SERVIER

Clinical Trial Summary

A Study of PRS-344/S095012 (PD-L1x4-1BB bispecific antibody) in patients with solid tumors

Full scientific title: A first in human Phase 1/2 open-label, multicenter, dose escalation and expansion study of PRS-344/S095012 in patients with solid tumors

We thank all the participants who took part in the study. Clinical study participants are very important for making progress in science, for the benefit of patients.
This document is a summary of the study. It is written for a general audience.

Researchers need many studies to decide which medicines work the best and are the safest for patients. For medical science to progress, many studies involving patients are running all around the world. This summary only shows the results from this one study. Other studies, evaluating the same drug, may find different results. You should not change your current treatment based on the results of this study. If you have any questions about this study, please talk to your doctor.

Therapeutic area:
Oncology

Disease:
Solid tumors

Study phase:
Phase 1/2

Final version
03/03/2026

In this summary:

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1 Why was this study done?

This study was done to test a new cancer drug called S095012 (also known as PRS-344/S095012) in participants with advanced solid tumors.

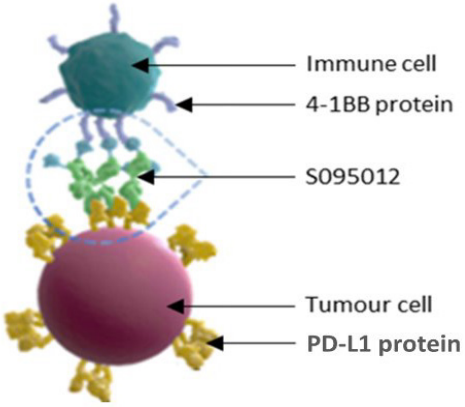
Solid tumors are abnormal growths of cancer cells in organ(s) of the body such as the lung, breast, or brain. Advanced solid tumors can be locally advanced or metastatic. Locally advanced means that the cancer has grown beyond the area where it first started, but it has not yet spread to other parts of the body. Metastatic means that the cancer has spread to other parts of the body.

In the body, S095012 is intended to bind to 2 proteins: one called PD-L1 and the other called 4-1BB.

PD-L1 proteins are present on tumor cells, helping them avoid or escape the immune system (the body's defense system). This is called an immune escape mechanism.

4-1BB proteins are present on immune cells. When activated, 4-1BB can boost immune cells to attack and destroy tumor cells.

S095012 is designed to block PD-L1 on tumor cells, while activating 4-1BB in immune cells. If the treatment is effective, S095012 should block the escape mechanism of the tumor cells and activate the immune cells in the neighbourhood of the tumor cells to destroy them.



The main objectives of this study were:

- To look at the safety of S095012.
- To find the highest dose of S095012 that participants could take without too much risk (highest tolerated dose). This highest tolerated dose helps to find the recommended dose (the one that is both safe and effective for participants).
- To see how well S095012 works in participants with solid tumors.

2 When and where did this study take place?

When did the study take place?

- This study started in September 2021.
- It ended in April 2025.

Where did the study take place?

Country	Number of participants
Australia	9
Belgium	9
Spain	26
United States	2

3 Who participated in the study?

Which participants were included in the study?

To take part, participants had to:

- Be at least 18 years old.
- Have solid tumor that worsened despite previous treatments.
- Have good blood, kidney and liver function.

Participants were not included in the study if they had:

- Received prior medicines similar to S095012.
- Any major surgery within 4 weeks of starting the study.

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How many participants took part in the study?

A total of 46 participants took part in the study: 21 women and 25 men.

How old were the participants?

The average age of the participants was 60 years. The youngest participant was 27 years old and the oldest was 82 years old.

4 Which treatments did the participants receive?

S095012 was given through infusion (an injection given slowly, usually over 30 to 60 minutes) into a vein once every two weeks in each cycle of treatment. Each cycle consisted of 28 days. The 28-day cycles were repeated for as long as the cancer did not progress and if the participant did not have too severe side effects. The participant could also decide to stop the treatment at any time.

Participants received S095012 at doses ranging between 12 to 80 milligrams (mg).

To maintain levels of S095012 in the blood 13 participants received a pre-treatment with another anticancer medicine called obinutuzumab. It was given through infusion in one dose of 2000 mg or 2 doses of 1000 mg on two days in a row, one to two weeks before starting S095012.

5 How was the study carried out?

The study is called an “open-label” study. This means that both the participants and the research doctors knew which treatment was taken.

