Effects of nintedanib in patients with idiopathic pulmonary fibrosis and varying severities of cough

Wim A. Wuyts,[1] Carlo Vancheri,[2] Francesco Bonella,[3] Anne-Marie Russell,[4] Dirk Lievens,[5] Wibke Stansen,[6] Marlies S. Wijsenbeek[7] on behalf of the INPULSIS trial investigators

[1]Unit for Interstitial Lung Diseases, Department of Pulmonary Medicine, University Hospitals Leuven, Leuven, Belgium; [2]Department of Clinical and Experimental Medicine, University of Catania, Catania, Italy; [3]Center for Interstitial and Rare Lung Diseases, Ruhrlandklinik, University Hospital, Duisburg-Essen University, Essen, Germany; [4]College of Medicine and Health University of Exeter, UK; [5]Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; [6]Boehringer Ingelheim GmbH & Co. KG, Ingelheim am Rhein, Germany; [7]Department of Respiratory Medicine, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands.

INTRODUCTION

- Cough can be a major problem for patients with IPF and may be related to disease progression.[1-3]
- The cough symptoms and cough impact domains of the Cough and Sputum Assessment Questionnaire (CASA-Q) assess the frequency of cough and its impact on everyday activities.[4,5]
- Nintedanib is an approved treatment for IPF that reduces the rate of decline in forced vital capacity (FVC).[6]

AIM

- To assess the effect of nintedanib on decline in FVC and changes in cough scores in subgroups of patients with IPF by cough scores at baseline.

METHODS

- Data were pooled from the two INPULSIS trials in which patients with IPF were randomized to receive nintedanib or placebo for 52 weeks.
- The cough symptoms and cough impact domains of the CASA-Q were completed at baseline and weeks 6, 12, 24 and 52.

Cough and Sputum Assessment Questionnaire (CASA-Q)

- 11 items evaluate cough and its impact on usual activities over the last 7 days
- Response options range from "never" to "always" on a 5-point scale

CASA-Q cough symptoms and cough impact domains

100 / 0

Cough symptoms and cough impact scores range from **0–100**

Higher scores represent fewer symptoms/less impact of cough

- We assessed the effects of nintedanib on the rate of FVC decline (mL/year) and change from baseline in CASA-Q cough symptoms and impact scores over 52 weeks in subgroups by median CASA-Q cough symptoms and impact scores at baseline.
- Interaction p-values were calculated to assess potential heterogeneity in the treatment effect of nintedanib versus placebo between subgroups. No adjustment for multiplicity was made.

CONCLUSIONS

- Patients with IPF who had worse cough at baseline had a numerically faster rate of decline in FVC and more pronounced effect of nintedanib on decline in FVC over 52 weeks.
- Based on the CASA-Q, no clinically meaningful effect of nintedanib was observed on changes in cough scores.
- Patient-reported outcomes developed in patients with IPF may provide more insights into the prognostic implications of cough and the effects of nintedanib on cough.

- A total of 638 patients received nintedanib and 423 received placebo.

Median CASA-Q cough symptoms score at baseline: **58.3**

Median CASA-Q cough impact score at baseline: **81.3**

Baseline characteristics

CASA-Q cough symptoms score ≤58.3 (worse)		CASA-Q cough symptoms score >58.3 (better)			CASA-Q cough impact score ≤81.3 (worse)		CASA-Q cough impact score >81.3 (better)	
Nintedanib (n=262)	Placebo (n=166)	Nintedanib (n=376)	Placebo (n=257)		Nintedanib (n=335)	Placebo (n=221)	Nintedanib (n=302)	Placebo (n=202)
78.6	75.3	80.1	81.3	Male, %	75.8	77.8	83.4	80.2
66.3	66.6	66.8	67.2	Age, years	66.7	66.9	66.5	67.1
28.7	27.7	27.7	27.6	BMI, kg/m²	28.5	27.6	27.6	27.7
70.2	72.3	74.5	70.4	Former or current smoker, %	67.2	67.0	78.8	75.7
76.9	76.5	81.7	81.0	FVC % predicted	77.0	76.1	82.6	82.8
45.1	46.6	49.0	47.2	DLco % predicted	45.7	46.2	49.3	47.8

