PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: IMMU-132-14

Date of Study: August 2020 to October 2024

Short Study Title: Rollover Study in Participants With Metastatic Solid Tumors Benefiting From Therapy With Sacituzumab Govitecan

Date of this Plain Language Summary: October 2025

The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who contributed to the clinical study for **sacituzumab govitecan**, also known as **IMMU-132** or **GS-0132**, brand name: **Trodelvy**.

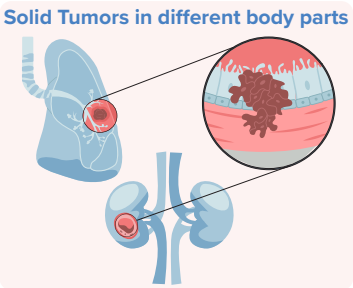
Immunomedics, Inc. sponsored this study and was later acquired by Gilead Sciences. Gilead Sciences believe it is important to share the results with study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or healthcare provider before making any treatment changes.

This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

General information about the study



What are solid tumors?

Solid tumors are abnormal masses of cells that form in organs or tissues like the lungs, breast, or colon. Unlike fluid-filled cysts, these tumors consist of a solid mass of cells, which can be either cancerous or non-cancerous. Sometimes, the solid cancer becomes metastatic, which means it spreads to other parts of the body. Therefore, its early detection and treatment are important.

There are treatments available for solid tumors. However, these treatments may not always work, lose their effectiveness over time or cause side effects. Therefore, there is a need for new treatments to treat solid tumors.

Sacituzumab govitecan (SG) is an approved medicine for certain types of breast cancer. SG is also being studied in other cancer types. SG is a **monoclonal antibody** connected to an anti-cancer drug. In cancer treatment, a **monoclonal antibody** is created in a lab to target specific proteins in cancer cells in the body and deliver drugs directly to the cancer cells to stop the cancer from growing.

The study included people with metastatic solid tumors who benefit from their ongoing SG therapy in other Gilead clinical studies. Participants continued taking the same dose of SG in this study.

This was a **Phase 4** study. This means the researchers observed participants for the long-term safety of SG in this study.

What was the purpose of the study?

The purpose of the study was to provide treatment continuity with SG to participants who benefited and learn about the long-term safety of SG in participants with solid tumors.

The main questions the researchers wanted to answer in this study were:

- How many participants had **unwanted medical events** during the study?
- How many participants had changes in their laboratory test results during the study?

An **unwanted medical event** is any unwanted sign or symptom that participants may have during the study. This may or may not be caused by study drug.

Researchers also wanted to know if participants had any **side effects** during the study. A **side effect** is an unwanted medical event that the study doctors thought might be caused by the study drug, SG.

Who took part in the study?

- **25** participants with advanced or metastatic solid tumors who continued to get benefit from SG, from the **United States**, **Belgium**, and **France** took part in the study.

People could take part in the study if they:

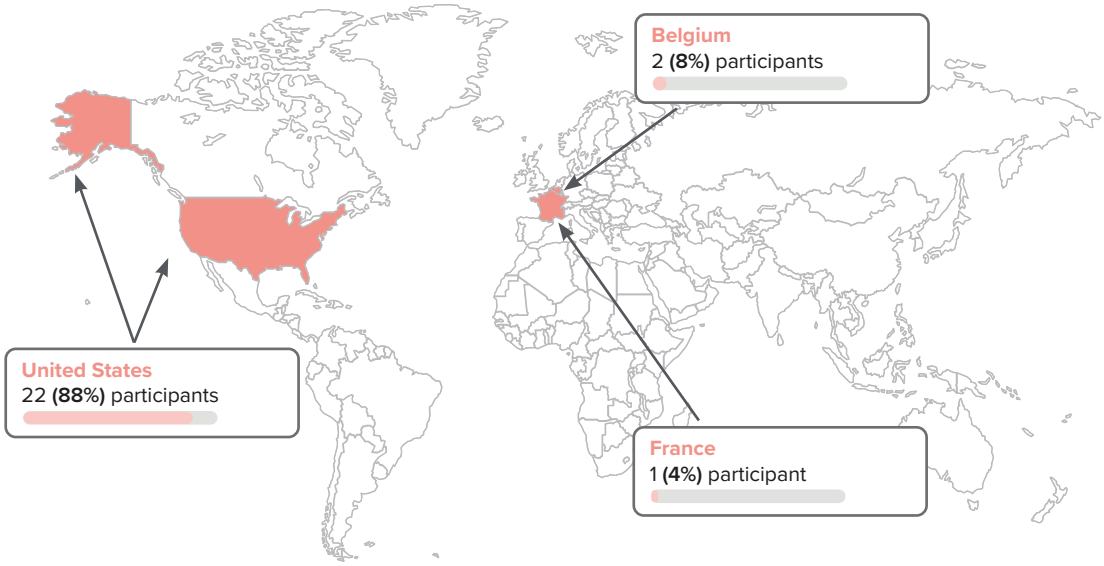
Were at least 18 years of age

Had confirmed solid tumors

Received SG in other Gilead clinical studies

The study participants were between the ages of **21** and **81** years.

