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Effects of nintedanib by inclusion criteria for progression of interstitial lung disease

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Shareable abstract (@ERSpublications)
In the INBUILD trial in patients with fibrosing ILDs, the relative effect of nintedanib *versus* placebo on reducing the rate of FVC decline was consistent across subgroups based on the criteria regarding ILD progression that patients fulfilled on trial entry https://bit.ly/35jpOiE

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Abstract

Background The INBUILD trial investigated nintedanib *versus* placebo in patients with progressive fibrosing interstitial lung diseases (ILDs). We investigated the decline in forced vital capacity (FVC) in subgroups based on the inclusion criteria for ILD progression.

Methods Subjects had a fibrosing ILD other than idiopathic pulmonary fibrosis and met the following criteria for ILD progression within the 24 months before screening despite management deemed appropriate in clinical practice: Group A, relative decline in FVC ⩾10% predicted; Group B, relative decline in FVC ⩾5–<10% predicted with worsened respiratory symptoms and/or increased extent of fibrosis on high-resolution computed tomography (HRCT); Group C, worsened respiratory symptoms and increased extent of fibrosis on HRCT only.

Results In the placebo group, the rates of FVC decline over 52 weeks in Groups A, B and C, respectively, were −241.9, −133.1 and −115.3 mL per year in the overall population (p=0.0002 for subgroup-by-time interaction) and −288.9, −156.2 and −100.1 mL per year among subjects with a usual interstitial pneumonia (UIP)-like fibrotic pattern on HRCT (p=0.0005 for subgroup-by-time interaction). Nintedanib had a greater absolute effect on reducing the rate of FVC decline in Group A than in Group B or C. However, the relative effect of nintedanib *versus* placebo was consistent across the subgroups (p>0.05 for heterogeneity).

Conclusions The inclusion criteria used in the INBUILD trial, based on FVC decline or worsening of symptoms and extent of fibrosis on HRCT, were effective at identifying patients with progressive fibrosing ILDs. Nintedanib reduced the rate of decline in FVC across the subgroups based on the inclusion criteria related to ILD progression.

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