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Plain language summary: tarlatamab for patients with previously treated small cell lung cancer

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Plain Language Summary of Publication

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Plain language summary: tarlatamab for patients with previously treated small cell lung cancer

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Author affiliations can be found at the end of this article

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Where can I find the original article on which this summary is based?

You can read the original article, 'Tarlatamab for patients with previously treated small cell lung cancer' for free at https://www.nejm.org/doi/full/10.1056/NEJMoa2307980

Summary

How to say (download PDF and double click sound icon to play sound)...

- **Tarlatamab:** Tar-LAT-a-mab

What is this summary about?

This is a summary of a phase 2 clinical study called DeLLphi-301. The study looked at how effective and safe a medicine called tarlatamab was in participants with small cell lung cancer (SCLC). Participants previously received at least two other treatments for their SCLC. Tarlatamab is a new medicine that locates a **protein** called DLL3 on the cancer, which allows T cells to attack the cancer. T cells belong to the body's natural defense system known as the immune system. The DeLLphi-301 study separated participants into two groups to receive tarlatamab 10 mg or 100 mg to determine which dose best shrank SCLC with minimal side effects. All participants received a small first dose (1 mg tarlatamab) to decrease the risk of an immune system reaction called **cytokine release syndrome (CRS)**. Tarlatamab was given through the participant's vein once every 2 weeks. This method of administration is known as intravenous (IV) infusion.

Protein: A complex molecule that performs a task in a person's body.
CRS: A reaction that can happen when your immune system is turned on and releases a large number of molecules called cytokines into your blood. This can lead to fever, low blood pressure, and/or low levels of oxygen in your blood. In severe cases, it can be life-threatening.
Constipation: Difficulty passing bowel movements.
Anemia: Low levels of healthy red blood cells.
ICANS: An immune reaction that affects the brain and can cause symptoms like confusion, shaking, seizures, and issues with the nerves. It can happen a few days to weeks after treatment. Severe cases of ICANS are serious and can be life-threatening.

What were the results of the DeLLphi-301 study?

In the group given 10 mg tarlatamab, 40% of participants responded to treatment (cancer shrank). In the group given 100 mg tarlatamab, 32% of participants responded to treatment (cancer shrank). After taking tarlatamab at either dose, 59% of participants lived for at least 6 months without their cancer growing or getting worse.

The most common side effect was CRS, which occurred in 51% of participants in the group given 10 mg tarlatamab and 61% of participants in the group given 100 mg tarlatamab. Other common side effects were decreased appetite, fever, **constipation**, and **anemia**. Some participants had a type of immune reaction called **immune effector cell–associated neurotoxicity syndrome (ICANS)**. A small number of participants (3%) stopped taking tarlatamab because of side effects related to tarlatamab.

What do the results from the DeLLphi-301 study mean?

The study found that tarlatamab given every 2 weeks shrank SCLC in participants with SCLC who received previous treatments. Participants given the 10 mg tarlatamab dose had fewer side effects than those given the 100 mg tarlatamab dose.

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What is the purpose of this plain language summary?

- The purpose of this plain language summary is to help you to understand the findings from recent research.
- Tarlatamab is a medicine that is approved to treat the condition we are talking about in this study.
- The results of this study may differ from those of other studies. Healthcare professionals should make treatment decisions based on all available evidence, and not on the results of a single study. This study described is still ongoing; therefore, the final outcomes of this study may differ from the outcomes described in this summary.

Who sponsored this research?

This research study, DeLLphi-301, was **sponsored** by Amgen.

Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor and study investigators collect and analyze the information that is generated during the study.

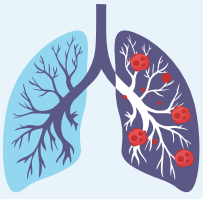
Who should read this article?

This summary may be helpful for people with SCLC, family members of people with SCLC, patient advocates, caregivers, and healthcare professionals.

What is small cell lung cancer (SCLC)?

