A regulatory requirement non-interventional study to monitor the safety and effectiveness of Ofev (Nintedanib, 150mg/100mg, BID) in Korean patients

First published: 07/07/2021

Last updated: 10/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47414

EU PAS number

EUPAS41912

Study ID

47414

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

To monitor the safety and effectiveness of Ofev in Korean patients in a routine clinical practice setting.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Hyelin Lee

Study contact

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Primary lead investigator

Hyelin Lee

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/12/2020

Actual: 29/12/2020

Study start date
Planned: 31/03/2021

Actual: 16/03/2021

Date of final study report
Planned: 20/07/2023

Actual: 27/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Korea

Study protocol

1199-0417_CTP_final-rule_Redacted.pdf(1.03 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

1199-0417

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Main study objective:

The primary objective is to monitor the safety profile of Ofev in Korean patient in a routine clinical setting.

Study drug and medical condition

Name of medicine

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

Idiopathic pulmonary fibrosis

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)

Special population of interest

Hepatic impaired

Renal impaired

Estimated number of subjects

59

Study design details

Data analysis plan

Descriptive analysis will be performed.

Documents

Study report

1199-0417_redacted Synopsis.pdf(235.37 KB)

Data management

Data sources

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes