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

First published: 04/08/2020

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Study Finalised

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

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

Hiroko Noguchi hiroko.noguchi@boehringer-ingelheim.com

Study contact

hiroko.noguchi@boehringer-ingelheim.com

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

Actual: 26/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

Protocol_and_Protocol_Amendment_30_Sep_2025__Redacted.pdf (383.07 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

Other study registration identification numbers and links

1199-0402

NCT04559581

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a non-interventional study based on newly collected data of patients under routine care to confirm safety of Ofev Capsules in the real-world setting in Japanese patients with PF-ILD.

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

Short description of the study population

Inclusion criteria

-Patients in Japan with PF-ILD who are prescribed with Ofev Capsules and have never been treated with Ofev Capsules before enrolment will be included.

Exclusion criteria

- Diagnosis of IPF
- Patients with PF-ILD due to systemic scleroderma as the underlying disease

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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

Setting

Sites throughout entire country will be equally listed according the size of the hospitals or general clinics at which Ofev Capsules are available for prescription.

Planned number of sites: Approximately 100 Sites

A medical representative will explain the objective and design of this study to investigators at each study site and conclude a written contract with the head of the study site (e.g., hospital director).

Comparators

None

Outcomes

The incidence of adverse drug reactions (ADRs)

Data analysis plan

analyses are descriptive in nature, including confidence intervals.

Summary results

There was no notable difference in the safety profile observed in the PMS and the information provided in the Japanese package insert. The study does not indicate any changes on Risk and Benefit concerning Ofev
Capsules treatment.

Documents

Study results

1199-0402_Synopsis.pdf (242.56 KB)

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 source(s), other

Patients’ data were collected by electronic CRF on Electronic Data Capture (EDC) system

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