A randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of nintedanib for at least 52 weeks in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) (NCT02597933)\(^1\)

**Design**

- **Nintedanib 150 mg bid (n=260)**
- **Placebo (n=260)**

**Endpoints**

**Primary endpoint**
- Annual rate of decline in FVC (mL/year) assessed over 52 weeks

**Key secondary endpoints**
- Change from baseline in modified Rodnan Skin Score at week 52
- Change from baseline in St. George’s Respiratory Questionnaire total score at week 52

**Ongoing clinical trial**

- USA
- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- Chile
- China
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- India
- Ireland
- Israel
- Italy
- Japan
- Malaysia
- Mexico
- The Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden
- Switzerland
- Thailand
- UK
- Thailand
- The Netherlands
- Norway
- Poland
- Portugal
- Spain
- Sweden
- Switzerland
- Thailand
- UK

FVC, forced vital capacity.

Please find additional information at www.clinicaltrials.gov (NCT02597933).

Nintedanib is not approved for the treatment of interstitial lung disease associated with systemic sclerosis.