Safety of nintedanib in real world in China: a non interventional study based on Idiopathic Pulmonary (Interstitial) Fibrosis Registry China Study (PORTRAY) data

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Study Planned

Administrative details

EU PAS number

EUPAS49529

Study ID

49530

DARWIN EU® study

No

Study countries

China

Study status

Planned

Research institutions and networks

Institutions

China-Japan Friendship Hospital

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Institution

Contact details

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Primary lead investigator

Yi Shi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/12/2022

Study start date

Planned: 29/12/2023

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim (China) Investment Co., Ltd

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To evaluate the incidence rates of ADRs and fatal AEs among IPF patients in China who initiate nintedanib during the study period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

800

Study design details

Outcomes

The primary outcomes (safety outcomes) will only be assessed for the nintedanib group. Patient follow-up will start from the index date and will end when one of the situations listed below occurs, whichever occurs first: • Death, • Loss of follow-up, • 4 weeks after the discontinuation of nintedanib, • The end of the PORTRAY study follow-up, Mean age at baseline of IPF patients in China who are new usersof nintedanib, new users of pirfenidone, and those who receiveneither of the two antifibrotic drugs. Percentage of each gender of IPF patients in China who are new users of nintedanib, new users of pirfenidone, and those who receive neither of the two antifibrotic drugs

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Data analysis plan

The study is descriptive in nature. For continuous data, descriptive statistics (mean, standard deviation SD, minimum, median, interquartile range IQR, and maximum) will be presented. Categorical data will be presented as frequency and incidence rate with 95% CI or counts with percentages as appropriate.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Idiopathic Pulmonary fibrosis registry China Study PORTRAY

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No