high resolution computerized tomography (HRCT) Increased the time prior to randomization for acceptance of historical HRCT from Revised inclusion criterion #11 and Protocol Summary regarding the lower limit for diffusion capacity of the lung for carbon monoxide (DLCO) In response to recommendations of investigators, the lower limit for hemoglobincorrected percent predicted DLCO was changed from ≥30% to ≥ 25%. Revised exclusion criterion #9 regarding respiratory disorder Added to the term pulmonary arterial hypertension, requiring treatment to exclude those patients with more advanced disease. Revised exclusion criterion #12 regarding IPF targeted therapies Mycophenolate mofetil was added to the list of excluded medications as it may be used off-label to treat IPF. Included External Data Monitoring Committee (DMC) (Section 9.9.3 and Protocol Summary) Revised Acute Exacerbation Criteria Mandatory Discontinuation Due to Unsuccessful Treatment of Acute Exacerbation
18 July 2018	The rationale for the following changes is to allow idiopathic pulmonary fibrosis (IPF) subjects who were randomized to placebo the opportunity to receive CC-90001 (200 mg or 400 mg orally [PO] once a day [QD]) after 24 weeks of treatment. In the current study design, these subjects are not given the opportunity to receive CC-90001. It will also afford all subjects to receive active treatment for an additional 52 weeks (80-week Active Treatment Extension Phase).
28 August 2019	The primary purpose of this amendment is to allow subjects with idiopathic pulmonary fibrosis (IPF) receiving protocol-allowable standard of care (SOC) treatment to be enrolled in the study. Consequently, the number of subjects planned for enrollment was increased from 135 to 165 to obtain an adequate number of subjects receiving SOC. Another significant change incorporated into this amendment is the exclusion of nintedanib as an SOC treatment option, which was initially communicated to all sites as an Administrative Investigator Letter globally on 26 Sep 2018, based on results from a drug-drug interaction (DDI) study. A separate, exploratory substudy in subjects with progressive pulmonary fibrosis (PPF) will be initiated after a decision from an interim analysis allows continuation of the IPF study as planned. Approximately 45 qualifying PPF subjects would be enrolled into the substudy. As a result, the total number of randomized subjects into the entire study would increase from 165 to approximately 210 subjects.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported