Clinical trial results:
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, 24-Week Study to Evaluate the Efficacy, Safety, and Tolerability of BBT-877, as Mono- or add-on Therapy, in Patients with Idiopathic Pulmonary Fibrosis (IPF)

Summary

EudraCT number	2022-001414-18
Trial protocol	PL
Global end of trial date	20 February 2025

Results information

Result version number	v1 (current)
This version publication date	09 November 2025
First version publication date	09 November 2025

Trial information

Trial identification

Sponsor protocol code	BBT877-IPF-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05483907
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bridge Biotherapeutics, Inc.
Sponsor organisation address	Suite 303, C’s tower 58, Pangyo-ro 255 beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea, Republic of, 13486
Public contact	Clinical Trial Leader, Bridge Biotherapeutics, Inc., +82 31-8092-3280, bbt877-ipf-004@bridgebiorx.com
Scientific contact	Clinical Trial Leader, Bridge Biotherapeutics, Inc., +82 31-8092-3280, bbt877-ipf-004@bridgebiorx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 February 2025
Global end of trial reached?	Yes
Global end of trial date	20 February 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of BBT-877 in patients with IPF by measuring the reduction in forced vital capacity (FVC) in mL decline compared to placebo after 24 weeks of treatment.

Protection of trial subjects:

This study was conducted in accordance with the protocol and with the following:
• Consensus ethical principles derived from international guidelines, including the Declaration of Helsinki and the Council for International Organizations of Medical Sciences International Ethical Guidelines.
• Applicable International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines.
• Applicable laws and regulations

Prior to starting participation in the study, each patient was provided with a study-specific ICF detailing the study treatments, procedures, and potential risks of the study.
Patients or their legally authorized representative were required to sign a statement of informed consent that met the requirements of local regulations, ICH guidelines, and the IRB/EC or study site, where applicable. The patient was given a copy of the signed ICF, and the original was maintained with the patient’s records.

Background therapy:

BBT-877 is used in patients with IPF, with or without AF approved background therapies (pirfenidone or nintedanib).

Evidence for comparator:

This study is placebo-controlled and placebo is used for comparator.

Actual start date of recruitment	23 February 2023
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	1 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 13
Country: Number of subjects enrolled	Israel: 23
Country: Number of subjects enrolled	Korea, Republic of: 49
Country: Number of subjects enrolled	United States: 41
Country: Number of subjects enrolled	Poland: 3
Worldwide total number of subjects	129
EEA total number of subjects	3

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)	17
From 65 to 84 years	110
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

A total of 226 patients were assessed for eligibility, and 129 eligible patients were randomly assigned to 1 of 2 treatment groups (64 patients to the BBT-877 group and 65 patients to the placebo group). All 129 patients were treated. The numbers of patients who completed study treatment were 57 in the BBT-877 group and 60 in the placebo group.

Pre-assignment

Screening details:

Screening period - up to 6 weeks before Baseline

Period 1

Period 1 title	24-week treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	BBT-877 200 mg

Arm description:

Study arm: BBT-877 200 mg BID administered orally for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	BBT-877
Investigational medicinal product code	
Other name	BBT-877 100 mg capsule
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 capsules twice daily (BID), approximately 12 hours apart, taken with food (eg, meal,small meal, or a snack).

Arm title	Placebo

Arm description:

Control arm: Placebo administered orally, for 24 weeks.

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

Dosage and administration details:

2 capsules twice daily (BID), approximately 12 hours apart, taken with food (eg, meal, small meal, or a snack).

Number of subjects in period 1	BBT-877 200 mg	Placebo
Started	64	65
Completed	57	60
Not completed	7	5
Adverse event, serious fatal	1	-
Withdrawal of Consent	1	2
Adverse event, non-fatal	4	3
Other	1	-

Baseline characteristics

Reporting groups	
Reporting group title	BBT-877 200 mg
Reporting group description:	
Study arm: BBT-877 200 mg BID administered orally for 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Control arm: Placebo administered orally, for 24 weeks.	

