Baseline characteristics of patients enrolled in FIBRONEER™-IPF, a Phase III randomized placebo-controlled trial of the preferential PDE4B inhibitor nerandomilast (BI 1015550) in patients with idiopathic pulmonary fibrosis

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INTRODUCTION

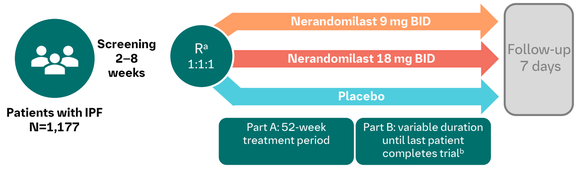
- Current antifibrotic treatments for IPF (nintedanib and pirfenidone) slow, but do not stop, decline in pulmonary function.[1]
- Nerandomilast (BI 1015550) is an oral preferential inhibitor of PDE4B.
- Phase III trials are investigating the efficacy and safety of nerandomilast in patients with IPF (FIBRONEER™-IPF) and PPF (FIBRONEER™-ILD).[1,2]
- Enrolment for both trials[1,2] is now complete.

AIM

- To report the baseline demographics and characteristics of patients in the FIBRONEER™-IPF trial.

METHODS

- FIBRONEER™-IPF is a randomized, double-blind, placebo-controlled, multicenter study underway in 44 countries worldwide.[1]
- Patients aged ≥40 years with a diagnosis of IPF, FVC ≥45% predicted and DLco ≥25% predicted were allowed to participate in this trial.[1]



[a]Randomization is stratified by background antifibrotic use.
[b]Variable period where patients will continue blinded treatment and have trial visits every 12 weeks.

Primary endpoint

Absolute change from baseline in FVC (mL) at Week 52 for Part A[1]

Key secondary endpoint

Time to first acute IPF exacerbation, hospitalization due to respiratory cause, or death over the duration of the trial for Parts A and B[1]

CONCLUSIONS

- Nerandomilast is the first preferential PDE4B inhibitor currently in a Phase III trial in IPF.[1]
- The characteristics of patients enrolled in the FIBRONEER™-IPF trial are representative of the IPF population and consistent with other Phase III trials.[3–5]

RESULTS

Baseline patient demographics and disease characteristics for all patients

- Overall, 1,177 patients were randomized in a 1:1:1 ratio to receive nerandomilast 9 mg, 18 mg, or placebo BID for at least 52 weeks.

78% receiving background antifibrotics

Mean age **70 years**

79% of patients are ≥65 years old

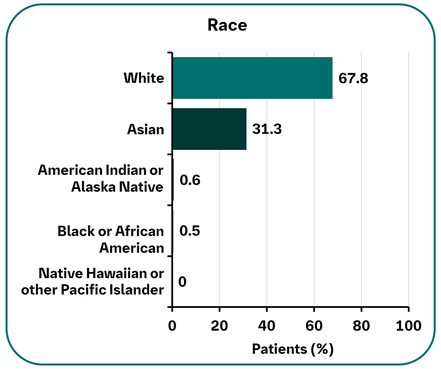
83% of patients are male

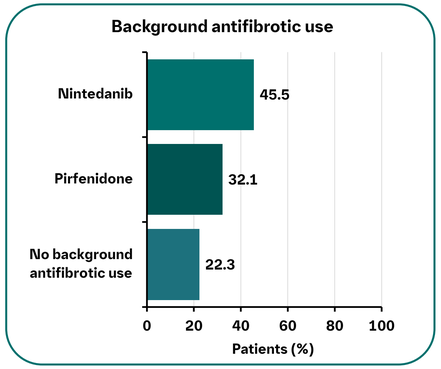
Mean FVC **78%** predicted

Mean DLco **51%** predicted

Median **3.0 years** since diagnosis of IPF (range 1.5–4.8 years)

21% of patients were using supplemental oxygen at baseline





Baseline patient demographics and disease characteristics by background antifibrotic use (treated patients)

- Patients receiving background antifibrotics had a lower FVC% predicted, a longer median time from diagnosis of IPF to study entry and were more likely to be using supplemental oxygen at baseline.

	Background antifibrotic use (n=914)	No background antifibrotic use (n=263)
Age, years, mean ± SD	70.2±7.5	70.4±8.4
Age categories, years, n (%)		
40–65	188 (21)	59 (22)
≥65	726 (79)	204 (78)
Male, n (%)	777 (85)	200 (76)
Race, n (%)[a]		
White	677 (74)	121 (46)
Asian	230 (25)	138 (53)
American Indian or Alaska Native	4 (<1)	3 (<1)
Black or African American	4 (<1)	2 (<1)
Native Hawaiian or other Pacific Islander	0 (0)	0 (0)
Smoking status, n (%)		
Never	265 (29)	77 (29)
Former	617 (68)	175 (67)
Current	32 (4)	11 (4)
FVC% predicted, mean ± SD	77.1±17.1	82.2±17.9
DLco% predicted, mean ± SD	49.7±15.5	55.0±18.3
Time since diagnosis of IPF, years, median (range)	3.2 (1.7–5.0)	1.9 (0.6–4.1)
Baseline supplemental oxygen use, n (%)	205 (22)	42 (16)

[a]One patient in the antifibrotic group and one in the non-antifibrotic group identified in more than one race category.

