SERVIER

Clinical Trial Summary

Immuno-positron emission tomography study of ^{89}Zr-S095012 in patients with advanced solid tumours

Full scientific title: An open label, multicentre, positron emission tomography (PET) imaging study using Zirconium-89 to investigate the biodistribution and tumour uptake of a PD-L1x4-1BB bispecific antibody (S095012) in patients with advanced solid tumours

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 single study. If you have any questions about this study, please talk to your doctor.

Therapeutic area:
Oncology

Disease:
Solid Tumours

Study phase:
Phase 1

Final Version
30/01/2025

In this summary:

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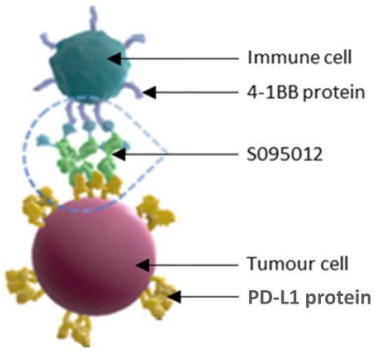
1 Why was this study done?

This study was done to assess how a new cancer drug called S095012 behaves in the body and targets cancer in participants with advanced solid tumours.

Solid tumour cancers are abnormal growths of cancer cells in organ(s) of the body such as the lung, breast, or brain. Advanced solid tumour can be locally advanced or metastatic. Locally advanced means that the cancer has grown outside the part of the body where it started in but 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 tumour cells, helping them avoid the immune system. 4-1BB proteins are present on immune cells. When activated, 4-1BB can boost immune cells to attack and destroy tumour cells. S095012 is designed to block PD-L1 on tumour cells, while activating 4-1BB in immune cells. If the treatment is effective, S095012 should block the escape mechanism of the tumour cells and activate the immune cells in the neighbourhood of the tumour cells to destroy them.



To understand how and where S095012 moves in the body, researchers used a special imaging technique called positron emission tomography (PET) scans. They used a tracer drug called ^{89}Zr-S095012 to track S095012 in the body. This tracer was made by adding a tiny, safe amount of a radioactive (emits radiations) substance called zirconium-89 to S095012. This made ^{89}Zr-S095012 visible on the PET scans, allowing doctors to see where the study drug moved in the body.

The main objectives of this study were:

- To determine the appropriate amount of S095012 to use for imaging and to select the best moments for the imaging.
- To assess how ^{89}Zr-S095012 moved in the body and how much of it was taken up by tumours.
- To see how ^{89}Zr-S095012 was processed by the body.
- To look at the safety of ^{89}Zr-S095012 and S095012.

Because the study ended earlier than planned, some of the main study objectives could not be met (see explanations in section 7 of this summary).

2 When and where did this study take place?

When did the study take place?

- This study started in November 2022.
- It ended in July 2023.

Where did the study take place?

The study took place in the Netherlands.

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 a locally advanced or metastatic solid tumour for which standard treatment options were not available, were no longer working, or were not tolerated.
- Have at least one tumour area that could be measured.
- Have organs that were working properly, especially the liver.

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How many participants took part in the study?

Because the study was stopped earlier than planned, only 3 participants took part in the study. All were men.

How old were the participants?

The youngest participant was 52 years old and the oldest was 55 years old.

4 Which treatments did the participants receive?

In this study, participants received the following treatments:

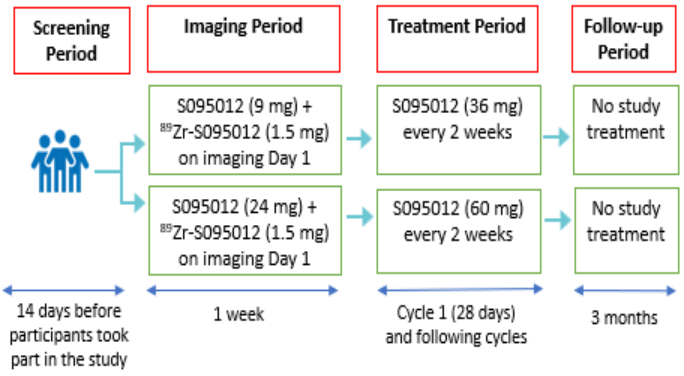
- During the **imaging period**:
  - ^{89}Zr-S095012 through infusion (injection given slowly) on imaging Day 1.
  - And S095012 through infusion, along with ^{89}ZrS095012 on imaging Day 1.
    S095012 was given in small amount to prevent the tracer from leaving the body too quickly.
- During the **treatment period**:

S095012 was given through infusion every 2 weeks in each cycle of treatment. The participants received S095012 during time periods called "cycles". Each cycle was of 28 days. The 28-day cycles were repeated as long as the cancer did not progress and if the participant did not have too severe side effects. Each participant could also decide to stop the treatment at any time.

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 design is presented in the image below.



The study started with a screening period, which lasted up to 14 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 imaging period. On the first day of the imaging period, participants were given the tracer (^{89}Zr-S095012) along with a small dose of S095012. Doctors performed several scans over 7 days to see how the tracer moved in the body and how much of it was taken up by tumours and other organs.

Then, participants entered the treatment period. During this period, they received S095012 every 2 weeks.

Once the treatment ended, participants entered a 3-month follow-up period. During this time, doctors checked participants' health and whether they had any side effects after stopping S95012.

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 study drug 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.

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The table below shows the number of participants who had side effects.

	S095012 9 mg + 36 mg (out of 1 participant)	S095012 24 mg + 60 mg (out of 2 participants)
Participants who had side effect(s)	1	2
Participants who had serious* side effect(s)	0	1
Participants who stopped the treatment because of side effect(s)	0	0

**See definition of serious side effects below*

What were the types of side effects?

The table below shows the side effects reported in the study.

	S095012 9 mg + 36 mg (out of 1 participant)	S095012 24 mg + 60 mg (out of 2 participants)
Flu-like illness	0	1
Headache	0	1
Red raised skin rash	0	1
Skin rash characterized by pus-containing blisters	1	0
Strong unwanted body reaction to the treatment given intravenously (leading to fever, vomiting, shortness to breath, etc.)	0	2
Tiredness	1	1

= 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.
- it causes a health problem in the participant's baby.

The table below shows the serious side effects reported in this study.

	S095012 9 mg + 36 mg (out of 1 participant)	S095012 24 mg + 60 mg (out of 2 participants)
Strong unwanted body reaction to the treatment given intravenously (leading to fever, vomiting, shortness to breath, etc.)	0	1

= participants

In the study, no participant died because of an unwanted event thought to be caused by S095012.

7 What were the study results?

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

The study was stopped earlier than planned by the sponsor (the company that organised and funded the research).

The study was stopped for strategic reasons and safety issues that occurred in another related study in which participants received an additional drug (CL1-95012-001). As a result, the sponsor decided not to continue the development of S095012.

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.

Side effects of the study drug (safety results) are described in section 6 of this summary.

8 How has this study helped research?

This study helped researchers gather more information about how safe the S095012 is and how it moves through the human body. Even though the study was stopped early, the participation of patients still provided valuable information that can help with future cancer research.

This summary shows only the main results from this one study with only 3 participants. 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: CL1-95012-002
- EudraCT number: 2021-001764-20
- NCT number: NCT05638334

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
- https://www.clinicaltrialsregister.eu/ctr
- 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/