Multicenter, Randomized, Double-blind, Placebo-controlled Phase II Trial to Evaluate the Efficacy and Safety of HRS-9813 in Subjects With Pulmonary Fibrosis

NCT07192939

Status	RECRUITING
Phase	Phase 2
Sponsor	Guangdong Hengrui Pharmaceutical Co., Ltd
Enrollment	270 participants

Key Eligibility Criteria

Inclusion (9)

- Informed consent was obtained to participate in the trial
- Patients were aged e21 years for PPF and e45 years for IPF.
- IPF diagnosed within 7 years before screening (including the screening period) or evidence of progressive ILD within 12 months before screening;
- HRCT and surgical lung biopsy or transbronchial lung cryobiopsy, when available, support the clinical diagnosis;
- The central HRCT reading results of PPF at screening showed that the whole lung parenchymal fibrosis was \> 10%;

... and 4 more (see full listing online)

Exclusion (32)

- IPF cohort: i. Interstitial lung disease (ILD) of other known cause; ii. Diagnosis of sarcoidosis or any systemic autoimmune disease
- PPF cohort: IPF diagnosis and UIP features supported by HRCT central reading, surgical lung biopsy, or cryobiopsy pathology.
- The presence of emphysema of 50% or more on centrally read HRCT or the degree of emphysema greater than the degree of fibrosis on the basis of the most recent HRCT report.
- The presence of clinically significant nonsubstantial lung disease was considered by the investigator to be likely to affect the assessment of the study.
- Subjects were known to have pulmonary hypertension requiring treatment with multiple medications.

... and 27 more (see full listing online)

Locations (1 total)

Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, Beijing Municipality, China