OTEZLA® tablets General use-results survey (BCT) (20200279)

First published: 14/08/2020

Last updated: 26/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37753

EU PAS number

EUPAS36072

Study ID

37753

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This survey will be conducted at approximately 40 sites in Japan which have previously introduced OTEZLA®. Around 100 patients who have oral ulcers due to Behçet’s Disease that also had an inadequate response to topical treatment are planned to be included.
The planned survey period is 4 years after survey initiation.
Information will be collected to evaluate the safety of OTEZLA® in a clinical setting.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Chiba University Hospital Chiba, Japan

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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: 06/07/2020

Actual: 06/07/2020

Study start date

Planned: 20/10/2020

Actual: 22/10/2020

Data analysis start date

Planned: 04/03/2025

Actual: 04/03/2025

Date of final study report

Planned: 31/05/2025

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: 20200279

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The objective of this survey is to evaluate the safety of OTEZLA® tablets in actual clinical settings of use in OTEZLA-naïve subjects with oral ulcers due to Behçet’s Disease who have had an inadequate response to topical treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OTEZLA

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

APREMILAST

Anatomical Therapeutic Chemical (ATC) code

(L04AA32) apremilast

apremilast

Medical condition to be studied

Behcet's syndrome

Additional medical condition(s)

Subjects with oral ulcers due to Behçet’s Disease

Population studied

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)

Estimated number of subjects

100

Study design details

Outcomes

Incidence of Adverse Drug Reactions, especially incidence of gastrointestinal disorders.

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.

Data management

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Survey

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