Prospective Observational Study on the Safety and Effectiveness of Imdelltra (tarlatamab) 20230176

First published: 04/11/2025

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Study Planned

Administrative details

EU PAS number

EUPAS1000000778

Study ID

1000000778

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

20230176 is regulatory mandated prospective observational multicenter study in patients who are prescribed tarlatamab within the approved indication (small cell lung cancer (SCLC)) in a post-marketing setting in South Korea. The primary objective of the study is to evaluate safety and effectiveness of tarlatamab in real world clinical practice.

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

DreamCIS

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/09/2025

Actual: 16/10/2025

Study start date

Planned: 15/12/2025

Data analysis start date

Planned: 16/02/2030

Date of interim report, if expected

Planned: 15/07/2026

Date of final study report

Planned: 15/07/2030

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Protocol-Published Original tarlatamab 20230176 .pdf (1.14 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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:

Combined primary data collection and secondary use of data

Study design:

20230176 is an observational multicenter study in patients who are prescribed tarlatamab within the approved indication in a post-marketing setting in South Korea.

Main study objective:

The main objective of this study is to describe safety of tarlatamab in post-marketing clinical practice within the approved indication.
The Secondary objective is to describe effectiveness of tarlatamab in clinical practice within the approved indication.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tarlatamab

Anatomical Therapeutic Chemical (ATC) code

(L01FX33) tarlatamab

tarlatamab

Medical condition to be studied

Small cell lung cancer

Population studied

Short description of the study population

Study enrollment will be offered to patients meeting the eligibility criteria at participating medical sites in South Korea. Subjects prescribed tarlatamab in routine clinical practice according to the approved therapeutic indications (SCLC), dosage, and administration in South Korea will be enrolled on a continuous basis at participating sites. Enrollment will start (estimated Q3 2025) after launch of tarlatamab in South Korea and is planned to end 4 years later if enrollment targets are met. If the target enrollment can’t be reached within 4 years, a discussion with MFDS will be needed to determine if a study period extension is required. Patients will be enrolled at participating sites and will be followed for up to 60 days after completion of 4 cycles (approximately 17 weeks) of tarlatamab use, 60 days after discontinuation of tarlatamab, withdrawal of consent, death, or lost to follow-up, whichever occurs first.

Age groups

- 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

73

Study design details

Setting

Inclusion Criteria:

• Subjects prescribed tarlatamab in clinical practice according to the approved therapeutic indications, dosage, and administration in South Korea

• Subjects or their authorized representative who provide written informed consent to
participate in this study

Exclusion Criteria:

• Subjects with contraindications as listed on the approved local label

• Subjects concurrently participating in another interventional study will not be allowed
to participate in this study

• Subjects who have received any prior treatment with tarlatamab prior to Day 1 of
study

Outcomes

Primary outcomes:

- 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 tarlatamab discontinuation
- Incidence of fatal events

Secondary outcomes:

- Overall Response Rate (ORR) at each follow-up visit and end of study (EOS)
- Clinical outcome measure by the investigator at EOS assigning one of the four descriptions: Improved, not changed, disease progression, unable to evaluate

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Data analysis plan

The data will be summarized descriptively. The cumulative incidence of adverse events will be presented as frequency and percentage.

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 source(s), other

Participant Medical Records

Data sources (types)

Electronic healthcare records (EHR)

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