Uveitis in chronic inflammatory conditions and ulcerative colitis-related pyoderma gangrenosum and axial spondylarthritis: an observational study of patients receiving advanced therapies in the United States

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/199002

EU PAS number
EUPAS107604

Study ID
199002

DARWIN EU® study
No

Study countries
United States

Study description
Tofacitinib is a Janus kinase (JAK) inhibitor approved for 5 indications in the US(United States): adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), adults with moderately to severely active ulcerative colitis (UC), adults with active ankylosing spondylitis (also known as radiographic axSpA), and in patients 2 years of age or older with polyarticular course juvenile idiopathic arthritis (JIA).

Data on tofacitinib clinical efficacy in anterior uveitis (AU) from the clinical trial program across all the indications, and pyoderma gangrenosum (PG) and axial spondylarthritis (axSpA) in the UC clinical trial program, is very limited due to study design, inclusion criteria, and baseline characteristics of the different study populations, which would not allow to perform a post-hoc analysis for these outcomes. In the last years, however, several case reports and small observational studies have highlighted the potential beneficial use of JAK inhibitors (including tofacitinib) in treating uveitis as an extra-musculoskeletal or extra-intestinal manifestations, such as AU, PG, and axSpA. In addition, there is an ongoing phase 3 trial assessing the clinical effectiveness of another JAK inhibitor, baricitinib, in JIA-associated uveitis. This non-interventional study aims to provide data on the comparative clinical effectiveness of advanced therapies on incidence of AU among several chronic inflammatory conditions (UC, PsA, JIA, and axSpA) as well as incidence of PG and axSpA in patients with UC. The results are intended to provide useful information to healthcare professionals and patients in real-world clinical decision making on treatment choice for patients with these conditions.

Study status
Planned

Research institution and networks

Institutions

Pfizer
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Institution

Komodo Health

Contact details

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Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
11/11/2023

Study start date
Planned:
31/01/2024

Date of final study report
Planned:
01/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921444_NIS_protocol_Cross_indication_uveitis__EIM_12Jan2024.pdf(5.6 MB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

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:
This non-interventional study aims to provide data on the comparative clinical effectiveness of advanced therapies on incidence of uveitis among several chronic inflammatory conditions, as well as incidence of pyoderma gangrenosum and axial spondylarthritis in patients with ulcerative colitis (UC).

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Xeljanz

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

Medical condition to be studied
Colitis ulcerative
Psoriatic arthropathy
Juvenile idiopathic arthritis
Axial spondyloarthritis

Population studied

Short description of the study population
All individuals meeting study entry criteria will be included in the analysis. Estimated number of patients will be updated after data analysis.

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)

Estimated number of subjects
1

Study design details

Outcomes
To estimate the distributions of demographic and clinical characteristics among patients with inflammatory conditions on tofacitinib and other advanced treatments. To estimate crude incidence rates and hazard ratios of anterior uveitis among patients with inflammatory conditions, and pyoderma gangrenosum and axial spondylarthritis in UC patients on tofacitinib and other treatments.,To examine the stratified incidence rates and adjusted hazard ratios of anterior uveitis and pyoderma gangrenosum by previous history of uveitis and pyoderma gangrenosum, respectively.

Data analysis plan
Number of events, person-years at risk, and crude incidences will be calculated for each outcome. IRs for select safety events will be calculated with person-time at risk starting on the index date and ending on the date of a censoring event: 1) death, 2) end of study period, 3) the event of interest, 4) treatment switch, 5) treatment discontinuation (+ 90 days), or 6) end of enrollment in the database. IRs per 100 person-years will be calculated based on the number of new events divided by the sum of the duration of patient exposures from the index date to censoring date during the risk period. Hazard ratios will be estimated using an inverse probability (IP) weighted Cox proportional hazards model with time since treatment start as timescale. IP weighting will be used to control for potential confounding variables at baseline, and selected based on a priori knowledge and statistical properties of the cohorts under study.

Data management

Data sources

Data source(s), other
Komodo Health United States

Data sources (types)
Administrative data (e.g. claims)

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