Plain Language Clinical Study

Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine Studied: Maplirpacept (also called PF-07901801)

Protocol Number: C4971003

Dates of Study: 04 August 2023 to 01 May 2025

Title of this Study: Effects of Maplirpacept (PF-07901801), Tafasitamab, and Lenalidomide in People With Relapsed or Refractory Diffuse Large B-cell Lymphoma

[A Phase 1b/2 Study of PF-07901801, A CD47 Blocking Agent, With Tafasitamab and Lenalidomide for Participants With Relapsed/Refractory Diffuse Large B Cell Lymphoma not Eligible for Stem Cell Transplantation]

Date of this Report: 28 October 2025

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

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This summary will describe the study results. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

Why was this study done?

What is diffuse large B-cell lymphoma?

Diffuse large B-cell lymphoma, or **DLBCL**, is a fast-growing (aggressive) blood cancer that affects the lymphatic system. It starts when the B cells, a type of white blood cell that helps fight infection, become cancerous and grow out of control. The lymphatic system is made up of lymph nodes, tissues, and organs that help fight infection in the body.

What is maplirpacept?

Maplirpacept [ma-PLUR-pa-sept] is an injectable fusion protein made by combining 2 different proteins. It is designed to target and block a protein called CD47.

> CD47 is a protein found on the surface of cells in the body but is found in much higher amounts ("highly expressed") on cancer cells. CD47 is used by cancer cells to hide from the body's defense system by sending a "don't eat me" signal to defense cells. This signal stops the defense cells from attacking and destroying the cancer cells.

Blocking CD47 with maplirpacept may help the body's defense system find and destroy the cancer cells.

What was the purpose of this study?

This study had 2 parts called Phase 1b and Phase 2.

- In **Phase 1b**, the main goal was to learn about the safety of different doses of **maplirpacept** given in combination with **tafasitamab** and **lenalidomide**. The combination of tafasitamab and lenalidomide is an approved treatment for participants with "relapsed" (cancer came back after treatment) or "refractory" (cancer did not respond to treatment) DLBCL.

  Up to 2 doses of maplirpacept tested in Phase 1b were to be chosen to compare in Phase 2.

- In **Phase 2**, the main goal was to learn which one of the 2 doses of maplirpacept selected in Phase 1b, when given in combination with tafasitamab and lenalidomide, can better treat relapsed or refractory DLBCL. Phase 2 was not started.

The study was stopped early due to slow participant enrollment and was not completed as planned. This decision was not due to safety reasons or requests from any health authorities.

Researchers wanted to know:

- **Were participants able to tolerate maplirpacept given in combination with tafasitamab and lenalidomide?**
- **What medical problems did participants have during the study?**

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What happened during the study?

How was the study done?

In Phase 1b, researchers tested 3 different dose levels of maplirpacept in combination with fixed doses of tafasitamab and lenalidomide. The fixed dose of tafasitamab was 12 milligrams for every kilogram of body weight (mg/kg), and the fixed dose of lenalidomide was 25 milligrams (mg).

- **Dose Level 1:** 3 participants received **4 mg/kg** maplirpacept in combination with tafasitamab and lenalidomide
- **Dose Level 2:** 2 participants received **10 mg/kg** maplirpacept in combination with tafasitamab and lenalidomide
- **Dose Level 3:** 1 participant received **18 mg/kg** maplirpacept in combination with tafasitamab and lenalidomide

Each participant received the study treatments on scheduled days of each 28-day period called a "cycle". Maplirpacept and tafasitamab were to be given until participants met a condition for stopping treatments, such as their DLBCL worsened or they had severe medical problems. Lenalidomide was to be given up to Cycle 12.

Maplirpacept and tafasitamab were given as injections into a vein (also called intravenous or IV infusion). Lenalidomide was taken by mouth (orally).

Participants and researchers knew the study treatments and doses given during Phase 1b. This is known as "open-label".

Researchers took imaging scans and samples of blood from participants during the study. Researchers also checked the participants' health during the study and asked them how they were feeling.

Where did this study take place?

The Sponsor ran this study at a total of 4 locations in Japan and the United States.

When did this study take place?

It began on 04 August 2023 and ended on 01 May 2025.

Who participated in this study?

The study included participants at least 18 years of age with relapsed or refractory DLBCL. Participants must have had at least 1 treatment in the past, and one of them should have included a drug designed to find and attach to a protein called “CD20”. They must not have been candidates for high-dose chemotherapy or stem cell transplant.

A total of 6 participants were enrolled and received treatments in Phase 1b, of which 3 were men and 3 were women. All participants were between the ages of 40 years and 81 years.

- All 6 participants stopped receiving maplirpacept and tafasitamab. The most common reasons for stopping these treatments were death or worsening of DLBCL.
- Three (3) participants stopped taking lenalidomide due to worsening of DLBCL. The other 3 participants completed 12 cycles of treatment with lenalidomide.

How long did the study last?

Study participants were in the study for different lengths of time, depending on how long they got maplirpacept in combination with tafasitamab and lenalidomide. The entire study ran for about 1 year and 9 months until it was stopped early.

In July 2024, the Sponsor decided to end the study earlier than planned due to slow participant enrollment. This decision was not due to safety reasons or requests from any health authorities.

When the study ended in May 2025, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Were participants able to tolerate maplirpacept given in combination with tafasitamab and lenalidomide?

To answer this question, researchers checked the medical problems that participants had during the study. Researchers also looked at whether participants developed a **dose-limiting toxicity** (DLT). A DLT is a severe medical problem during Cycle 1 (the first 28-day treatment cycle) that researchers believe could be related to any of the study treatments or their combination.

Acknowledging the small number of participants in the study, researchers found that participants with relapsed or refractory DLBCL were generally able to tolerate the tested doses of maplirpacept in combination with tafasitamab and lenalidomide. None of the participants had a DLT.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

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What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

All 6 participants (100%) in this study had at least 1 medical problem. The most common medical problems – those reported by at least 50% of total participants – were:

- Diarrhea in 4 out of 6 participants (67%)
- Low levels of neutrophils, a type of white blood cell (WBC) that fights infection, in 4 out of 6 participants (67%)
- Nausea in 3 out of 6 participants (50%)
- Low levels of platelets (cells that help blood to clot) in 3 out of 6 participants (50%)

None of the participants left the study because of medical problems.

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

A total of 3 out of 6 participants (50%) had serious medical problems, all of whom received Dose Level 1 of maplirpacept (4 mg/kg) in combination with tafasitamab and lenalidomide.

The most common serious medical problem – reported by 2 participants – was “sepsis,” or when bacteria and their toxins circulate in the blood leading to organ damage.

A total of 2 out of 6 participants (33%) died during the study.

- 1 participant died due to “leukemia,” or cancer of the WBCs. Researchers believe that this serious medical problem was related to lenalidomide and not related to maplirpacept and tafasitamab.
- 1 participant died due to “cardiac arrest,” or when the heart suddenly stops beating. Researchers do not believe that this serious medical problem was related to any of the study treatments.

  The participant that died due to cardiac arrest was diagnosed with high blood pressure, too much sugar in the blood (or diabetes), high levels of fats in the blood, and stage 3 kidney disease before joining the study. These conditions can increase the risk of heart problems.

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Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results

Use the protocol number **C4971003**

The full scientific report of this study is available online at:

www.clinicaltrials.gov

Use the study identifier **NCT05626322**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study, **thank you** for volunteering.
We do research to try to find the best ways to help patients, and you helped us to do that!

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