**Background:** In the SENSCIS trial, nintedanib reduced the progression of SScILD 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 events, including weight loss (≤5% vs >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%.

**Discussion:** In the SENSCIS trial in patients with SScILD, 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%.

**References:**


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**SAT0329**

**IS THE RATE OF LUNG FUNCTION DECLINE THE SAME IN PATIENTS WITH SYSTEMIC SCLEROSIS-ASSOCIATED IILD (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 SScILD 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 (≤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 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 of patients treated with nintedanib or 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 events, including weight loss (≤5% vs >5%) over 52 weeks. AEs leading to discontinuation of nintedanib were not more frequent in patients with weight loss ≥5% vs ≤5%.

**Results:** In the nintedanib (n=288) and placebo (n=288) groups, 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 SScILD, 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%.

**References:**

[1] Lesmac A, Jouneau S, Crestani B, Riemekasten G, Kondoh Y, Smith V, Patel N, Pefail J, Huggins J, Stock C, Gahlemann M, Alves M, Denton C, CHU South Hospital, Internal Medicine, Rennes, France; 2Department of Respiratory Medicine, Competences Centre for Rare Pulmonary Diseases, CHU Rennes, Université de Rennes, Rennes, France; 3Hospital Bichat, Pneumologie, Paris, France; 4University Hospital Charité, Rheumatology and Clinical Immunology, Berlin, and University Hospital Schleswig-Holstein, Rheumatology, Lübeck, Germany; 5Rsbi General Hospital, Department of Respiratory Medicine and Allergy, Seto, Japan; 6Department of Rheumatology, Ghent University Hospital, Ghent, Belgium; 7Department of Internal Medicine, Ghent University, Ghent, Belgium; 8Columbia University College of Physicians and Surgeons/New York Presbyterian Hospital, Division of Pulmonary, Allergy, and Critical Care Medicine, New York, NY, United States of America; 9Medical University of South Carolina, Charleston, South Carolina, United States of America; 10Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany; 11Boehringer Ingelheim (Schweiz) GmbH, Basel, Switzerland; 12Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; 13Centre for Rheumatology and Connective Tissue Diseases, University College London Division of Medicine, London, United Kingdom.

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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
are typically treated with immunosuppressants, which may create a variety of severe side-effects, especially for long-term treatment. As the pathogenesis of SSc is still a matter of debate, growing evidences have focused on the immune disorders. However, the quantitative status of lymphocyte subsets in SSc patients are unclear and effects of immunomodulatory combination therapies (avoiding side-effects of conventional therapy) on the lymphocyte subsets are unknown.

**Objectives:** To investigate the quantitative status of peripheral lymphocyte subpopulations and CD4+ T subsets in SSc patients for the exploration of SSc pathogenesis and evaluate the effects of new immunomodulatory combination therapies on these cells.

**Methods:** From July 2014 to December 2019, total 166 patients with SSc and 206 healthy controls (HCs) were enrolled in this study, in which, 79 follow-up patients received immunomodulatory drugs (IMIDs) such as low-dose interleukin-2, rapamycin, metformin, retinoic acid and coenzyme Q10. The absolute numbers of T, B, NK, CD4+, CD8+, Th1, Th2, Th17 and Tregs in peripheral blood of these subjects were detected by flow cytometry combined with standard absolute counting beads.

**Results:** Patients with SSc had lower absolute counts of total T, NK, Th2, Th17 and Tregs as compared with those of HCs (P<0.05) (Figure 1). After immunomodulatory combination treatments, there were increases in a various of peripheral lymphocyte subsets such as T, B and CD8+ T (P < 0.05). Moreover, the increased level of Tregs was much more dramatical than those of other lymphocyte subsets, resulting in the decrease ratios of Teffs/Tregs such as Th1/Tregs and Th2/ Tregs and rebuilding immunologic equilibrium (Figure 2).

**Conclusion:** This cross-sectional study clarified the abnormal status of lymphocyte subsets in SSc patients, suggesting lymphocyte subsets, especially Tregs, might be relevant and play a crucial role in the pathogenesis of SSc, thus providing a potential therapeutic target for SSc patients. Immunomodulatory combination therapies effectively increase the level of Tregs as well as other lymphocytes to some degree and maintain the immunologic equilibrium, which may help for SSc patients' symptom remission.

**References:**