An Active Surveillance, Post-Authorization Study to Characterize the Safety of Tofacitinib in Patients With Moderately to Severely Active Ulcerative Colitis in the Real-World Setting Using Data From the United Registries for Clinical Assessment and Research (UR-CARE) in the European Union (EU)

First published: 21/07/2023

Last updated: 02/07/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/103633

EU PAS number

EUPAS103632

Study ID

103633

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] France
- [ ] Greece
- [ ] Netherlands
- [ ] Poland
- [ ] Romania
- [ ] Slovenia
- [ ] Spain

Study description

Tofacitinib, an inhibitor of the Janus kinase (JAK) family of kinases, was approved in the European Union (EU) in July 2018 at a dose of 5 mg twice daily or 10 mg twice daily for the treatment of adults with moderate-to-severe ulcerative colitis (UC), who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. Malignancy excluding non-melanoma skin cancer (NMSC) is an important potential risk and venous thromboembolism (VTE) is an important identified risk associated with the use of tofacitinib, and follow-up of large cohorts of patients over a long period is needed to evaluate the risks of these safety events, as well as other potential safety events of interest, that may be associated with tofacitinib treatment. Pfizer will implement a post-approval, active surveillance study of

tofacitinib-exposed and unexposed patients using actively collected prospective data included in the UR-CARE platform.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

United Registries for Clinical Assessment and Research (UR-CARE)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/11/2020

Actual: 18/11/2020

Study start date

Planned: 31/01/2024

Date of interim report, if expected

Planned: 31/08/2024

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921352_TOFACITINIB UC PASS PROTOCOL_V4.0_ 27FEB2023.pdf(605.65 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

What are the incidence rates of safety events of interest in adult ulcerative colitis (UC) patients aged ?18 years treated with tofacitinib in routine clinical care, as compared to the incidence rates in UC patients treated with other approved systemic agents, and UC patients naïve to biologics and immunomodulators/immunosuppressants (hereafter referred to as

immunosuppressants)?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Colitis ulcerative

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)

Estimated number of subjects

500

Study design details

Outcomes

Estimate the incidence rates of malignancy and VTE (deep venous thrombosis DVT and pulmonary embolism PE) among adult UC patients years who initiate tofacitinib in the course of routine clinical care, as well as the incidence rates in UC patients treated with other approved systemic agents such as biologics and immunosuppressants, and in UC patients naïve to biologics and immunosuppressants, Estimate incidence rates of other safety events among adult UC patients who initiate tofacitinib in the course of routine clinical care, in UC patients treated with other approved systemic agents, and in comparator cohorts. Estimate incidence rates of primary and secondary safety events of interest stratified by tofacitinib dose.

Data analysis plan

Baseline demographic and clinical characteristics for each cohort, including proportion of patients with ?1 VTE risk factors will be described. For all the safety events of interest, descriptive statistics, counts and proportions, unadjusted cumulative incidence proportions, and crude incidence rates (i.e. number of events per person-years) and age/sex standardized incidence rates with associated 2-sided 95% confidence intervals will be calculated as appropriate. The estimated incidence rates will be based on survival analysis of time to first event based on an index date defined for each cohort with appropriate censoring rules applied for those who do not experience an event by end of follow-up period.

Data management

Data sources

Data source(s), other

United Registries for Clinical Assessment and Research (UR-CARE) Austria

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

No