# 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

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**Study start date**

Planned: 01/09/2017

Actual: 05/09/2017

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**Data analysis start date**

Planned: 30/11/2024

Actual: 11/12/2022

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**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

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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-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

**Medicinal product name**

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

## 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

**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