SCLC is a type of cancer that starts in the lungs. SCLC can quickly grow and spread to other parts of the body, making it challenging to treat.

There are two stages of SCLC, which describe how far the lung cancer has spread:



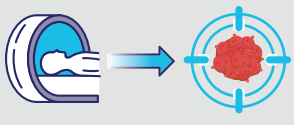
Limited-stage SCLC: The cancer is either in just one lung or in one lung and nearby lymph nodes (small organs that help the body recognize and fight germs and cancer).

Extensive-stage SCLC: The cancer has spread widely to both lungs or to other parts of the body.

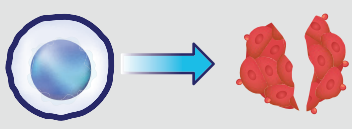
What are the treatment options for SCLC?

People with SCLC generally have few treatment options when a selected treatment does not shrink the cancer or the cancer returns. Treatment for SCLC varies depending on whether or not the cancer has spread. Surgery and/or radiation therapy are the first treatment options for people with limited-stage SCLC. Other treatment options for both stages of SCLC may include a combination of chemotherapy, radiation therapy, and/or immunotherapy.

Chemotherapy
medicines kill rapidly dividing cells, including cancer cells.



Radiation therapy
uses high-energy beams to damage cancer cells, making it hard for them to grow again.



Immunotherapy
helps the body's own immune system attack cancer cells.

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What is tarlatamab?

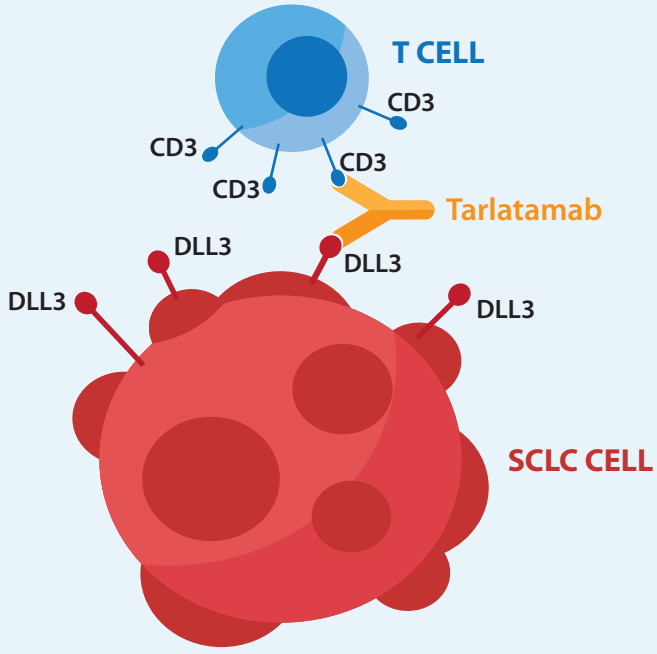
Tarlatamab is a type of immunotherapy that helps your immune system attack SCLC.

What are T cells?
T cells are specialized cells within your immune system that protect you from infection and may help kill cancer cells in the body.

What is CD3?
CD3 is a type of protein found on T cells.

What is DLL3?
DLL3 is a protein found on SCLC cells. It was present on SCLC cells in 96% of the participants in this trial who had available cancer tissue that could be tested.

How does tarlatamab help T cells?
Tarlatamab attaches to CD3 and DLL3. This brings the T cells and cancer cells close together and allows the T cells to attack SCLC cells.



What is the DeLLphi-301 study about?

The study tested two different doses of tarlatamab to find out which dose worked and was safe for participants whose SCLC had been previously treated.

The main goal of the study was to answer the following question:

1. Did the cancer shrink for participants?

Key secondary goals of the study were to answer the following questions:

2. For the participants whose cancer shrank (responded) to the treatment, how long did this response last?
3. How long did participants live without their SCLC getting worse?
4. How long did participants live?
5. What were the side effects of tarlatamab?

Where did the DeLLphi-301 study take place?

The study took place at 56 medical research centers located in 17 countries across Asia, Europe, and North America. Participants enrolled in the study from December 2021 through May 2023.

