# Effect of Nintedanib on Categorical Changes in FVC in Patients with Progressive Fibrosing ILDs: Further Analyses of the INBUILD trial

Toby M Maher,[1] Stefania Cerri,[2] Robert W Hallowell,[3] Dirk Koschel,[4] Janet Pope,[5] Leslie Tolle,[6] Heiko Mueller,[7] Klaus B Rohr,[8] Yoshikazu Inoue[9] on behalf of the INBUILD trial investigators

[1]National Heart and Lung Institute, Imperial College London, UK, National Institute for Health Research Clinical Research Facility, Royal Brompton Hospital, London, UK, and Keck School of Medicine, University of Southern California, Los Angeles, California, USA; [2]Center for Rare Lung Disease – Azienda Ospedaliero-Universitaria Policlinico di Modena, Modena, Italy; [3]Massachusetts General Hospital, Boston, MA, USA; [4]Fachkrankenhaus Coswig, Coswig, Germany; [5]Division of Rheumatology, University of Western Ontario, Schulich School of Medicine, London, Ontario, Canada; [6]Department of Pulmonary Medicine and Critical Care Medicine, Cleveland Clinic, Cleveland, OH, USA; [7]Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany; [8]Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; [9]Clinical Research Center, National Hospital Organization Kinki-Chuo Chest Medical Center, Sakai City, Osaka, Japan.

## INTRODUCTION

- In the INBUILD trial in patients with progressive fibrosing interstitial lung diseases (ILDs) other than idiopathic pulmonary fibrosis (IPF), nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) over 52 weeks by 57% versus placebo.[1]
- No heterogeneity was detected in the effect of nintedanib on FVC decline across subgroups by ILD diagnosis.[2]
- Declines in FVC of >5% and >10% predicted have been associated with mortality in patients with fibrosing ILDs.[3-5]

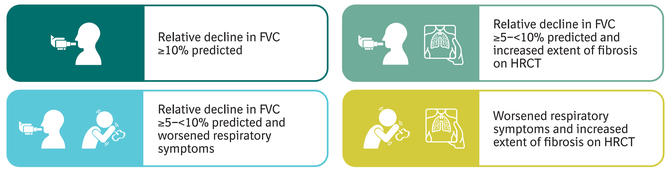
## AIM

- To assess the effect of nintedanib on categorical changes in FVC % predicted over 52 weeks in the INBUILD trial.

## METHODS

**Trial design[1]**

- Subjects had diffuse fibrosing ILD (reticular abnormality with traction bronchiectasis, with or without honeycombing) of >10% extent on high-resolution computed tomography (HRCT), FVC ≥45% predicted, and diffusion capacity of the lungs for carbon monoxide (DLco) ≥30%–<80% predicted. Subjects with IPF were excluded.
- Subjects met ≥1 of the following criteria for ILD progression at any time within the 24 months before screening, despite management deemed appropriate in clinical practice:




- Subjects were randomized to receive nintedanib or placebo, stratified by HRCT pattern (usual interstitial pneumonia [UIP]-like fibrotic pattern or other fibrotic patterns).

**Analyses**

- In post-hoc descriptive analyses, we assessed the proportions of subjects with absolute and relative declines or increases in FVC >0% to ≤5%, >5% to ≤10%, >10% to ≤15%, and >15% predicted at week 52 in the overall population and in the subgroup of subjects with autoimmune disease-related ILDs.
- Missing values at week 52 were imputed using multiple imputation.

## CONCLUSIONS

- In the overall population of the INBUILD trial, and in the subgroup with autoimmune disease-related ILDs, the proportions of subjects with clinically relevant declines in FVC over 52 weeks were lower in the nintedanib group than in the placebo group.
- These results provide further support for the benefit of nintedanib on slowing the progression of ILD in patients with progressive fibrosing ILD other than IPF.

## RESULTS

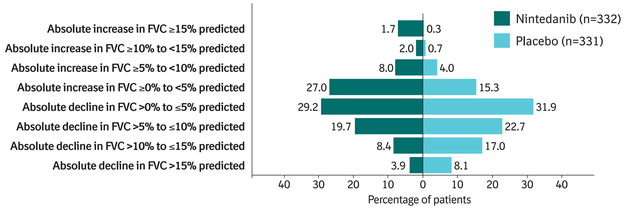
### Baseline characteristics of overall population

| Nintedanib (n=332) | | Placebo (n=331) |
|---|---|---|
| 65.2 | Mean age (years) | 66.3 |
| 53.9 | Male, % | 53.5 |
| 50.9 | Former or current smoker, % | 51.1 |
| 62.0 | UIP-like fibrotic pattern on HRCT | 62.2 |
| 68.7 | Mean FVC % predicted | 69.3 |
| 44.4 | Mean DLco % predicted | 47.9 |

### Baseline characteristics of subjects with autoimmune-disease related ILDs

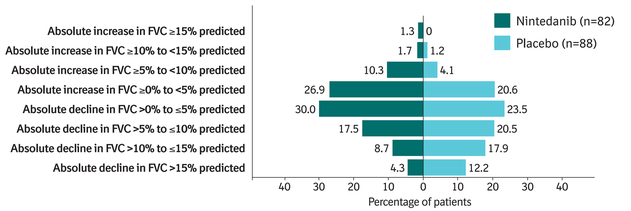
| Nintedanib (n=82) | | Placebo (n=88) |
|---|---|---|
| 63.3 | Mean age (years) | 65.1 |
| 42.7 | Male, % | 51.1 |
| 48.8 | Former or current smoker, % | 51.1 |
| 75.6 | UIP-like fibrotic pattern on HRCT | 73.9 |
| 69.6 | Mean FVC % predicted | 72.1 |
| 44.9 | Mean DLco % predicted | 50.8 |

### Proportions of subjects in overall population with absolute increases and declines in FVC % predicted at week 52



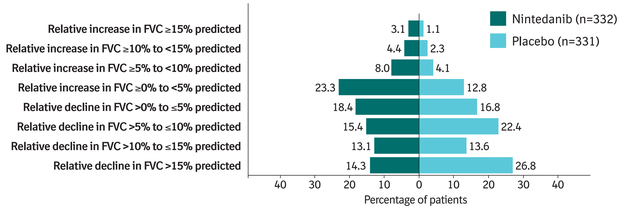

Missing values at week 52 were imputed using multiple imputation.

### Proportions of subjects with autoimmune disease-ILDs with absolute increases and declines in FVC % predicted at week 52



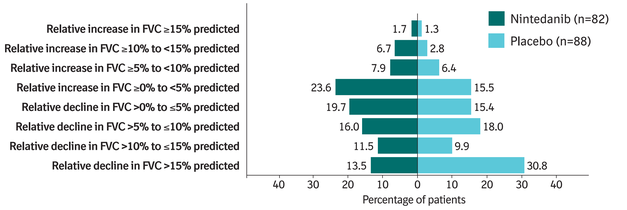

Missing values at week 52 were imputed using multiple imputation.

### Proportions of subjects in overall population with relative increases and declines in FVC % predicted at week 52




Missing values at week 52 were imputed using multiple imputation.

### Proportions of subjects with autoimmune disease-ILDs with relative increases and declines in FVC % predicted at week 52

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