

General Use-results Survey of IMDELLTRA in Patients with Small Cell Lung Cancer Progressed after Cancer Chemotherapy (20230313)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000000817

Study ID

1000000817

DARWIN EU® study

No

Study countries

Japan

Study status

Ongoing

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: 01/11/2025

Study start date

Planned: 31/03/2026

Actual: 03/03/2026

Data analysis start date

Planned: 01/11/2029

Date of final study report

Planned: 31/12/2030

Study protocol

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:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a prospective observational cohort study of Small Cell Lung Cancer (SCLC) patients treated with tarlatamab in the post-marketing clinical setting in Japan.

Main study objective:

The main objectives of this study are to describe the incidence, frequent time of onset and management after occurrence of Interstitial Lung Disease (ILD) in Small Cell Lung Cancer (SCLC) patients treated with tarlatamab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

IMDELLTRA (active substance: tarlatamab)

Medical condition to be studied

Interstitial lung disease

Population studied

Short description of the study population

Small Cell Lung Cancer patients treated with tarlatamab in the post-marketing clinical setting in Japan.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
 - Neonate
 - Preterm newborn infants (0 – 27 days)
 - Term newborn infants (0 – 27 days)
 - Infants and toddlers (28 days – 23 months)
 - Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
- **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

300

Study design details

Setting

This study will be conducted in the post-marketing clinical setting in Japan.

Outcomes

The primary outcomes of this study are:

1. To describe the incidence of ILD.

2. To summarize the frequent time of onset for ILD.
3. To summarize management after occurrence of ILD.

The secondary outcomes of this study are:

1. To describe the incidence of adverse drug reactions (ADR).
 2. To describe the incidence of serious ADRs.
 3. To describe the incidence of adverse events (AE).
 4. To describe the incidence of serious AEs.
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Data analysis plan

As primary analysis for safety, safety specifications (ie, Interstitial Lung Disease/ILD) related will be summarized such as incidence proportion, frequent time of onset or management after onset.

As secondary analysis for safety, the participant incidence proportion of all AEs/ADRs will be summarized.

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)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes