Decline in forced vital capacity (FVC) in subjects with systemic sclerosis-associated interstitial lung disease (SSc-ILD) in the SENSCIS trial versus hypothetical reference subjects without lung disease

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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) over 52 weeks by 44% compared with placebo, with adverse events that were manageable for most patients.[1]
- Healthy individuals have varied FVC depending on age, sex, ethnicity and height. Expected values can be determined using internationally recognised reference equations based on data from over 70,000 healthy subjects.[2]

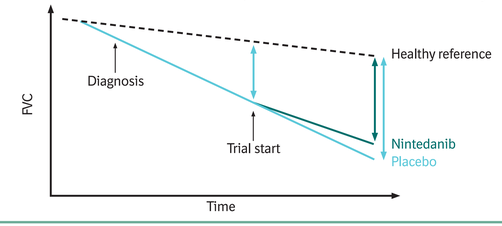
AIM

- To compare FVC at baseline and the decline in FVC over 52 weeks in subjects with SSc-ILD in the SENSCIS trial with values in hypothetical subjects without lung disease matched for age, sex, ethnicity and height.

METHODS

- Subjects in the SENSCIS trial had SSc with first non-Raynaud symptom ≤7 years before screening, fibrotic ILD of ≥10% extent on HRCT, FVC ≥40% predicted and DLco 30–89% predicted. Subjects taking prednisone ≤10 mg/day and/or stable therapy with mycophenolate or methotrexate for ≥6 months prior to randomisation were allowed to participate.
- Baseline FVC (mL) and changes in FVC (mL) at week 52 were assessed in the nintedanib and placebo groups, with missing values at week 52 imputed using predictions from the random slope and intercept model used in the primary analysis of the rate of decline in FVC.
- Baseline FVC and changes in FVC in the SENSCIS trial were compared to values in hypothetical healthy reference subjects 1:1 matched to the SENSCIS subjects for age, sex, ethnicity and height, predicted using the reference equations published by the European Respiratory Society Global Lung Function Initiative.[2]

Schematic illustration of course of FVC decline in subjects in the SENSCIS trial and healthy reference subjects



CONCLUSIONS

- Subjects with SSc-ILD in the SENSCIS trial, who had a median duration of SSc of 3.4 years, had marked lung function impairment at baseline compared with healthy reference subjects matched for age, sex, ethnicity and height.
- Over 52 weeks, the decline in FVC in the placebo group of the SENSCIS trial was 4-fold greater than in healthy reference subjects. Subjects treated with nintedanib had a decline in FVC that was only 2-fold greater than the decline in healthy reference subjects.
- These data put the SENSCIS trial results into context and support the clinical relevance of the reduction in the rate of FVC decline provided by nintedanib in patients with SSc-ILD.

RESULTS

Subjects

- A total of 576 subjects were treated in the SENSCIS trial. Three subjects aged <25 years were excluded from the analysis.

Baseline characteristics of subjects in the SENSCIS trial

- Mean age 54.0 years
- 67.2% White
- 75.2% female
- Mean height 164cm
- Median time since first non-Raynaud symptom 3.4 years
- 48.4% taking mycophenolate

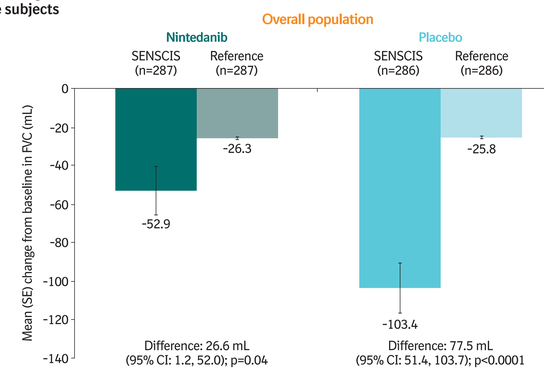
Mean (SD) FVC (mL) at baseline in subjects in the SENSCIS trial compared with healthy reference subjects

	Nintedanib		Placebo	
	SENSCIS (n=287)	Reference (n=287)	SENSCIS (n=286)	Reference (n=286)
Overall population	2460 (737)	3403 (787)	2544 (817)	3516 (887)
Taking mycophenolate	2499 (726)	3569 (754)	2581 (816)	3666 (897)
Not taking mycophenolate	2423 (748)	3250 (789)	2509 (820)	3375 (856)

Change in FVC

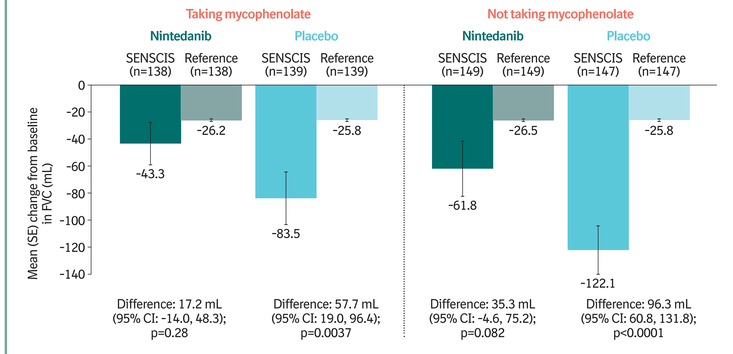
- In both the placebo and nintedanib groups, the decline in FVC in subjects in the SENSCIS trial was significantly greater than in healthy reference subjects.

Absolute change from baseline in FVC (mL) at week 52 in subjects in the SENSCIS trial versus healthy reference subjects



- In both the nintedanib and placebo groups, the difference in the change from baseline in FVC at week 52 between subjects in the SENSCIS trial and healthy reference subjects was numerically lower in subjects taking mycophenolate at baseline.

Absolute change from baseline in FVC (mL) at week 52 in subjects in the SENSCIS trial versus healthy reference subjects in subgroups by mycophenolate use at baseline



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