**References:**


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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 SENSCIS TRIAL**

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**Background:** In the SENSCIS 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 ≤5% vs >5% over 52 weeks in the SENSCIS trial.

**Methods:** Patients with SSC-ILD with first non-Raynaud symptom <7 years before screening and ≤10% fibrosis of the lungs on HRCT scan were ran-domised to nintedanib or placebo. In a non-randomised comparison, we ana-lysed the rate of decline in FVC (mL/year) and AEs over 52 weeks in subgroups by weight loss (≤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 ≤5%. In the placebo group, the mean (SE) annual rate of decline in FVC was similar between patients who had weight loss ≤5% and >5% over 52 weeks (-9.27 [14.7] mL/year and -9.64 [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 ≤5% vs >5% of 48.9 mL/year (95% CI 4.2, 95.6) and 30.2 mL/year (95% CI -50.5, 110.9), respectively, with no evidence of heter-ogeneity between subgroups by weight loss (p=0.68 for interaction). Standard-ised 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 ≤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 170% and 8.6% of patients with weight loss ≤5% and 14.3% and 9.3% of patients with weight loss >5% over 52 weeks.

**Conclusion:** In the SENSCIS 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 ≤5% and >5% over 52 weeks. AEs leading to discontinuation of nintedanib were not more frequent in patients with weight loss >5% vs ≤5%.

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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 connec-tive tissue disease associated with high mortality and high morbidity. Active SSC