OTEZLA® Tablets Drug Use-Results Survey (CC-10004-PSOR-018)

First published: 20/08/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36684

Study ID

36685

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This survey will be conducted at approximately 150 sites in Japan. Around 1000 patients with psoriasis vulgaris and patients with psoriatic arthritis who are treated with OTEZLA® tablets are planned to be included. The planned survey

period is 4 years from 6 months after launch. The key survey items include serious infections, gastrointestinal disorders, serious hypersensitivity, weight decrease, vasculitis, malignancies, depression and suicidal ideation. Information will be collected to evaluate the safety and efficacy of OTEZLA® in actual clinical settings.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 150 centres are involved in the study

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

Planned: 01/07/2017

Actual: 04/08/2017

Study start date

Planned: 01/09/2017

Actual: 05/09/2017

Data analysis start date

Planned: 30/11/2024

Actual: 11/12/2022

Date of final study report

Planned: 31/05/2025

Actual: 21/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

Protocol number-CC-10004-PSOR-018

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to evaluate the safety and efficacy of OTEZLA® tablets in patients with psoriasis vulgaris and patients with psoriatic arthritis in actual clinical settings.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational study

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

The study population comprised of patients with psoriasis vulgaris and psoriatic arthritis received treatment with OTEZLA® tablets in a routine clinical practice in Japan.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Patients with psoriasis

Estimated number of subjects

1000

Study design details

Outcomes

Incidence of Adverse Drug Reactions, especially incidence of serious infections, gastrointestinal disorders, serious hypersensitivity, weight decrease, vasculitis, malignancies, depression and suicidal ideation.

Data analysis plan

Analyses are descriptive in nature, including confidence intervals. Due to the nature of the observational study, no confirmatory statistical testing is foreseen in this study. Subgroup analyses are also performed if sample size allows.

Documents

Study results

20200068 ORSR Abstract.pdf(126.59 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective 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