SERVIER

Clinical Trial Summary

Efficacy and safety of S95011 in Primary Sjögren's Syndrome patients.

Full scientific title: A phase IIa efficacy and safety trial with intravenous S95011 in primary Sjögren's Syndrome patients. An international, multicentre, randomised, double-blind, placebo-controlled study.

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:
Autoimmune diseases

Disease:
Primary Sjögren's Syndrome

Study phase:
Phase II

Final Version
08/11/2023

In this summary:

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1 Why was this study done?

This study was done to test if S95011 (study drug) is a safe and effective treatment for patients with Primary Sjögren's Syndrome (PSS).

PSS is a condition in which the body's immune system can attack all the body organs but especially the glands that make fluids like tears, saliva, or sweat. This causes dryness in the eyes, mouth, and other areas of the body. PSS is often associated with fatigue and pain. PSS is much more common in women than in men.

Interleukin-7 (IL-7) is a specific protein that promotes disease by triggering the cells of the immune system. In PSS, IL-7 is found in higher-than-normal amounts.

S95011 is a drug that blocks IL-7 protein's action. This drug is yet to be approved by regulatory agencies to treat patients who have PSS.

The main goal of this study was to test if S95011 can improve symptoms of patients with PSS, as compared to a placebo. A placebo looks like S95011 but does not have any medicine in it.

2 When and where did this study take place?

When did the study take place?

- This study started in August 2021.
- It ended in May 2023.

Where did the study take place?

The study took place in the following countries:

Country	Number of participants
Hungary	13
Spain	9
Germany	8
United Kingdom	6
Australia	5
France	5
United States of America	2

3 Who participated in the study?

Which participants were included in the study?

To take part, participants had to:

- Be 18 to 75 years old.
- Be diagnosed with PSS according to specific criteria.

How many participants took part in the study?

A total of 48 participants took part in the study: 42 women and 6 men.

How old were the participants?

The average age of the participants was 54 years. The youngest participant was 28 years old and the oldest was 76 years old.

4 Which treatments did the participants receive?

Participants received either S95011 or placebo.

- S95011 was given through infusion into a vein at the dose of 750 milligrams (mg). An infusion is an injection given slowly. S95011 was given for at least 60 minutes.
- Placebo was given through infusion.

Participants received infusions as follows:

- 1st infusion,
- 2nd infusion after 2 weeks,
- 3rd infusion after 4 weeks,
- 4th infusion after 7 weeks, and
- 5th infusion after 10 weeks.

The participants also continued to take some other drugs that are usually given for PSS, as agreed by the doctor.

5 How was the study carried out?

The study is called a "randomised" study. This means that the participants were put by chance into one of the 2 groups of treatment. They had 2 chances out of 3 to be in the S95011 group and 1 chance out of 3 to be in the placebo group.

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Among the 48 participants included in the study:

- 31 participants took S95011.
- 17 participants took placebo.

The study is called a "double-blind" study. This means that neither the participants nor the research doctors knew which treatment was taken. This was to avoid any influence on the results.

During the screening period of up to 1 month, doctors checked if the participants could take part in this study. Then, the participants took either S95011 or placebo according to their treatment group. The doctors observed the participants up to 15 weeks after they received the last dose of the study treatment.

The participants had their treatment as below:

- 43 participants received 5 infusions
- 2 participants received 4 infusions
- 1 participant received 3 infusions
- 1 participant received 2 infusions
- 1 participant received 1 infusion

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. 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.

	S95011 (out of 31 participants)	Placebo (out of 17 participants)
Participants who had side effect(s)	6 (19%)	2 (12%)
Participants who had serious* side effect(s)	1 (3%)	0
Participants who stopped the treatment because of side effect(s)	2 (6%)	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.

	S95011 (out of 31 participants)	Placebo (out of 17 participants)
Bowel pain	1 (3%)	0
Diarrhoea	1 (3%)	0
Feeling sick	1 (3%)	0
Headache	1 (3%)	0
Viral infection (shingles)	1 (3%)	0
Strong unwanted body reaction to the treatment given intravenously (leading to fever, vomiting, shortness to breath, etc.)	1 (3%)	1 (3%)
Increase in liver enzyme called GGT	1 (3%)	0
Thrush, a fungal infection in the mouth	1 (3%)	0
Low level of neutrophils, a type of white blood cells	1 (3%)	1 (3%)
Low levels of lymphocytes, a type of white blood cell	1 (3%)	0
Stomach pain	1 (3%)	0

= *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.

In this study, one participant (3%) had a serious side effect: one viral infection (shingles) (thought to be caused by S95011).

No participant died during the study.

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7 What were the study results?

The study was completed as planned.

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 doctors measured the disease activity in the body to see if the study drug was effective against PSS. Disease activity here refers to the effect of PSS on the different symptoms in different organs of the body. The results showed that the study drug was not effective against PSS.

8 How has this study helped research?

The study found that S95011 was not effective in treating participants with PSS. The study helped researchers in their understanding of the study drug.

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 S95011 are planned by the sponsor. Due to the study results, the sponsor decided to stop the development of S95011 in PSS. This decision was not due to the safety of the study drug. Please refer to section 10 for more details on the sponsor.

10 Further information

What are the identification numbers of the study?

- Protocol code: CL2-95011-001
- EudraCT number: 2020-001526-59
- US NCT number: NCT04605978

Who did the study?

The company that organised and funded the research, called the "sponsor", is the Institut de Recherches Internationales Servier based in Suresnes, 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
- www.clinicaltrialsregister.eu/ctr-search
- https://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/