Continued nintedanib treatment in patients with progressive fibrosing ILDs: interim analysis of INBUILD-ON

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INTRODUCTION

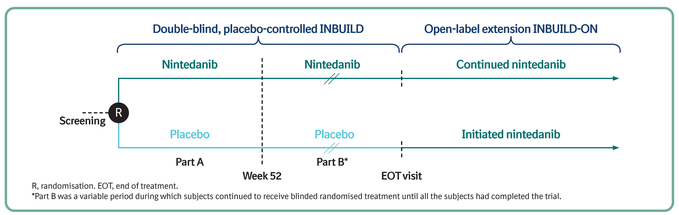
- In the INBUILD trial in patients with progressive fibrosing interstitial lung diseases (ILDs) other than idiopathic pulmonary fibrosis (IPF), nintedanib significantly reduced the rate of decline in forced vital capacity (FVC) compared with placebo, with a safety profile characterised mainly by gastrointestinal events.[1]
- INBUILD-ON (NCT03820726) is an open-label extension of the INBUILD trial that is collecting data on FVC decline and adverse events in patients treated with nintedanib over the longer term.

AIM

- To assess adverse events and FVC decline in patients with progressive fibrosing ILDs treated with open-label nintedanib in INBUILD-ON.

METHODS

- Patients in the INBUILD trial had diffuse fibrosing ILD (reticular abnormality with traction bronchiectasis, with or without honeycombing) of >10% extent on HRCT, FVC ≥45% predicted, DLco ≥30%–<80% predicted. Patients with IPF were excluded.[1]
- Patients met criteria for ILD progression at any point within the 24 months before screening, based on worsening of FVC, abnormalities on HRCT, or symptoms, despite management deemed appropriate in clinical practice.[1]
- Patients were randomised to receive nintedanib or placebo, stratified by fibrotic pattern on HRCT (usual interstitial pneumonia [UIP]-like fibrotic pattern or other fibrotic patterns).
- Patients who were still on treatment at the end of INBUILD could enter INBUILD-ON:
  - Patients who had received nintedanib in INBUILD and continued nintedanib in INBUILD-ON comprised the "continued nintedanib" group.
  - Patients who had received placebo in INBUILD and initiated nintedanib in INBUILD-ON comprised the "initiated nintedanib" group.



R, randomisation. EOT, end of treatment.
*Part B was a variable period during which subjects continued to receive blinded randomised treatment until all the subjects had completed the trial.

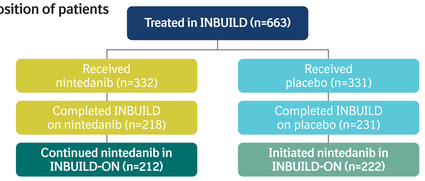
- We analysed changes from baseline in FVC (mL) and adverse events in INBUILD-ON based on a data snapshot taken on 15 October 2020. Analyses were descriptive.

CONCLUSIONS

- Among patients with progressive fibrosing ILDs, the adverse event profile of nintedanib over longer-term use in INBUILD-ON was consistent with that reported in INBUILD, characterised mainly by gastrointestinal events that were manageable for most patients.
- The rate of decline in FVC in patients receiving nintedanib was similar during INBUILD and INBUILD-ON.

RESULTS

Disposition of patients



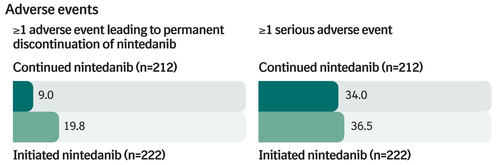
Baseline characteristics at inclusion in INBUILD-ON

	Continued nintedanib (n=212)	Initiated nintedanib (n=222)
Mean (SD) age, years	65.4 (9.8)	66.4 (10.0)
Male, %	51.9	50.9
Mean (SD) body mass index, kg/m²	26.5 (4.8)	27.9 (5.2)
White, %	65.1	64.0
Current or former smoker, %	45.8	50.5
Mean (SD) years since diagnosis of ILD	5.7 (4.3)	5.5 (3.7)
UIP-like fibrotic pattern on HRCT, %	59.9	59.5
Mean (SD) FVC % predicted	64.8 (18.3)	64.0 (16.6)

Exposure to nintedanib in INBUILD-ON

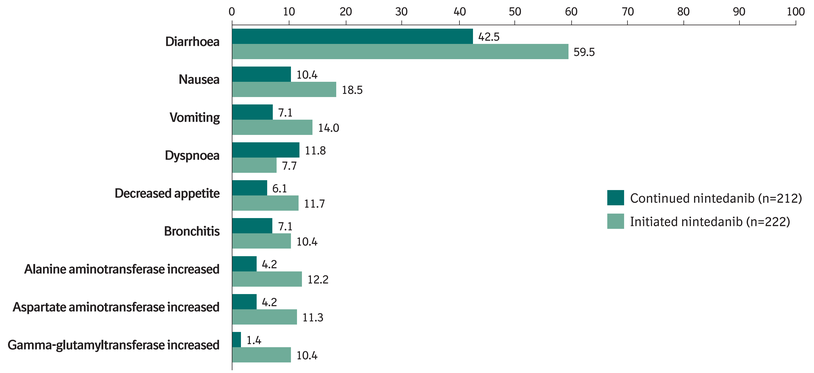
Median exposure: **15.4 months**

Adverse events



Data are % of patients with ≥1 such adverse event with onset between first nintedanib intake and last intake plus 28 days.

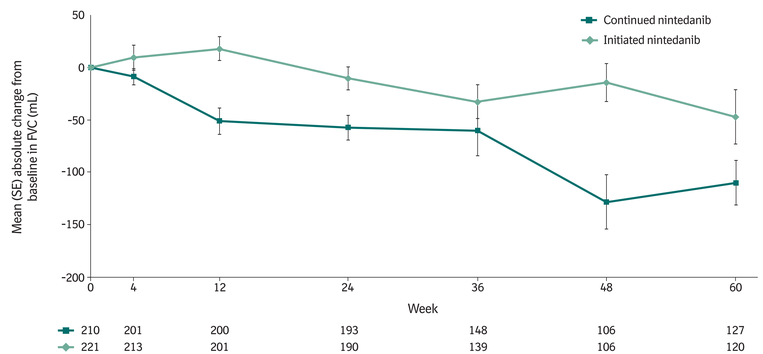
Adverse events (reported irrespective of causality)



Adverse events were coded based on preferred terms in the Medical Dictionary for Regulatory Activities. Data are % of patients with ≥1 such adverse event with onset between first nintedanib intake and last intake plus 28 days. Adverse events that were reported in >10% of patients in either group are shown.

Absolute change from baseline in FVC (mL) over time

The last patient was enrolled in INBUILD-ON on 30 July 2019. Based on the data snapshot taken on 15 October 2020, at weeks 36, 48, and 60, respectively, 33.6%, 51.2% and 43.1% of patients had missing FVC values. These high rates of missing data were mainly due to the COVID-19 pandemic.



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REFERENCE
1. Flaherty KR et al. N Engl J Med 2019;381:1718–1727.

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