Observational Study on the Safety and Effectiveness of Tepezza (teprotumumab) in South Korea

First published: 02/09/2026

Last updated: 20/10/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001085

Study ID

1000001085

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

This is a multicenter prospective observational study in patients who are prescribed TEPEZZA within the approved indication in a post-marketing setting in South Korea.

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

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Institution

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: 28/02/2026

Actual: 26/02/2026

Study start date
Planned: 01/02/2027

Data analysis start date
Planned: 01/02/2027

Date of interim report, if expected
Planned: 02/08/2027

Date of final study report
Planned: 16/08/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study is funded through Amgen, the study sponsor.

Study protocol

Protocol-Published Original teprotumumab-trbw 20240224.pdf (1.86 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This study is an observational, prospective, cohort, multicenter study based on primary data collection in patients treated with TEPEZZA in routine clinical practice in South Korea.

Main study objective:

The main objective of the study is to describe the safety of TEPEZZA in routine clinical practice and evaluate effectiveness in patients with thyroid eye disease.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TEPEZZA

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

TEPROTUMUMAB

Additional medical condition(s)

Thyroid Eye Disease (TED)

Population studied

Short description of the study population

Adult patients (≥19 years) prescribed TEPEZZA according to the approved indication in South Korea who provide informed consent. Patients with contraindications or participating in another interventional study are excluded.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

41

Study design details

Setting

Approximately 20 participating sites in South Korea enrolling patients prescribed TEPEZZA according to routine clinical practice. Patients are followed from first dose until end of study, up to 8 weeks after the last dose or longer for unresolved hearing impairment.

Comparators

None (single-cohort observational study)

Outcomes

The primary outcomes of the study are:

• Incidence of adverse events
• Incidence of serious adverse events
• Incidence of adverse drug reactions
• Incidence of serious adverse drug reactions
• Incidence of unexpected adverse events
• Incidence of unexpected serious adverse events
• Incidence of unexpected adverse drug reactions
• Incidence of unexpected serious adverse drug reactions
• Incidence of adverse events leading to TEPEZZA discontinuation
• Incidence of fatal events

The secondary outcomes of the study are:

• Proptosis response at End of Study (EOS)
• The change in proptosis measurement in the study eye from baseline at EOS
• Overall response at EOS (in case of acute thyroid eye disease [TED])
• Achieving Clinical Activity Score (CAS) value of 0 or 1 at EOS (in case of acute TED)
• Clinical outcome assessment by the investigator at EOS

Data analysis plan

Analyses will be descriptive. Categorical variables will be summarized using frequencies and percentages, and continuous variables using descriptive statistics. Safety analyses will include all subjects receiving at least one dose of TEPEZZA with one safety follow-up. Effectiveness analyses will include subjects with at least one follow-up assessment.

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)

Electronic healthcare records (EHR)

Non-interventional study

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

Not applicable