Post-marketing Surveillance of Ofev Capsules in Chronic (PMS for PF-ILD)

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Study Ongoing

Administrative details

EU PAS number

EUPAS36605

Study ID

40512

DARWIN EU® study

No

Study countries

☐ Japan

Study description

The primary objective is to evaluate the incidence of adverse drug reactions (focus on hepatic function disorders) of Ofev Capsules under the real world setting in patients with PF-ILD.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hiroko Noguchi

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/09/2020

Actual: 28/09/2020

Study start date
Planned: 01/10/2020

Actual: 02/10/2020

Data analysis start date
Planned: 03/03/2025

Date of final study report
Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

1199-0402-non-interventional-study-protocol_ver4.0_Redacted.pdf (409.46 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

Main objective is to confirm the incidence of adverse drug reactions (ADRs) by overall, each individual (especially focus on the safety specification on J-RMP: hepatic function disorders)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OFEV

Study drug International non-proprietary name (INN) or common name

NINTEDANIB

Anatomical Therapeutic Chemical (ATC) code

(L01EX09) nintedanib

nintedanib

Medical condition to be studied

Interstitial lung disease

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

440

Study design details

Outcomes

The incidence of adverse drug reactions (ADRs)

Data analysis plan

analyses are descriptive in nature, including confidence intervals.

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

Prospective patient-based data collection

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