An Observational, Post-Authorization Safety Study (PASS) within the Consortium of Rheumatology Researchers of North America (CORRONA) Registry ComparingRates of Malignancy, Cardiovascular and Serious Infection Outcomes among Patients Treated for Moderately to Severely Active Rheumatoid Arthritis (CORRONA Surveillance PASS)

First published: 30/01/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/34710

EU PAS number

EUPAS5708

Study ID

34710

DARWIN EU® study

No

Study countries

☐ United States

Study description

Tofacitinib is a potent, selective inhibitor of the Janus kinase family of kinases with a high degree of selectivity against other kinases in the human genome. To enable assessment of rare events and endpoints with long latency periods, Pfizer will implement a post-approval, population-based active surveillance study of tofacitinib-exposed patients using the Consortium of Rheumatology Researchers of North America registry to actively collect data in a prospective manner.

Study status

Finalised

Research institutions and networks

Institutions

CORRONA

Contact details

Study institution contact

Madsen Ann

Study contact

ann.madsen@pfizer.com

Primary lead investigator

Madsen Ann

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/01/2013

Actual: 15/07/2013

Study start date

Planned: 04/12/2012

Actual: 04/12/2012

Date of final study report

Planned: 31/12/2019

Actual: 13/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

A3921205_PROTOCOL_23DEC2013.pdf(1.08 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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:

Secondary use of data

Main study objective:

The main objective of the study is to assess the safety of tofacitinb in the post-approval setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

All patients, 18 years of age and older, who receive tofacitinib for the treatment of RA following US approval and marketing through the end of the study period (estimated to be 5 years from the launch date). Incident and prevalent users of tofacitinib were included.

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

Rheumatoid arthritis patients

Estimated number of subjects

3000

Study design details

Outcomes

The primary outcomes are serious infections, malignancies and cardiovascular events. Secondary outcomes include events commonly seen in patients with RA.

Data analysis plan

For the safety endpoints of interest, summary statistics, frequencies, crude cumulative incidence proportions, and crude incidence rates (ie, number of events per person-years) and associated 95% confidence intervals will be calculated as appropriate. Depending on data availability, subgroupanalyses may be performed.

Documents

Study results

a3921205-report-body.pdf(1.22 MB)

Data management

Data sources

Data source(s), other

CORRONA databases

Data sources (types)

Disease registry

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