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SAT0329

IS THE RATE OF LUNG FUNCTION DECLINE THE SAME IN PATIENTS WITH SYSTEMIC SCLEROSIS-ASSOCIATED ILD (SSc-ILD) WHO EXPERIENCE WEIGHT LOSS? DATA FROM THE SENSISCIS TRIAL

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Background: In the SENSISCIS trial, nintedanib reduced the progression of SSc-ILD vs placebo, as shown by a lower rate of decline in forced vital capacity (FVC). The adverse event (AE) profile of nintedanib was characterised mainly by gastrointestinal (GI) events, including weight loss.

Objectives: Assess FVC decline and AEs in subgroups by weight loss $\leq 5\%$ vs $>5\%$ over 52 weeks in the SENSISCIS trial.

Methods: Patients with SSc-ILD with first non-Raynaud symptom <7 years before screening and $\geq 10\%$ fibrosis of the lungs on an HRCT scan were randomised to nintedanib or placebo. In a non-randomised comparison, we analysed the rate of decline in FVC (mL/year) and AEs over 52 weeks in subgroups by weight loss ($\leq 5\%$ vs $>5\%$) over 52 weeks.

Results: In the nintedanib (n=288) and placebo (n=288) groups, respectively, 112 (38.9%) and 43 (14.9%) patients had weight loss $>5\%$ over 52 weeks. At baseline, patients with weight loss $>5\%$ over 52 weeks had a higher mean age (57.0 vs 52.9 years), greater proportion of females (81.3% vs 72.9%), and similar mean BMI (26.5 vs 25.7 kg/m², respectively) and FVC % predicted (71.0% vs 73.1%, respectively) vs patients with weight loss $\leq 5\%$. In the placebo group, the mean (SE) annual rate of decline in FVC was similar between patients who had weight loss $\leq 5\%$ and $>5\%$ over 52 weeks (-92.7 [14.7] mL/year and -96.4 [34.9] mL/year, respectively). The estimated annual rate of decline in FVC was lower in patients treated with nintedanib than placebo, with between-group differences in patients who had weight loss $\leq 5\%$ and $>5\%$ of 49.9 mL/year [95% CI 4.2, 95.6]) and 30.2 mL/year [95% CI -50.5, 110.9]), respectively, with no evidence of heterogeneity between subgroups by weight loss (p=0.68 for interaction). Standardised differences in baseline values of potential confounders were <0.2 (indicating negligible differences). The most frequent AEs in patients treated with nintedanib were diarrhoea (74.4% and 77.7% of patients with weight loss $\leq 5\%$ and $>5\%$,

respectively), nausea (30.1% and 33.9%, respectively) and vomiting (19.3% and 33.3%, respectively). In the nintedanib and placebo groups, respectively, AEs leading to discontinuation of study drug occurred in 17.0% and 8.6% of patients with weight loss $\leq 5\%$, and 14.3% and 9.3% of patients with weight loss $>5\%$ over 52 weeks.

Conclusion: In the SENSISCIS trial in patients with SSc-ILD, a greater proportion of patients treated with nintedanib than placebo had weight loss $>5\%$ over 52 weeks. The rate of decline in FVC was numerically lower in the nintedanib group than in the placebo group both in patients with weight loss $\leq 5\%$ and $>5\%$ over 52 weeks. AEs leading to discontinuation of nintedanib were not more frequent in patients with weight loss $>5\%$ vs $\leq 5\%$.

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Figure. Rate of decline in FVC in subgroups by weight loss over 52 weeks in the SENSISCIS trial

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SAT0330

NEW IMMUNOMODULATORY COMBINATION THERAPIES IN PATIENTS WITH SYSTEMIC SCLEROSIS: A RETROSPECTIVE CROSS-SECTIONAL STUDY

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Background: Systemic sclerosis (scleroderma, SSc) is a rare complex connective tissue disease associated with high mortality and high morbidity¹. Active SSc