# Nintedanib in progressive interstitial lung diseases: data from the whole INBUILD trial

**Kevin R. Flaherty[1], Athol U. Wells[2], Vincent Cottin[3], Anand Devaraj[4,5], Yoshikazu Inoue[6], Luca Richeldi[7], Simon L.F. Walsh[5], Martin Kolb[8], Dirk Koschel[9], Teng Moua[10], Susanne Stowasser[11], Rainer-Georg Goeldner[12], Rozsa Schlenker-Herceg[13] and Kevin K. Brown[14] on behalf of the INBUILD Trial Investigators**

[1]Division of Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, MI, USA. [2]National Institute for Health Research Respiratory Biomedical Research Unit, Royal Brompton and Harefield NHS Foundation Trust, London, UK. [3]National Reference Center for Rare Pulmonary Diseases, Louis Pradel Hospital, Hospices Civils de Lyon, Claude Bernard University Lyon 1, UMR 754, Lyon, France. [4]Dept of Radiology, Royal Brompton and Harefield NHS Foundation Trust, London, UK. [5]National Heart and Lung Institute, Imperial College London, London, UK. [6]Clinical Research Center, National Hospital Organization Kinki-Chuo Chest Medical Center, Sakai City, Japan. [7]Fondazione Policlinico A. Gemelli IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy. [8]McMaster University and St Joseph's Healthcare, Hamilton, ON, Canada. [9]Fachkrankenhaus Coswig, Coswig, Germany. [10]Division of Pulmonary and Critical Care Medicine, Mayo Clinic Rochester, Rochester, MN, USA. [11]Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany. [12]Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany. [13]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA. [14]Dept of Medicine, National Jewish Health, Denver, CO, USA.

Corresponding author: Kevin K. Brown (brownk@njhealth.org)

Shareable abstract (@ERSpublications)
**In patients with fibrosing ILDs other than IPF who had shown progression of ILD within the prior 2 years, events indicating further progression occurred frequently. Over a 16-month period, nintedanib reduced the risk of such events *versus* placebo.** https://bit.ly/3yiZXnS

**Cite this article as:** Flaherty KR, Wells AU, Cottin V, *et al*. Nintedanib in progressive interstitial lung diseases: data from the whole INBUILD trial. *Eur Respir J* 2022; 59: 2004538 [DOI: 10.1183/13993003.04538-2020].



Received: 16 Dec 2020
Accepted: 24 July 2021

## Abstract

***Background*** The primary analysis of the INBUILD trial showed that in subjects with progressive fibrosing interstitial lung diseases (ILDs), nintedanib slowed the decline in forced vital capacity (FVC) over 52 weeks. We report the effects of nintedanib on ILD progression over the whole trial.

***Methods*** Subjects with fibrosing ILDs other than idiopathic pulmonary fibrosis, who had ILD progression within the 24 months before screening despite management deemed appropriate in clinical practice, were randomised to receive nintedanib or placebo. Subjects continued on blinded randomised treatment until all subjects had completed the trial. Over the whole trial, mean±SD exposure to trial medication was 15.6±7.2 and 16.8±5.8 months in the nintedanib and placebo groups, respectively.

***Results*** In the nintedanib (n=332) and placebo (n=331) groups, respectively, the proportions of subjects who had ILD progression (absolute decline in FVC ⩾10% predicted) or died were 40.4% and 54.7% in the overall population (hazard ratio (HR) 0.66, 95% CI 0.53–0.83; p=0.0003) and 43.7% and 55.8% among subjects with a usual interstitial pneumonia (UIP)-like fibrotic pattern on high-resolution computed tomography (HRCT) (HR 0.69, 95% CI 0.53–0.91; p=0.009). In the nintedanib and placebo groups, respectively, the proportions who had an acute exacerbation of ILD or died were 13.9% and 19.6% in the overall population (HR 0.67, 95% CI 0.46–0.98; p=0.04) and 15.0% and 22.8% among subjects with a UIP-like fibrotic pattern on HRCT (HR 0.62, 95% CI 0.39–0.97; p=0.03).

***Conclusion*** Based on data from the whole INBUILD trial, nintedanib reduced the risk of events indicating ILD progression.

## Introduction

Nintedanib, an intracellular inhibitor of tyrosine kinases, inhibits processes fundamental to the progression of lung fibrosis [1]. Randomised placebo-controlled trials demonstrated that nintedanib reduces the rate of progression of interstitial lung disease (ILD) over 52 weeks in patients with idiopathic pulmonary fibrosis