# 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