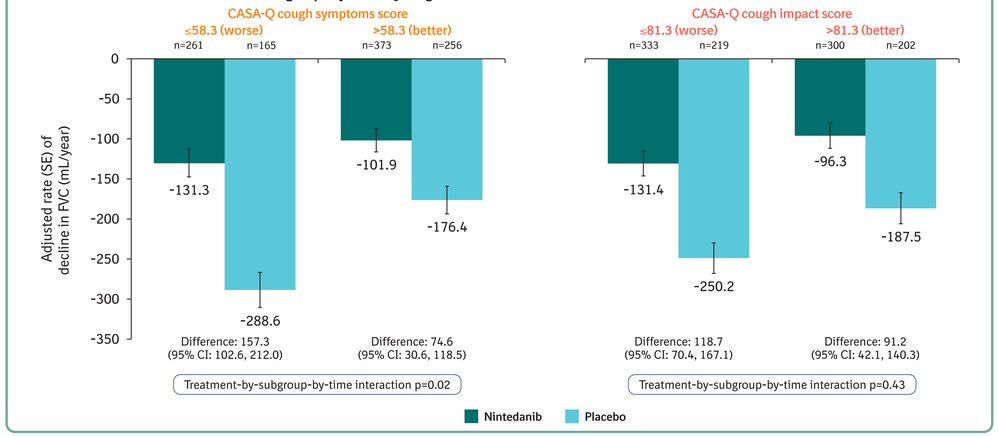
Data are mean or % of patients.

Decline in FVC

- The rate of decline in FVC was numerically greater in patients with lower (worse) CASA-Q cough symptoms or impact scores at baseline.
- Nintedanib reduced the rate of decline in FVC versus placebo in all the subgroups, with a more pronounced effect in patients with a lower (worse) cough symptoms score at baseline.

RESULTS

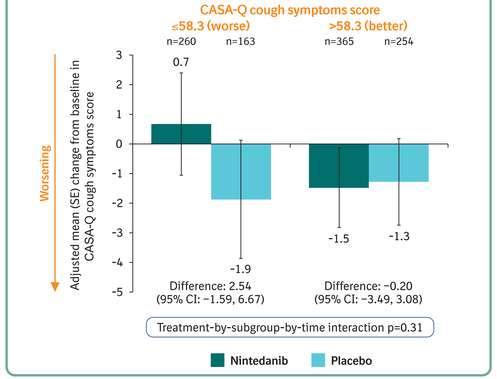
Rate of decline in FVC over 52 weeks in subgroups by CASA-Q cough domain scores at baseline



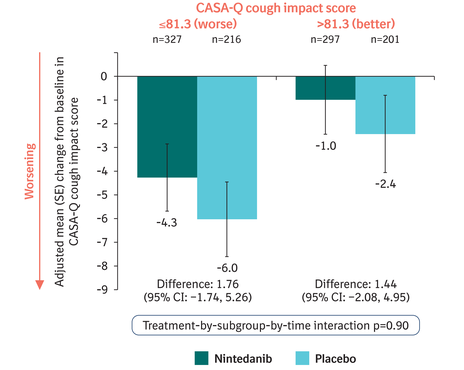
Changes in CASA-Q cough symptoms and impact scores

- Changes in CASA-Q cough scores over 52 weeks were small across subgroups in both treatment groups. Nintedanib did not have a clinically meaningful effect on cough score in any of the subgroups.

Change in CASA-Q cough symptoms score over 52 weeks



Change in CASA-Q cough impact score over 52 weeks



Scan QR code or visit URL for a device-friendly version of this poster with a voiceover from the lead author.

https://www.usscicomms.com/respiratory/ATS2021/Wuyts

INTERACTIVE

Scan QR code or visit URL for a webpage featuring all BI-supported publications at ATS 2021.

https://www.usscicomms.com/respiratory/ATS2021

REFERENCES

1. van Manen MJG et al. Eur Respir Rev 2016;25: 278–286.
2. Ryerson CJ et al. Respirology 2011;16:969–975.
3. Case AH et al. Ann Am Thorac Soc 2020;17:699–705.
4. Crawford B et al. Respir Med 2008;102:1545–1555.
5. Esser D et al. Glob J Health Sci 2013;5:131–141.
6. Richeldi L et al. N Engl J Med 2014;370:2071–2082.

ACKNOWLEDGEMENTS AND DISCLOSURES

The INPULSIS trials were funded by Boehringer Ingelheim International GmbH (BI). The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). The authors did not receive payment for the development of this poster. Editorial support and formatting assistance were provided by Julie Fleming and Wendy Morris of FleishmanHillard, London, UK, which was contracted and funded by BI. BI was given the opportunity to review the poster for medical and scientific accuracy as well as intellectual property considerations. WAW reports grants and other support provided to his institution from BI and Roche. MSW reports grants and other support provided to her institution from BI and Roche and other support provided to her institution from Galapagos, Novartis, Respivant, Savara.

Boehringer Ingelheim

Poster developed for the American Thoracic Society International Conference, 2021.