Post-Authorisation Safety Study of Esbriet® (Pirfenidone): A Prospective Observational Registry to Evaluate Long-Term Safety in Real-World Setting (PASSPORT)

First published: 21/02/2012

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Study | Finalised

Administrative details

EU PAS number

EUPAS2165

Study ID

23388

DARWIN EU® study

No

Study countries

Germany

Study description

Idiopathic pulmonary fibrosis (IPF) is a progressive illness with an extremely poor prognosis, median survival after diagnosis is 2-5 years. Esbriet® is an orally bioavailable small synthetic non-peptide molecule that attenuates fibroblast proliferation, production of fibrosis-associated proteins and cytokines, and the increased biosynthesis and accumulation of extracellular matrix in response to cytokine growth factors such as transforming growth factor-beta and platelet-derived growth factor. Esbriet® is authorised for the treatment of mild to moderate IPF. Although data from the development programme including Phase 3 trials demonstrate that Esbriet® has an acceptable risk benefit profile in the treatment of mild to moderate IPF, there is a need, in real-world clinical practice, to establish the long-term safety profile of Esbriet® treatment. The objective of this study is to evaluate the long-term safety profile of Esbriet® in patients with IPF and to monitor for any unknown or potential risks of treatment with Esbriet®. This product registry is a multicentre, long-term, prospective, observational study to evaluate the long-term safety of Esbriet® in patients with IPF. Patients will receive Esbriet® at the discretion of their physicians and will be followed through the registry for 2 years after they begin treatment with Esbriet®. This registry complies with the requirement of a post-authorisation safety study (PASS) and is a post-authorisation commitment, which has been approved by the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA). The registry is observational, therefore, all treatment decisions are at the discretion of the patient’s health care provider and are not mandated by study design or protocol. Cooperation of health care professionals is based on goodwill and no contractual sanctions will be applied by the MAH.

Study status

Finalised

Research institutions and networks

Institutions

N/A

Multiple centres: 106 centres are involved in the study

Contact details

Study institution contact

Astrid Scalori global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Astrid Scalori

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2011

Actual: 01/12/2011

Study start date
Planned: 15/02/2012

Actual: 16/02/2012

Date of final study report
Planned: 30/09/2017

Actual: 28/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F Hoffmann La Roche, Ltd.

Study protocol

Protocol WB29908 (PIPF-025)_Redacted_final.pdf (292.68 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this study is to evaluate the long-term safety profile of Esbriet® in patients with IPF and to monitor for any unknown or potential risks of treatment with Esbriet®.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Safety Registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AX) Other immunosuppressants

Other immunosuppressants

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Patients with idiopathic pulmonary fibrosis (IPF) with newly prescribed Esbriet® therapy or within less then 30 days prior to study enrolment.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Other

Special population of interest, other

Idiopathic pulmonary fibrosis patients

Estimated number of subjects

1.000

Study design details

Data analysis plan

All data will be analyzed in a descriptive manner, no formal hypotheses will be tested. Frequencies and incidence rates of reported adverse drug reactions (ADRs) will be summarized by MedDRA SOC, HLT, and PT. Clinical characteristics of the study population will be analyzed by frequency and percentages for categorical variables and by mean, standard deviation, minimum, median, and maximum for continuous variables. The study population for analysis of safety will include all patients who receive at least one dose of Esbriet® regardless of the length of follow up.

Documents

Study results

WB29908 CSR Synopsis_Redacted.pdf (13.79 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 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

Unknown