ERS CONGRESS | 2026
5-9 September | Barcelona, Spain

Effect of nerandomilast in patients with progressive pulmonary fibrosis (PPF) according to guideline criteria: data from the FIBRONEER-ILD trial

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Background: Various criteria have been proposed to identify PPF.

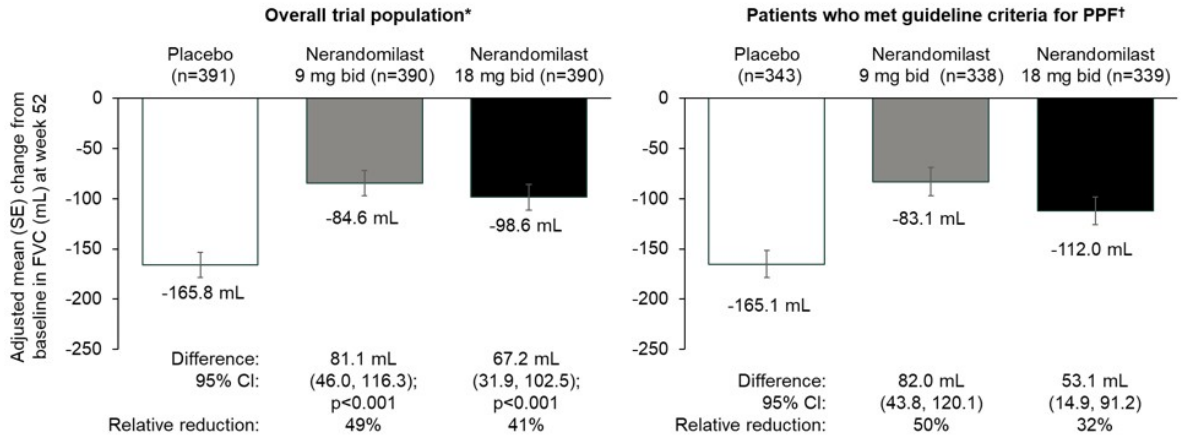
Objective: Assess the effect of nerandomilast in patients in the FIBRONEER-ILD trial who met criteria for PPF proposed in the ATS/ERS/JRS/ALAT guideline.

Methods: In the inclusion criteria for the FIBRONEER-ILD trial, PPF was defined using the same criteria as in the INBUILD trial of nintedanib. Investigators reported whether patients also met guideline criteria for PPF at baseline. Change in FVC and time to death were assessed in the overall population and in patients who met guideline criteria.

Results: Of 1176 patients treated, 1025 (87.2%) met guideline criteria, 102 (8.7%) did not, and for 49 (4.2%), this was unknown. Change in FVC at week 52 was similar in the overall population and patients who met guideline criteria (Figure). In the overall population, up to final database lock (mean exposure to trial drug: 15.1 months), 64 (16.3%) patients in the placebo group died versus 36 (9.2%) and 34 (8.7%) in the nerandomilast 9 mg bid and 18 mg bid groups, respectively (HR: 0.51 [95% CI: 0.34, 0.78] for both). Among patients who met guideline criteria, 57 (16.6%) in the placebo group died versus 33 (9.7%) in the nerandomilast 9 mg bid group (HR: 0.55 [0.36, 0.85]) and 31(9.1%) in the nerandomilast 18 mg bid group (HR: 0.54 [0.35, 0.84]).

Conclusions: Most patients in the FIBRONEER-ILD trial met guideline criteria for PPF. The efficacy of nerandomilast was consistent between patients who met guideline criteria and the overall trial population.

Figure 1. Change in FVC (mL) at week 52 in the FIBRONEER-ILD trial in patients with PPF in the overall trial population and in the subgroup who met guideline criteria for PPF.



*Met ≥1 of the following within the prior 24 months: relative decline in FVC % predicted ≥10%; relative decline in FVC % predicted ≥5–<10% with worsened respiratory symptoms and/or increased extent of fibrotic changes on imaging; worsened respiratory symptoms and increased extent of fibrotic changes on imaging.
†Met ≥2 of the following within the prior year: worsened respiratory symptoms; absolute decline in FVC % predicted ≥5% or in DLco % predicted ≥10%; radiological evidence of disease progression.