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 or TTI-622)

Protocol Number: C4971002 (TTI-622-02)

Dates of Study: 01 August 2022 to 15 February 2024

Title of this Study: A Study of Maplirpacept in Combination With Pegylated Liposomal Doxorubicin (PLD) in Participants With Platinum-Resistant Ovarian Cancer

[A Phase I/II Study of TTI-622 in Combination With Pegylated Liposomal Doxorubicin in Patients With Platinum-Resistant Ovarian Cancer]

Date of this Report: 12 February 2025

Pfizer

– Thank You –

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

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 ovarian cancer?

Ovarian cancer is a cancer that forms in tissues of the ovary, one of a pair of female reproductive glands in which the ova (or eggs) are formed. The most common type of ovarian cancer is **epithelial ovarian cancer**, which forms in the cells on the surface of the ovary.

What is maplirpacept?

Maplirpacept is an injectable medicine being studied. It is a fusion protein made by combining 2 protein structures and is designed to target and block a protein called CD47.

> CD47 is present on the cells of 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 immune system.

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

Pfizer

What was the purpose of this study?

The study was planned to have 2 parts: Phase 1 and Phase 2. Only Phase 1 was started.

- In **Phase 1**, the main goal was to find out about the safety of **maplirpacept** given in combination with **pegylated liposomal doxorubicin (PLD)**. PLD is approved in the United States as a chemotherapy for ovarian cancer. One of the dose levels of maplirpacept tested in Phase 1 was to be recommended for further testing in Phase 2, given with PLD.
- In **Phase 2**, the main goal was to find out whether maplirpacept in combination with PLD can treat epithelial ovarian cancer. Phase 2 was not started because this study was stopped early and was not completed as planned.

Researchers wanted to know:

Were participants able to tolerate maplirpacept with PLD?

This summary includes information about Phase 1 only, as Phase 2 was removed from the study.

What happened during the study?

How was the study done?

Researchers tested 3 increasing (or escalating) dose levels of maplirpacept in combination with a fixed dose of PLD in 3 groups of participants. This was done to find out about the safety of maplirpacept when given with PLD. For each group, the researchers checked whether the participants could tolerate the dose of maplirpacept with PLD before enrolling the next group of participants.

Participants were assigned to a group that was open at the time they joined the study. They received maplirpacept and PLD as an injection into the vein ("intravenous infusion") given separately one after another. Maplirpacept was given in milligrams per kilogram (mg/kg) of their body weight. PLD was given in milligrams per square meters (mg/m^2) of their body surface area.

- **Group 1:** A total of 3 participants received **maplirpacept** 12 mg/kg in combination with **PLD** 40 mg/m^2.
- **Group 2:** A total of 3 participants received **maplirpacept** 24 mg/kg in combination with **PLD** 40 mg/m^2.
- **Group 3:** A total of 4 participants received **maplirpacept** 48 mg/kg in combination with **PLD** 40 mg/m^2.

All participants were to take their assigned treatment on scheduled days every 28-day cycle. Participants could continue taking their assigned treatment until they met a condition for stopping treatment, such as their ovarian cancer continued to worsen or they had severe medical problems. About 1 month after stopping maplirpacept with PLD or before starting a new cancer treatment, participants returned to the study site for their health checks.

The participants and researchers knew which dose of maplirpacept was given with PLD. This is known as an "open-label" study.

Researchers took samples of blood from participants during the study. Researchers also checked the participants' health during the study and asked them how they were feeling. Researchers checked the disease status by the location and size of the participants' cancer using imaging scans such as computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET).

Where did this study take place?

The Sponsor ran this study in the United States.

When did this study take place?

It began on 01 August 2022 and ended on 15 February 2024.

Who participated in this study?

The study included female adults with **platinum-resistant recurrent epithelial ovarian cancer**, which means their cancer no longer responds to a treatment regimen containing a chemotherapy called platinum (**"platinum-resistant"**) and has returned or worsened (**"recurrent"**) within 6 months of platinum therapy.

A total of 10 participants were treated with maplirpacept in combination with PLD. All participants were between the ages of 52 and 77 years old.

All 10 participants were discontinued from the study or had stopped taking part in the study by the time of the final analysis.

- 3 participants died because their ovarian cancer continued to worsen.
- 6 participants were discontinued from the study because the study was stopped early.
- 1 participant stopped taking part in the study because of "other" reason.

How long did the study last?

Study participants were in the study for different lengths of time depending on how long they got maplirpacept with PLD in the study. The entire study took about 1 year and 6 months until the last visit of the last participant in the study.

In September 2023, this study was stopped early, and Phase 2 of the study was removed. This decision was because of business or administrative reasons and not because of any safety concerns or request from any health authority.

When the study ended in February 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

Pfizer

What were the results of the study?

Were participants able to tolerate maplirpacept with PLD?

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**, a severe medical problem during Cycle 1 (the first 28-day treatment cycle).

Participants were generally able to tolerate up to 3 increasing dose levels of maplirpacept in combination with a fixed dose of PLD in this study. None of the participants had a dose-limiting toxicity.

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.

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 10 participants (100%) had at least 1 medical problem during the study. Overall, 3 participants (30%) stopped taking maplirpacept and 1 participant (10%) stopped taking PLD because of medical problems.

The most common medical problems – those reported by more than 20% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by more than 20% of participants are listed.
- The **2nd** column tells how many of the 10 participants who took the study treatment (maplirpacept with PLD) reported each medical problem. Next to this number is the percentage of the 10 participants who took the study treatment and reported the medical problem.
- Using these instructions, you can see that 7 out of the 10 participants (70%) who took the study treatment reported nausea.

Table 1. Commonly reported medical problems by study participants	
Medical Problem	**Maplirpacept With PLD – All 3 Groups (10 Participants)**
Nausea	7 out of 10 participants (70%)
Low number of a type of white blood cell called neutrophils	7 out of 10 participants (70%)
Tiredness	7 out of 10 participants (70%)
Vomiting	6 out of 10 participants (60%)
Low number of a type of blood cell called platelets	6 out of 10 participants (60%)
Abdominal pain	5 out of 10 participants (50%)
Excessive sweating	5 out of 10 participants (50%)
Low number of red blood cells (anemia)	5 out of 10 participants (50%)
Swelling and redness of the mouth and lips	4 out of 10 participants (40%)
High levels of an enzyme called lactate dehydrogenase	4 out of 10 participants (40%)
Low levels of a protein called albumin	4 out of 10 participants (40%)
Diarrhea (loose stools)	3 out of 10 participants (30%)
Dry skin	3 out of 10 participants (30%)
Cough	3 out of 10 participants (30%)
Bruising	3 out of 10 participants (30%)

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 2 out of 10 participants (20%) had serious medical problems during the study. Of these participants:

- 1 participant had abdominal pain, which the study doctors thought was not caused by maplirpacept or PLD.
- 1 participant had problems with walking (“gait disturbance”) and muscle weakness, which the study doctors thought may have been related to maplirpacept.

None of the participants died because of medical problems during the study.

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 **C4971002 or TTI-622-02**

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

www.clinicaltrials.gov	Use the study identifier **NCT05261490**

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!

Pfizer