Continued Treatment with Nintedanib in Patients with Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Two-Year Data from SENSCIS-ON

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INTRODUCTION

- In the SENSCIS trial in patients with SSc-ILD, nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) compared with placebo, with adverse events that were manageable for most patients.[1,2]
- Patients in the SENSCIS trial received nintedanib for a maximum of 100 weeks. SENSCIS-ON (NCT03313180) is an extension study in which all patients receive open-label nintedanib and data are collected on the safety and efficacy of nintedanib over the longer term.

AIM

- To assess adverse events and decline in FVC in patients treated with nintedanib over 100 weeks in SENSCIS-ON.

METHODS

- Patients in SENSCIS-ON came from two parent trials:

1 **SENSCIS trial[1]**

- Patients remained on blinded treatment until the last patient had reached week 52 but for ≤100 weeks
- Patients who completed the SENSCIS trial on treatment and attended a follow-up visit were eligible to enter SENSCIS-ON

2 **Open-label drug-drug interaction study of nintedanib and Microgynon (ethinylestradiol + levonorgestrel) in female patients with SSc-ILD (NCT03675581)[3]**

- Patients received nintedanib over a period of ≥14 days to approximately 28 days
- Patients who completed the study on treatment were eligible to enter SENSCIS-ON

- We analyzed changes in FVC and adverse events over 100 weeks in SENSCIS-ON in:
  - Patients who had received nintedanib in the SENSCIS trial and continued nintedanib in SENSCIS-ON ("continued nintedanib" group)
  - Patients who had received placebo in the SENSCIS trial and initiated nintedanib in SENSCIS-ON, or who had received nintedanib for a short period in the drug-drug interaction study ("initiated nintedanib" group).
- Analyses of SENSCIS and SENSCIS-ON were based on observed FVC data available at the respective time-point.

CONCLUSIONS

- The safety profile of nintedanib over 100 weeks in SENSCIS-ON was consistent with that reported in the SENSCIS trial.
- The decline in FVC over 100 weeks in patients treated with nintedanib in SENSCIS-ON was consistent with the decline in FVC in patients treated with nintedanib over 100 weeks in the SENSCIS trial.
- These findings support a clinically meaningful benefit of nintedanib in slowing the progression of SSc-ILD and a consistent safety profile over longer-term use.

RESULTS

Patients

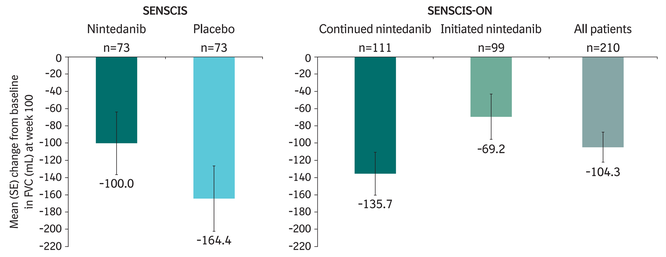
- The continued nintedanib group comprised 197 patients and the initiated nintedanib group comprised 247 patients (231 from SENSCIS, 16 from the drug–drug interaction study).
- In total, 148 (75.1%) and 145 (58.7%) patients in the continued nintedanib and initiated nintedanib groups, respectively, were still receiving nintedanib at week 100 of SENSCIS-ON.

Baseline characteristics at inclusion in SENSCIS-ON

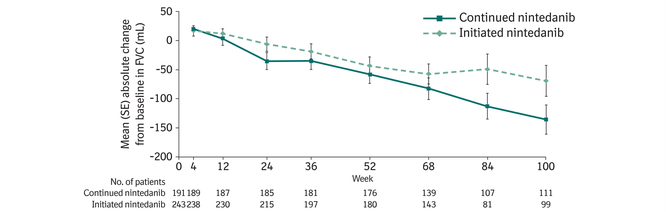
	Continued nintedanib (n=197)	Initiated nintedanib (n=247)
Mean age, years	55.8	54.4
Female, %	75.1	75.7
Mean body mass index, kg/m²	25.4	26.1
White, %	72.1	67.2
Mean FVC % predicted	70.4	70.8

Mean (SD) FVC at the start of SENSCIS was 72.4 and 72.7 % predicted in the nintedanib and placebo groups, respectively.

