Post Authorization Safety Study of Nintedanib in the treatment of patients with Idiopathic Pulmonary fibrosis in Argentina

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Study Planned

Administrative details

EU PAS number

EUPAS18150

Study ID

18151

DARWIN EU® study

No

Study countries

Argentina

Study description

According to the Orphan Drug regulation currently in force in Argentina (Provision 4622/2012, Annex I, Paragraph 2), BI must implement a registry of all patients with idiopathic pulmonary fibrosis (IPF) receiving nintedanib.The following registry objectives have been defined for all IPF patients receiving treatment with nintedanib in Argentina:1. To determine the baseline characteristics of the IPF population receiving treatment with nintedanib (with population stratified based on whether it had received prior treatment with pirfenidone, other therapies for IPF or no treatment).2. To collect data on adverse events in patients receiving nintedanib.The following registry objectives have been defined for IPF patients from two tertiary care centers (Hospital María Ferrer, located in Buenos Aires, and Hospital Cetrángolo, located in Vicente López):1. To determine the baseline characteristics of all IPF patients at two tertiary care centers.2. To collect adverse event data from patients receiving nintedanib (with population stratified based on whether it had received prior treatment with pirfenidone, other therapies for IPF or no treatment).3. To obtain an overall patient-reported assessment, as measured by the Patient Global Rating (PGR) scale, from patients newly diagnosed with IPF receiving treatment with nintedanib.4. To evaluate the decline in lung function, as measured by forced vital capacity (FVC), in patients newly diagnosed with IPF receiving treatment with nintedanib.

Study status

Planned

Research institutions and networks

Institutions

Hospital Cetrángolo

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Institution

Contact details

Study institution contact

Laura Cornejo laura.cornejo@boehringer-ingelheim.com

Study contact

laura.cornejo@boehringer-ingelheim.com

Primary lead investigator

Gabriela Tabaj

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/03/2017

Study start date

Planned: 03/04/2017

Date of final study report

Planned: 07/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

BI-NI-PASS Nintedanib in IPF V1.0 02Feb2017_FINAL Argentina.pdf (380.41 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The main objective of this study is to describe the safety and effectiveness of nintedanib in clinical practice

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Medicinal product name

OFEV

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

20

Study design details

Outcomes

Primary objective is to determine all adverse events of nintedanib use.

Secondary objective is to evaluate the effectiveness of nintedanib.

Data analysis plan

Descriptive statistics will be mainly used in the analysis. Categorical variables will be individually listed and summarized. Number of patients, standard deviations, mean, percentages will be used with graphics and tables when appropriate. Kaplan Meir curves will be used where appropriate.No imputation is planned for missing data.

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)

Disease registry

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