Reporting group values	BBT-877 200 mg	Placebo	Total
Number of subjects	64	65	129
Age categorical Units: Subjects			
Adults (18-64 years)	10	7	17
From 65-84 years	53	57	110
85 years and over	1	1	2
Age continuous Units: years			
median	71.0	71.0	
full range (min-max)	43 to 85	50 to 85	-
Gender categorical Units: Subjects			
Female	14	18	32
Male	50	47	97

End points

End points reporting groups

Reporting group title	BBT-877 200 mg
Reporting group description:	
Study arm: BBT-877 200 mg BID administered orally for 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Control arm: Placebo administered orally, for 24 weeks.	

Primary: Change from baseline in FVC at Week 24 (in mL)

End point title	Change from baseline in FVC at Week 24 (in mL)
End point description:	
Change from baseline in forced vital capacity FVC (in mL) compared to placebo at Week 24, stratified by the presence/absence of background therapy (standard of care [SoC])	
End point type	Primary
End point timeframe:	
at Week 24	

End point values	BBT-877 200 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: mL				
median (full range (min-max))				
Baseline	2937.0 (1460 to 5114)	2606.0 (1454 to 4673)		
Week 4	3005.5 (1506 to 5134)	2686.5 (1333 to 4686)		
Week 12	2915.0 (1429 to 5009)	2646.0 (1205 to 4674)		
Week 24	2910.0 (1367 to 4869)	2710.0 (1204 to 4616)		

Statistical analyses

Statistical analysis title	Mixed-effects model with repeated measures - MMRM
Comparison groups	Placebo v BBT-877 200 mg
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.385
Method	Mixed models analysis
Parameter estimate	Difference in LS Means (vs. Placebo)
Point estimate	-25.4

Confidence interval	
level	90 %
sides	2-sided
lower limit	-73.7
upper limit	22.8

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs reported from the first dose of study treatment and through 30 days after the last dose of study treatment - 34 weeks.

Adverse event reporting additional description:

BBT-877 was generally safe and well tolerated in patients with IPF, with or without AF background therapies.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	BBT-877 200 mg

Reporting group description: -

Reporting group title	Placebo

Reporting group description: -

Serious adverse events	BBT-877 200 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 64 (7.81%)	4 / 65 (6.15%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 64 (0.00%)	1 / 65 (1.54%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 64 (0.00%)	1 / 65 (1.54%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 64 (0.00%)	2 / 65 (3.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	

Pneumothorax spontaneous			
subjects affected / exposed	1 / 64 (1.56%)	0 / 65 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 64 (3.13%)	0 / 65 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 64 (1.56%)	0 / 65 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 65 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	BBT-877 200 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 64 (75.00%)	37 / 65 (56.92%)	
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 64 (7.81%)	3 / 65 (4.62%)	
occurrences (all)	5	3	
Gastrointestinal disorders			
Diarrhea			
subjects affected / exposed	10 / 64 (15.63%)	1 / 65 (1.54%)	
occurrences (all)	10	1	
Nausea			
subjects affected / exposed	7 / 64 (10.94%)	1 / 65 (1.54%)	
occurrences (all)	7	1	
Gastroesophageal reflux disease			

subjects affected / exposed	0 / 64 (0.00%)	4 / 65 (6.15%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 64 (1.56%)	8 / 65 (12.31%)	
occurrences (all)	1	8	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 64 (0.00%)	4 / 65 (6.15%)	
occurrences (all)	0	4	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	7 / 64 (10.94%)	7 / 65 (10.77%)	
occurrences (all)	7	7	
COVID-19			
subjects affected / exposed	7 / 64 (10.94%)	3 / 65 (4.62%)	
occurrences (all)	7	3	
Nasopharyngitis			
subjects affected / exposed	3 / 64 (4.69%)	4 / 65 (6.15%)	
occurrences (all)	3	4	
Bronchitis			
subjects affected / exposed	4 / 64 (6.25%)	1 / 65 (1.54%)	
occurrences (all)	4	1	
Sinusitis			
subjects affected / exposed	4 / 64 (6.25%)	1 / 65 (1.54%)	
occurrences (all)	4	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 October 2023	Protocol Version 7.0 dated 19 Oct 2023 • The randomization ratio of patients with AF and without AF-approved background therapies was removed, and the minimum number required for each group (with pirfenidone background therapy, with nintedanib background therapy, and without AF background therapy) was added. • The PK and PD analysis sets were updated to include patients who consented to participate in optional PK/PD part of the study after the first 20 patients were randomized from each group.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

None reported

Notes: