A longitudinal study of 4 cohorts of patients with psoriasis and psoriatic arthritis: one treated with Otezla (apremilast), one with an injectable comparator drug, one with an oral comparator drug and one with an oral and an injectable comparator drug (Otezla-CPRD-001)

First published: 15/02/2016

Last updated: 26/01/2021

Study Finalised

Administrative details

EU PAS number

EUPAS11891

Study ID

39206

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study is designed to provide long-term surveillance of as per the protocol defined adverse events of special interest (AESIs) in patients with psoriasis and/or psoriatic arthritis exposed to Otezla (apremilast) by calculating rates of events and comparing the rates with those in Otezla non-exposed populations.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 19/11/2015

Study start date
Planned: 13/02/2015

Actual: 13/02/2015

Data analysis start date
Planned: 01/12/2016

Actual: 01/12/2016

Date of interim report, if expected
Planned: 01/08/2018

Actual: 17/10/2018

Date of final study report
Planned: 13/08/2020

Actual: 26/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To identify all cases of adverse events of special interest (AESIs) among users of the newly marketed drug Otezla (exposed) and to compare the rates of these events with the rates in 2 populations of patients with psoriasis and/or psoriatic arthritis who received non-Otezla treatments (non-exposed): patients who received oral treatments and patients who received injectable treatments.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OTEZLA

Medical condition to be studied

Psoriasis

Psoriatic arthropathy

Population studied

Short description of the study population

Patients with psoriasis and/or psoriatic arthritis.

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

Immunocompromised

Estimated number of subjects

1065

Study design details

Outcomes

The outcomes proposed in the study were selected based on adverse events of special interest observed in the clinical trials for apremilast (marketed as Otezla). These events include:malignancy, opportunistic and serious infections, suicide and suicide ideation, depression, major adverse cardiovascular events (MACE), vasculitis, tachyarrhythmia, hypersensitivity, and anxiety/nervousness.

Data analysis plan

For phase 1, the population of Otezla users after the first year of marketing of the drug will be described since there is a gradual uptake of a new drug in a market and there may not be a sufficient number of patients exposed within the first year. Descriptions/counts of all AESIs that occur in this population of users

will be provided. Only data that do not allow identification of patients will be reported to comply with UKconfidentiality rulings. For phases 2 and 3, the rates of each AESI will be described separately for the Otezla study cohort and the Otezla non-exposed cohorts using Kaplan Meier curves. Composite events, which will include MACE codes, will also be examined. Incidence rates of each of the AESIs, with 95% confidence intervals, for each cohort will be estimated. Rates between the Otezla-exposed cohort and 2 treatment comparator cohorts will be compared by calculating both crude and adjusted incidence rate ratios.

Documents

Study results

20200261 Observational Research Study Report Published Report_Redacted.pdf (86.88 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 source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

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