The study started with a screening period, which lasted up to 28 days. During this time, doctors checked if people who wanted to enter the study met all the necessary requirements.

After the screening period, participants entered the treatment period.

Once the treatment ended, participants had a follow-up period (up to 3 months after the last dose of study drug). After this period, participants were contacted every 12 weeks to check on their health and disease status.

To find the highest tolerated dose, the doctors tested different doses of S095012 in small groups of participants. The first group received the lowest dose, then new groups received a higher dose.

For each dose, the doctors checked the safety of the study drug. Then, the researchers decided whether to increase the dose in the next group of participants. Once the highest tolerated dose was found, the researchers defined the recommended dose (dose that is both safe and effective for participants).

The participants visited the doctors regularly. During the visits, the doctors collected information about the participants’ health.

6 What were the side effects?

Side effects are unwanted medical events that the doctors think may be caused by the treatments in the study.

In this summary, we describe unwanted medical events thought to be caused by S095012.

The results may be presented differently in other documents related to the study.

The table below shows the number of participants who had side effects. Safety results were available for 45 participants who received at least one dose of S095012.

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	S095012 (out of 45 participants)
Participants who had side effect(s)	39 (87%)
Participants who had serious* side effect(s)	16 (36%)
Participants who stopped the treatment because of side effect(s)	13 (29%)

**See definition of serious side effects below*

What were the types of side effects?

The table below shows the most common side effects reported in the study (reported by at least 20% participants).

	S095012 (out of 45 participants)
Strong unwanted body reaction to the treatment given intravenously (leading to fever, vomiting, shortness to breath, etc.)	14 (31%)
Tiredness	12 (27%)
Symptoms caused by the release of a large amount of inflammatory substances called cytokines from cells following the drug infusion (leading to fever, vomiting, shortness of breath, headache and/or low blood pressure etc.)	11 (24%)
Increase in liver enzyme called AST	10 (22%)
Increase in liver enzyme called ALT	9 (20%)

= *participants*

What were the serious side effects?

A side effect is considered serious when:

- the participant needs to be hospitalised,
- it causes lasting damage or death,
- the participant's life is in danger or,
- it is medically important in the doctor's opinion.

The table below shows the serious side effects reported by at least 5% participants in this study.

	S095012 (out of 45 participants)
Symptoms caused by the release of a large amount of inflammatory substances called cytokines from cells following the drug infusion (leading to fever, vomiting, shortness of breath, headache and/or low blood pressure etc.)	7 (16%)
Strong unwanted body reaction to the treatment given intravenously (leading to fever, vomiting, shortness to breath, etc.)	3 (7%)
Liver injury considered to be caused by drugs	3 (7%)

In the study, 1 (2%) participant died from a condition in which some immune cells damage body tissues or organs, and from lung bleeding. Both were thought to be caused by S095012.

7 What were the study results?

The study was stopped earlier than planned. The sponsor (the company that organised and funded the research) stopped including new participants in the study because S095012 has more risks (mainly liver damage) than benefits.

This document presents only the results for the main goal of the study. Other results are available in other documents listed in section 10.

Due to the early end of the study and the small number of participants who took part in the study, most of the main objectives could not be met. As a result, there was not enough information for researchers to make any strong conclusions.

The side effects of S095012 are described in section 6 of this summary.

8 How has this study helped research?

The study helped researchers gather more information on the safety of S095012. This study also helped researchers better understand how these medicines work in treating solid tumors.

This summary shows only the main results from this one study. Other studies, evaluating the same drug, may find different results.

9 Are there plans for further studies?

No other studies with S095012 are planned.

10 Further information

What are the identification numbers of the study?

- Protocol code: CL1-95012-001
- CTIS number: 2023-510046-25-00
- US NCT number: NCT05159388

Who did the study?

The company that organised and funded the research, called the "sponsor", is the Institut de Recherches Internationales Servier based in Gif-Sur-Yvette, France.

How can you contact the sponsor?

Contact us on the Servier website https://servier.com/en/

Where can you learn more about this study?

You can find more information about this study on these websites:

- https://clinicaltrials.servier.com/find-clinical-trials
- http://www.clinicaltrialsregister.eu/ctr-search
- www.clinicaltrials.gov

In this document we translated medical terms into lay terms. You can find the corresponding medical terms in the Servier glossary at https://clinicaltrials.servier.com/glossary/

You can find general information about clinical trials on https://clinicaltrials.servier.com/