Tarlatamab vs. Real-world Physicians' Choice Therapies in Patients with Relapsed or Refractory Small Cell Lung Cancer After Two or More Prior Lines of Treatment: Patient-level Indirect Treatment Comparison (ITC) of DeLLphi-301 vs. Flatiron Real-world Data (20240049)

First published: 18/10/2024

Last updated: 12/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000298

Study ID

1000000298

DARWIN EU® study

No

Study countries

United States

Study description

This is an indirect treatment comparison study estimating the relative treatment effect of tarlatamab vs. real-world physician's choice of therapy (RWPT).

Efficacy data of tarlatamab was informed by the long-term follow-up data of the DeLLphi-301 trial (Oct 2023 data cutoff); while data of RWPT was obtained from an external control cohort created using the US Flatiron Health Research Database (Jan 2013 – Oct 2021).

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

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: 03/04/2024

Actual: 03/04/2024

Study start date

Planned: 03/04/2024

Actual: 03/04/2024

Data analysis start date

Planned: 04/05/2024

Actual: 04/05/2024

Date of final study report

Planned: 31/08/2024

Actual: 05/08/2024

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

20240049_tarlatamab_Protocol-Published Amendment.pdf (436.79 KB)

Regulatory

Was the study required by a regulatory body?

No

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)

Data collection methods:

Secondary use of data

Study design:

A patient-level ITC study will be conducted to estimate relative treatment effects of tarlatamab vs. comparator therapies among patients with relapsed or refractory SCLC who have progressed or recurred following one platinum-based regimen and at least one other line of therapy (LOT).

Main study objective:

The main study objective is to estimate the relative effect of tarlatamab versus comparator therapies on overall survival (OS).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Indirect treatment comparison

Study drug and medical condition

Name of medicine, other

Tarlatamab

Medical condition to be studied

Small cell lung cancer recurrent

Additional medical condition(s)

Relapsed or refractory small cell lung cancer

Population studied

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 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

Relapsed or refractory small cell lung cancer

Study design details

Setting

All patients randomized to the 10mg cohort in parts 1 and 2 of DeLLphi-301 trial are included in this study.

Patients meeting the key selection criteria of DeLLphi-301 were identified from the Flatiron data and included in the external control cohort of this study.

Comparators

Real-world physicians’ choice of therapy in 3L+ ES-SCLC setting

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Outcomes

Primary outcome:

• OS

Secondary outcome:

• Time to treatment discontinuation (TTD)

• Time to next treatment or death (TTND)

Data analysis plan

For the primary and secondary objectives, OS, TTD, and TTNTD will be compared between tarlatamab and comparator therapy groups before and after weighting, using unweighted and weighted Kaplan-Meier analyses and log rank tests.

Hazard ratios will be estimated before and after weighting using unweighted and weighted Cox proportional hazards models, respectively.

95% confidence intervals (CIs) for hazard ratios will be estimated based on a robust sandwich estimator.

Documents

Study report

20240049_ORSR Abstract_Redacted.pdf (215.01 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 source(s), other

Flatiron Health Research Database

Data sources (types)

Electronic healthcare records (EHR)

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