

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

**First published:** 14/08/2020

**Last updated:** 26/03/2025

Study

Ongoing

## Administrative details

### 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.

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## 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.  
medinfo@amgen.com

#### Study contact

[medinfo@amgen.com](mailto: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

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#### Study start date

Planned: 20/10/2020

Actual: 22/10/2020

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#### Data analysis start date

Planned: 04/03/2025

Actual: 04/03/2025

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#### 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

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**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

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**Study type:**

Non-interventional study

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**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

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

APREMILAST

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA32) apremilast

apremilast

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**Medical condition to be studied**

Behcet's syndrome

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## **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)

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### **Estimated number of subjects**

100

## Study design details

### **Outcomes**

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

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### **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

## 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 sources (types)

Other

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No