Change from baseline in FVC (mL) at week 100 in SENSCIS and SENSCIS-ON



Change from baseline in FVC (mL) over time in SENSCIS-ON

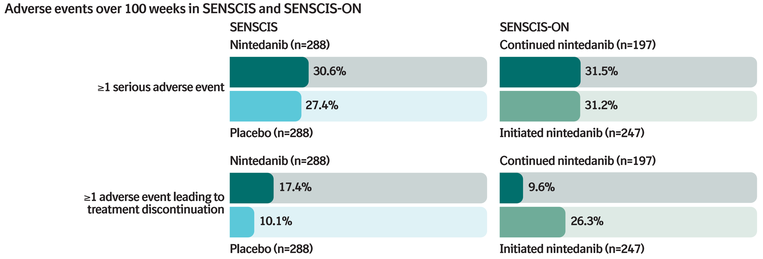


No. of patients

Continued nintedanib	191	189	187	185	181	176	139	107	111
Initiated nintedanib	243	238	230	215	197	180	143	81	99

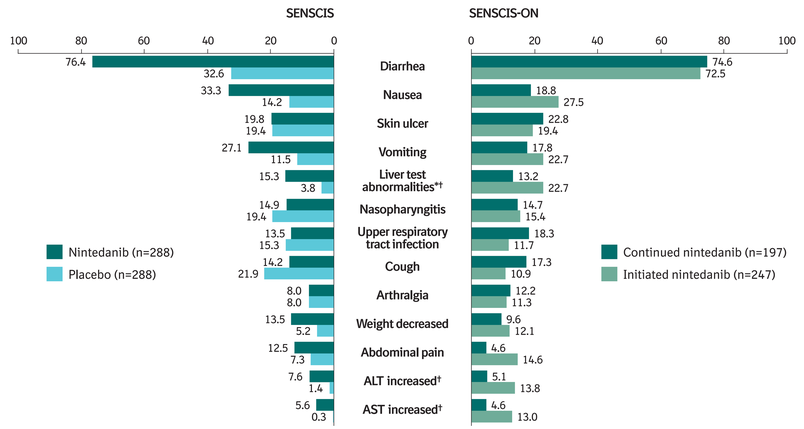
At week 84, 12.7% and 12.6% of patients in the continued and initiated nintedanib groups, respectively, completed a phone visit rather than a clinic visit, and so did not provide an FVC measurement, at week 100, 4.6% and 3.6% of patients in these groups, respectively, completed a phone visit.

Adverse events over 100 weeks in SENSCIS and SENSCIS-ON



Data are % of patients with ≥1 such event reported over 100 weeks (or until 28 days after last drug intake if earlier in SENSCIS, or until 7 days after last trial drug intake if earlier in SENSCIS-ON).

Most frequent adverse events over 100 weeks in SENSCIS and SENSCIS-ON



*Adverse events (reported irrespective of causality) were coded according to preferred terms in the Medical Dictionary for Regulatory Activities (MedDRA) except for "liver test abnormalities", which was based on the standardized MedDRA query "liver related investigations, signs and symptoms" (broad definition).
†Different laboratories, which used different references for the normal range of liver enzymes, were used in SENSCIS and SENSCIS-ON.
Data are % of patients with ≥1 such event reported over 100 weeks (or until 28 days after last drug intake if earlier in SENSCIS, or until 7 days after last trial drug intake if earlier in SENSCIS-ON).
Events reported in >12% of patients in either group in SENSCIS-ON are shown.
ALT, alanine aminotransferase. AST, aspartate aminotransferase.

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