The participants from each country are shown below (Number (%) of participants).



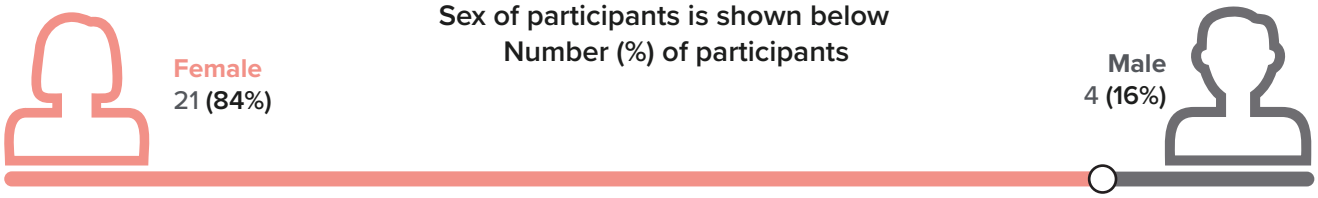
The race of participants is shown below (Number (%) of participants).

White	19 (76%)
Black or African American	2 (8%)
Asian	2 (8%)
American Indian or Alaska Native	1 (4%)
Other or More Than One Race	1 (4%)

The ethnicity of participants is shown below (Number (%) of participants).

Not Hispanic or Latino	21 (84%)
Hispanic or Latino	3 (12%)
Not Collected	1 (4%)

Sex of participants is shown below
Number (%) of participants



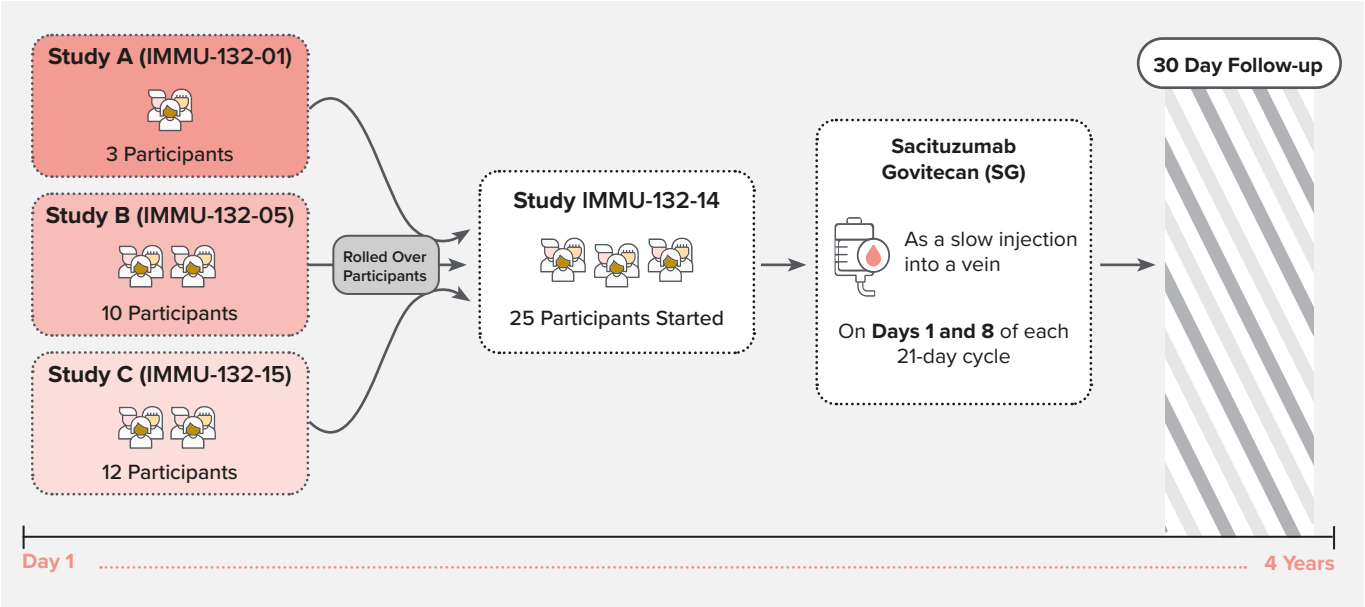
What happened during the study?

This was an **open-label**, **rollover** study.

Open-label means the participants, the doctors, and study staff knew the treatment the participants took.
Rollover means the participants in one study moved to a second related study.

Participants who were getting benefit from SG in 3 previous Gilead clinical studies entered this study to continue to receive SG and be monitored for safety for about 4 years.

The graphic below shows how the study was done.



The participants received treatment in 21-day cycles. A cycle is the time between one round of treatment and the start of the next. SG doses were based on participant's weight (mg/kg).

Participants continued taking the same dose of SG that they received in the previous study. There was no increase in dose in this study, and no participant received more than a 10 mg/kg dose of SG.

All 25 participants continued taking the treatment as long as it benefited them and they were able to tolerate it well. They stopped taking SG by the end of the study, most stopped because their cancer got worse; others stopped because SG wasn't helping anymore, they left the study, or for other reasons.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

How many participants had unwanted medical events during the study?