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ABBREVIATIONS

BID, twice daily; DLco, diffusing capacity of the lung for carbon monoxide; FVC, forced vital capacity; ILD, interstitial lung disease; IPF, idiopathic pulmonary fibrosis; PDE4B, phosphodiesterase 4B; PPF, progressive pulmonary fibrosis; R, randomization; SD, standard deviation.

DISCLOSURES

LR has received research grants from Boehringer Ingelheim and the Italian Medicine Agency; has been an advisory board member for Roche, Boehringer Ingelheim, FibroGen, Biogen and Promedior; has been involved in consulting activity for Biogen, Celgene, Nitto, Pliant Therapeutics, Toray, BMS, RespiVant, Zambon and CSL Behring; has received payment for lectures from Boehringer Ingelheim, Zambon and Cipla; has received support for attending meetings from Boehringer Ingelheim and Roche; and been a steering committee member for Boehringer Ingelheim and Roche. AA has received research grants and speaker fees from Boehringer Ingelheim and Taiho Pharm. Co.; and has been an advisory committee member for Boehringer Ingelheim, Taiho Pharm. Co., Toray Medical Co. and Kyorin Pharm. Co. VC has received unrestricted grants from Boehringer Ingelheim; consulting fees from AstraZeneca, Boehringer Ingelheim, Celgene/BMS, CSL Behring, Ferrer, Galapagos, Pliant Therapeutics, PureTech, RedX, Roche, Sanofi and Shionogi; lecture fees from Boehringer Ingelheim and Roche; support for attending meetings from Boehringer Ingelheim and F. Hoffmann-La Roche; has participated in data and safety monitoring boards for Galapagos, Galecto and Roche; and has been on an adjudication committee for FibroGen. MK is an advisor or review panel member for Boehringer Ingelheim, Galapagos and Roche; and has received consultancy fees, grants and speaker fees from Boehringer Ingelheim and Roche. TMM has received consulting fees from Boehringer Ingelheim, Roche/Genentech, AstraZeneca, Bayer, Blade Therapeutics, Bristol Myers Squibb, Galapagos, Galecto, GSK, IQVIA, Pliant Therapeutics, Respivant, Theravance Biopharma and Veracyte. He has also received speaker fees from Boehringer Ingelheim and Roche/Genentech. FJM has served on a steering committee, advisory board, data safety monitoring board or adjudication committee for Afferent/Merck, Bayer, Biogen, Boehringer Ingelheim, DevPro, Nitto, Novartis, Respivant, Roche and Veracyte; and has received consulting fees or payment for presentations from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Bridge Biotherapeutics, CSL Behring, DevPro, IQVIA, Lung Therapeutics, Roche/Genentech, Sanofi, Shionogi, twoXAR, United Therapeutics and Veracyte. JMO has received consultancy fees and grants from Boehringer Ingelheim and consultancy fees from Roche/Genentech and Lupin Pharmaceuticals. MG, YL, SS and DFZ are employees of Boehringer Ingelheim. CV has received personal fees from Boehringer Ingelheim, F. Hoffmann-La Roche and Bristol Myers Squibb; and support for attending meetings from Boehringer Ingelheim and F. Hoffmann-La Roche. MSW has received grants from AstraZeneca-Daiichi, Boehringer Ingelheim, F. Hoffmann-La Roche, The Netherlands Organisation for Health Research and Development, The Dutch Lung Foundation and The Dutch Pulmonary Society; consulting fees from Boehringer Ingelheim, Galapagos, Bristol Myers Squibb, Galecto, Respivant, NeRRe Therapeutics, Horizon Therapeutics, PureTech Health, Kinevant Sciences, Molecure, CSL Behring, Thyron and Vicore; speaker fees from Boehringer Ingelheim, Galapagos, F. Hoffmann-La Roche, Novartis and CSL Behring; support for attending meetings from Boehringer Ingelheim, Galapagos and F. Hoffmann-La Roche; has participated in advisory boards for Savara, Galapagos and Dutch lung fibrosis and sarcoidosis patient associations (unpaid); and has held leadership roles as Chair of the Idiopathic Interstitial Pneumonia group of the European Respiratory Society, Member of the board of the Netherlands Respiratory Society, Member of the scientific advisory board of the European Idiopathic Pulmonary Fibrosis and Related Disorders Federation and Chair of the educational committee of the European Reference Network for Rare Lung Diseases. All grants and fees were paid to her institution.

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