A 2-Year Observational Study to Describe the Characteristics and Progression of Patients Suffering from Idiopathic Pulmonary Fibrosis Treated with Esbriet® in the Conditions of Use

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Study Finalised

Administrative details

EU PAS number

EUPAS12456

Study ID

23871

DARWIN EU® study

No

Study countries

☐ France

Study description

At request of the EMA, InterMune (acquired by Roche) initiated a European post-marketing safety study, PIPF-025 or PASSPORT, to evaluate the safety profile of long-term use of Esbriet in patients with IPF and to monitor the potential or unknown risks over two years of treatment with Esbriet.Given the necessity for improved understanding of the clinical outcomes in real life for patients with IPF treated with Esbriet, Roche now plans to implement the FAS (French Ancillary Study), an observational and ancillary study to the PASSPORT study at the request of the French authorities (Haute Autorité de Santé and Direction Générale de la Santé).Efficacy data will be collected in FAS at French sites only to complement the safety data obtained in the PASSPORT study. The PASSPORT study and the FAS will be conducted in parallel involving the same French sites, patients and Principal Investigators.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences Europe Ltd.

Multiple centres: 22 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

Actual: 01/12/2015

Study start date

Planned: 20/05/2016

Actual: 17/05/2016

Date of final study report

Planned: 21/02/2017

Actual: 16/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

Protocol WA29961 (PIPF-028) v3_Redacted_final.pdf(865.63 KB)

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

WA29961

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Describe the clinical progression over two years of patients suffering from IPF treated with Esbriet in the conditions of use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PIRFENIDONE

Medical condition to be studied

Idiopathic pulmonary fibrosis

Population studied

Short description of the study population

Patients suffering from idiopathic pulmonary fibrosis (IPF) treated with Esbriet.

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

Other

Special population of interest, other

Patients with idiopathic pulmonary fibrosis (IPF)

Estimated number of subjects

214

Study design details

Outcomes

Over total treatment time (up to 2 years):• Change in % predicted Forced Vital Capacity (FVC)• Change in distance travelled during the 6MWT, 1.Modalities used to determine IPF2.Cases of IPF comorbidities, in particular acute exacerbation and PAH3.Progression-free survival, defined as time from initiation of Esbriet to the first occurrence of the following events:•An absolute decline in % predicted FVC ≥ 10% over the duration of the FU •An absolute decline in 6MWT distance ≥ 50m over the duration of the FU•Death from any cause

Data analysis plan

The statistical analyses will be descriptive.Continuous variables, including changes from baseline for continuous variables, will be summarized with means, standard deviations, medians, minimums and maximums, and amount of missing data.Categorical variables, including changes from baseline categories, will be summarized with counts and percentage of patients, and the amount of missing data.Kaplan-Meier estimates will be used to summarize the data for time-to-event variables.The primary and secondary endpoints will be estimated by the mean with 95% confidence interval for continuous variables and the frequency (percentage) with 95% confidence interval for categorical variables.

Documents

Study results

Final CSR Synopsis WA29961_Redacted.pdf(427.8 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, Part-retrospective 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