

# 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:** 27/03/2026

**Institution**

## Contact details

### **Study institution contact**

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### **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

**Medicinal product name, 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 ( $\geq 18$  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

---

## **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