The researchers kept track of any unwanted medical events that the participants may have had during the study.

An unwanted medical event is considered **serious** if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

The table below shows how many participants had any unwanted medical events during the study.

Unwanted Medical Events				
	Study A IMMU-132-01 (Out of 3 participants)	**Study B** IMMU-132-05 (Out of 10 participants)	**Study C** IMMU-132-15 (Out of 12 participants)	**Total** (Out of 25 participants)
	Number (%) of participants			
How many participants had **any** unwanted medical events?	2 (67%)	10 (100%)	11 (92%)	23 (92%)
How many participants had **any** unwanted **serious** medical events?	0	4 (40%)	1 (8%)	5 (20%)

None of the participants died due to any serious unwanted medical events in this study.

While only a small number of participants enrolled in this study, the rates of unwanted medical events were similar to what researchers already knew about SG's safety. There was no rise in serious or any unwanted medical events, and overall, SG was well tolerated over the long term in this study.

How many participants had changes in their laboratory test results during the study?

The researchers did laboratory tests and measurements of participants before and after taking the treatment. They checked if the changes in laboratory test values were abnormal, meaning they were out of normal reference range.

The table below shows the number of participants who had any abnormalities in their laboratory test results, as well as those whose results were severe or potentially life-threatening.

Out of 25 participants, these results were reported in participants who had at least 1 laboratory test result after the study started. This included 23 participants—3 in Study A, 9 in Study B and 11 in Study C.

Abnormalities in Laboratory Test Results

	Study A IMMU-132-01 (Out of 3 participants)	Study B IMMU-132-05 (Out of 9 participants)	Study C IMMU-132-15 (Out of 11 participans)	Total (Out of 23 participants)
	Number (%) of participants			
Participants with **any** abnormalities in their laboratory test results	3 (100%)	8 (89%)	9 (82%)	20 (87%)
Participants with **severe** or **potentially life-threatening** abnormalities in their laboratory test results	1 (33%)	4 (44%)	8 (73%)	13 (57%)

The rates of laboratory abnormalities seen in participants in this study were similar to those already seen in previous SG studies.

What side effects did participants have during the study?

In this summary, "**side effects**" are defined as unwanted medical events that the study doctors thought might be caused by the study drug. The results from several studies are usually needed to help decide if a study drug actually causes a side effect.

The table below shows how many participants had side effects during the study.

Overall Side Effects

	Study A IMMU-132-01 (Out of 3 participants)	Study B IMMU-132-05 (Out of 10 participants)	Study C IMMU-132-15 (Out of 12 participants)	Total (Out of 25 participants)
	Number (%) of participants			
How many participants had **any** side effects?	2 (67%)	8 (80%)	7 (58%)	17 (68%)
How many participants had **any serious** side effects?	0	1 (10%)	0	1 (4%)

None of the participants stopped taking SG or died due to any side effects during the study.

What were the serious side effects?

1 out of 10 (10%) participants who rolled over from study B (IMMU-132-05) had a serious side effect of **inflammation in large intestine causing severe illness (colitis)**.

What were the non-serious side effects?

The table below lists the most common non-serious side effects that occurred in **more than 20%** of the study participants. These side effects were not serious in nature and did not meet the definition of 'serious side effects' mentioned in the section above in this summary.

The table below shows how many participants had most common non-serious side effects during the study.

Most Common Non-Serious Side Effects

	Study A IMMU-132-01 (Out of 3 participants)	**Study B** IMMU-132-05 (Out of 10 participants)	**Study C** IMMU-132-15 (Out of 12 participants)	**Total** (Out of 25 participants)
	Number (%) of participants			
Feeling sick to the stomach (Nausea)	0	6 (60%)	3 (25%)	9 (36%)
Low number of a type of white blood cells (Neutropenia)	2 (67%)	4 (40%)	3 (25%)	9 (36%)
Loose watery stools (Diarrhea)	1 (33%)	5 (50%)	1 (8%)	7 (28%)
Extreme tiredness (Fatigue)	0	4 (40%)	2 (17%)	6 (24%)

There were other non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 side effect.

While only a small number of participants enrolled in this study, the types and rates of side effects were similar to what researchers had seen in previous SG studies. SG was well tolerated over the long term in this study.

? How has this study helped researchers?

The researchers learned more about the long-term safety of SG in participants with solid tumors.

The results from several studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Gilead Sciences plans to have further clinical studies with SG.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
European Medicines Agency www.euclinicaltrials.eu	EU CT Number: 2023-505336-34
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov Number: NCT04319198
Gilead Website www.gileadclinicaltrials.com	IMMU-132-14

Please note that information on these websites may be presented in a different way from this summary.

Full Study Title: Open-label Rollover Study to Evaluate Long-Term Safety in Subjects with Metastatic Solid Tumors that are Benefiting from Continuation of Therapy with Sacituzumab Govitecan

To learn more about clinical trials in general,
please visit this page on www.clinicaltrials.gov website

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Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

GILEAD