Who could take part in the DeLLphi-301 study?

To join the study, participants had to meet the following requirements:

- Be 18 years of age or older at the time of the study
- Have SCLC that had come back or did not respond to at least two lung cancer therapies; one of which had to be platinum-chemotherapy
- **Eastern Cooperative Oncology Group performance status (ECOG PS)** of 0-1
- Have cancer (a tumor or tumors) whose response to treatment can be measured by a method called **Response Evaluation Criteria In Solid Tumors (RECIST)**

ECOG PS: A standard way to measure how well someone with cancer can take care of themselves, perform daily activities, and carry out work (like housework or office tasks). The scale goes from 0 (best) to 5 (worst). An ECOG PS of 0 means a person can do all their usual tasks without any problems, while an ECOG PS of 1 means their ability is a bit more limited but they can still do most activities.

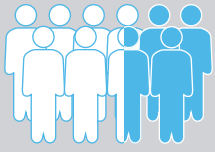
RECIST: A standard way to measure how well a cancer medication works. RECIST uses an imaging test to measure if a tumor shrinks, stays the same size, or gets bigger.

Median: Middle number in a group of numbers when listed in order from lowest to highest value.

Who took part in the DeLLphi-301 study?

222 people participated in the study who had received a **median** of 2 previous lines of treatment.

158 participants were male (71%) and 64 participants were female 29%)



Race/ethnicity: The majority of participants were White (63%) or Asian (36%)

Participants enrolled from Europe (57%), Asia (36%), and North America (7%)

The median age of participants was between 62 to 65.5 years old depending on which dose group they were assigned to

59 participants (27%) had cancer spread to the brain, which was required to be treated and stable before tarlatamab treatment began

81 participants (36%) had cancer spread to the liver before tarlatamab treatment began

How was tarlatamab tested in the DeLLphi-301 study?

There were three parts to the DeLLphi-301 study. During each part, participants were given tarlatamab through a vein (IV infusion). Tarlatamab treatment took around 1 hour to complete. Tarlatamab was given once a week for the first 3 doses, then every 2 weeks thereafter.

The participant's SCLC was assessed every 6 weeks for the first year using CT scans or other tests. After the first year, the participant's SCLC was assessed every 12 weeks (3 months), unless the cancer worsened, the participant decided to stop being part of the study, or the participant started a new cancer treatment.

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How was the DeLLphi-301 study carried out?

Part 1: Participants were randomly assigned to either the lower dose tarlatamab 10 mg group or the higher dose tarlatamab 100 mg group. All participants received a smaller first dose of 1 mg tarlatamab on day 1. This was done to decrease the chance of having cytokine release syndrome (CRS). Participants then received either the 10 mg tarlatamab or 100 mg tarlatamab dose depending on which group they were randomly assigned to.

Tarlatamab dosing in the DeLLphi-301 study:

