



Interim Analysis of SENSICIS-ON TRIAL for SSc-ILD Patients Treated with Nintedanib

SENSICIS-ON was the open-label extension trial from the main census trial, and as you may recall, the census trial compared nintedanib versus placebo for the treatment of SSc-ILD. In this study, patients were either randomized and in nintedanib versus placebo, and they were followed over the course of 52 weeks. In this open label extension trial, patients who had been originally assigned to placebo were then allowed to start nintedanib, and over the course of this study what they found was that, once again, nintedanib slowed the decline of the FVC in both groups. There was actually no difference in the rate of decline of FVC in the patients who had been originally assigned to placebo and had been put nintedanib, versus those patients who have been on nintedanib from the start and continued on nintedanib in the open-label extension study.

In addition, the adverse event profiles from both groups were very similar to what was seen in the census trial, and, again, the main side effect being diarrhea, which was found in the majority of patients. The implications of this work is that patients who had been started on nintedanib at a later disease stage, it was a year after the study, still derived a benefit with treatment with nintedanib, and, to me, this suggests that patients with SSc-ILD may benefit with treatment from an nintedanib at different disease stages, including that a stage, maybe, later in the course of the disease, but future studies are needed to look at this population of patients.