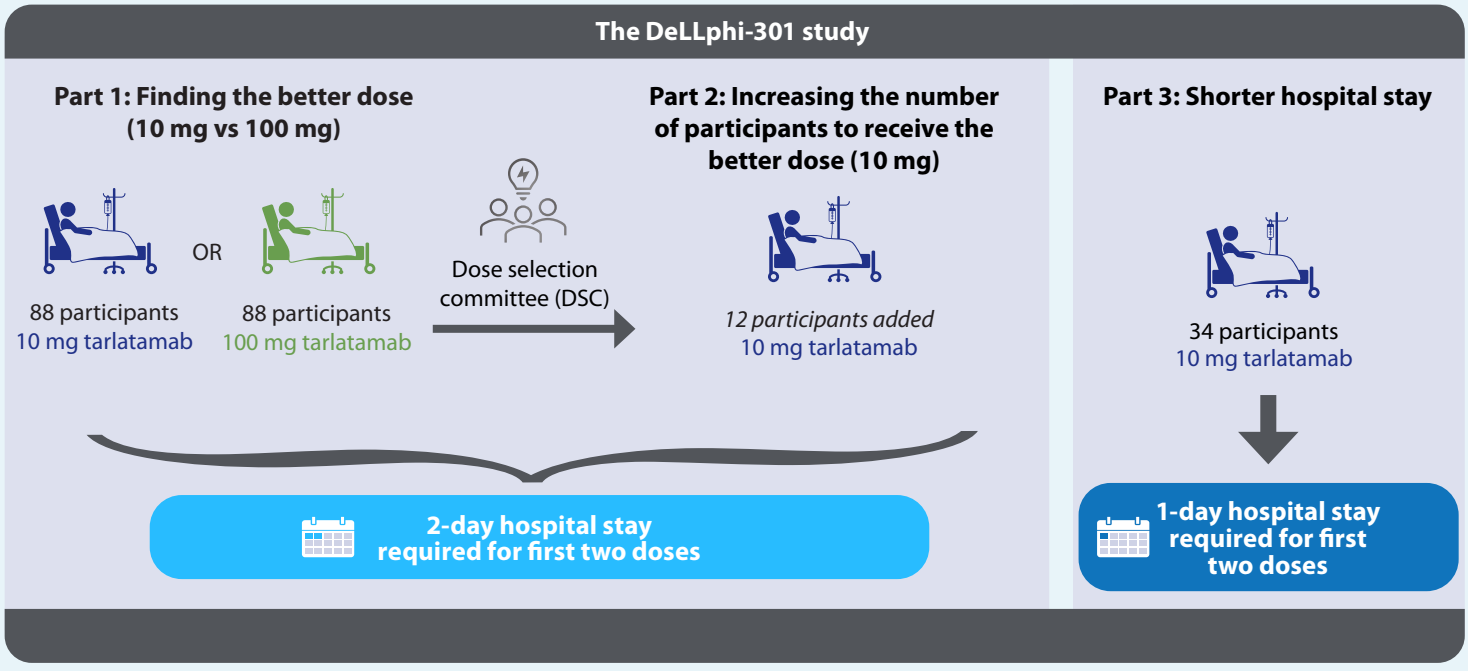
The purpose of part 1 was to find out which dose best shrank the cancer with the lowest risk of side effects. A **dose selection committee (DSC)** reviewed and assessed the data from part 1 and selected the 10 mg dose to be used for parts 2 and 3 of the study.

Part 2: Participants received the selected 10 mg tarlatamab dosing. The goal was for a total of 100 participants from parts 1 and 2 combined to receive the 10 mg dosing.

Part 3: This was an additional part of the study, and the goal was to find out whether a shorter hospital stay of 24 hours was safe.

Dose selection committee: A group of experts who are not part of the main research team. They look at all the data from the study and decide which dose of the medicine should be used for the next parts of the study.

All participants in the study (Parts 1–3) were monitored in the hospital following their tarlatamab doses, allowing doctors and nurses to manage and monitor any CRS or neurological events.



What were the findings of the DeLLphi-301 study?

1 Did the cancer shrink for participants?

10 mg tarlatamab

of participants responded to tarlatamab *(their cancer shrank).*

100 mg tarlatamab

of participants responded to tarlatamab *(their cancer shrank).*

"Responded" means that SCLC tumors shrank by at least 30%, and there were no new tumors growing.
Most participants (90%) whose cancer shrank saw this happen by their first check-up, about 1.4 months after starting tarlatamab treatment.

2 Among participants who responded, how long did the response last?

In 59% of participants who responded to tarlatamab, the response lasted for at least 6 months.
In 29% of participants who responded to tarlatamab, the response lasted for at least 9 months.

3 How long did participants live without their SCLC getting worse?

10 mg tarlatamab

4.9 months
(median)

100 mg tarlatamab

3.9 months
(median)

After 6 months, it was estimated that 40% of participants treated with 10 mg tarlatamab and 34% of participants treated with 100 mg tarlatamab would be alive without their SCLC getting worse.

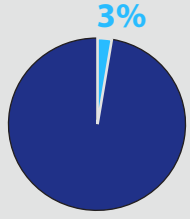
4 How long did participants live?

At the time of this publication, it was estimated that 68% of participants treated with 10 mg tarlatamab and 66% of participants treated with 100 mg tarlatamab would be alive at 9 months. Information on how long participants lived in this study is still being collected and may change.

5 Did participants have side effects related to tarlatamab?

Ninety percent of participants had side effects related to tarlatamab. Five percent of participants had side effects that were considered life-threatening. Unfortunately, one participant died because of breathing difficulties. Their doctor thought that this could be related to tarlatamab. This participant had a chronic disease before starting tarlatamab that required extra oxygen, and the participant decided against urgent and immediate treatment (intensive care).

Overall, 3% of participants in the study permanently stopped tarlatamab because of side effects related to tarlatamab.



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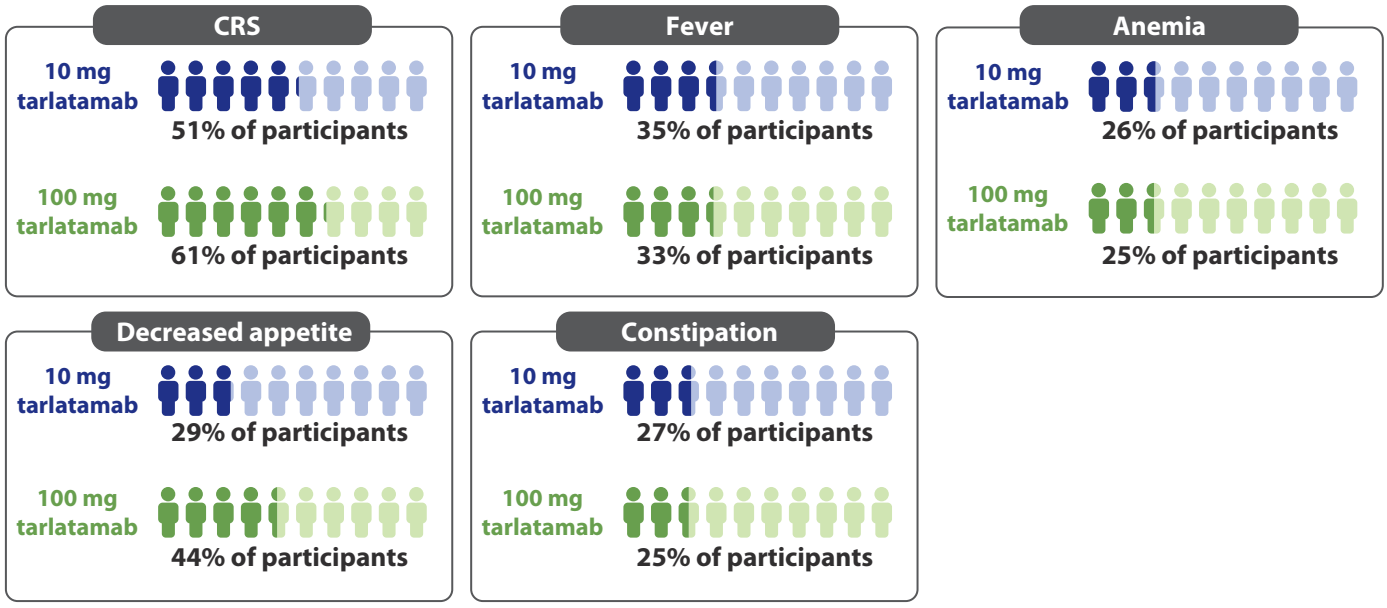
What were the most common side effects?



What percentage of participants had tarlatamab treatment interrupted because of a side effect?

10 mg tarlatamab

13% of participants had tarlatamab treatment interrupted because of side effects related to tarlatamab.

100 mg tarlatamab

29% of participants had tarlatamab treatment interrupted because of side effects related to tarlatamab.

What were the immune system–related side effects?

Two immune system-related side effects that may happen with tarlatamab treatment are cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). To lower the risk of CRS, three actions were taken:

- A smaller 1 mg tarlatamab dose was given as the first dose.
- Steroids (medicine to control inflammation) were given to participants 1 hour before the first two doses of tarlatamab.
- Fluids were given through a participant's vein after each of the first three doses of tarlatamab.

What percentage of participants had CRS?

10 mg tarlatamab

51% of participants had CRS (for less than 1%, it was severe). No participants died because of CRS.

100 mg tarlatamab

61% of participants had CRS (for 6%, it was severe). No participants died because of CRS.

When did CRS start and how long did it last?

For participants with CRS, symptoms began about 13 hours after a tarlatamab dose was given and lasted for about 4 days.

How was CRS treated?

Typically, CRS was treated with one or more of the following: a fever-reducing medicine (such as acetaminophen), fluids given through a vein, and/or steroids. Seven percent of participants needed medicine (tocilizumab) to help stop the immune system from overreacting. Nine percent of participants needed extra oxygen. Less than one percent of participants needed medicine to increase their blood pressure. CRS went away in almost all cases (98%).

What percentage of participants had ICANS?

10 mg tarlatamab

of participants had ICANS (none of the cases were severe).
No participants died because of ICANS.

100 mg tarlatamab

of participants had ICANS (for 5% of participants, it was severe).
No participants died because of ICANS.

When did ICANS start and how long did it last?

For participants with ICANS, symptoms began about 5 days after a tarlatamab dose was given and lasted for about 1 week (6.5 days). It generally occurred during the first cycle of treatment (first 28 days).

What do the findings from the DeLLphi-301 study mean?

The study found that tarlatamab given every 2 weeks shrank SCLC in participants whose SCLC had been previously treated. In the 10 mg tarlatamab group, forty percent of participants responded. Some participants had a long-lasting response. The most common side effect in the study was cytokine release syndrome, also known as CRS.

Although the tarlatamab 100 mg dose had similar tumor-shrinking effects compared to the 10 mg dose, participants receiving the 100 mg dose had more side effects. Therefore, the tarlatamab 10 mg dose was chosen for further tarlatamab clinical trials.

This summary has been written using information from the DeLLphi-301 study published in a medical journal. Longer **follow-up** may provide more information on how long the medication worked and how long participants in the study lived.

Follow-up: Keeping track of the health of the participants during the study and after the study ends.

Where can I find more information?

- If you took part in the study and have questions about these results, please speak with the medical staff at your study center.
- More information about clinical trials in general can be found at: https://clinicaltrials.gov/study-basics/learn-about-studies

The original article, 'Tarlatamab for patients with previously treated small cell lung cancer' was published in *The New England Journal of Medicine* (Ahn MJ, et al. *N Eng J Med*. 2023; 389(22):2063-2075).

You can read the full article for free at: https://www.nejm.org/doi/full/10.1056/NEJMoa2307980

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A-M Dingemans reports being a consultant for Amgen, AstraZeneca, Boehringer Ingelheim, Daiichi Sankyo, Eli Lilly, Janssen Pharmaceuticals, Pfizer, and Sanofi. A-M Dingemans reports being involved in data and safety monitoring for F. Hoffmann-La Roche and Bayer. M Reck reports being a consultant and a part of a speaker bureau for Amgen, BeiGene USA, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eli Lilly, F. Hoffman-La Roche, GlaxoSmithKline, Merck Sharp & Dohme, and Regeneron. M Reck reports being involved in data and safety monitoring for Sanofi. M Reck reports serving on an advisory board for AstraZeneca AB and being a part of a speaker bureau. M Reck also reports being a member of DMSB for Daiichi Sankyo. M Reck also reports being a member of a speaker bureau for Pfizer. R Dziadziuszko reports being a consultant for Amgen, AstraZeneca, Bristol Myers Squibb, F. Hoffman-La Roche, Merck Sharp & Dohme, Pfizer, and Takeda Oncology. 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