PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences (Immunomedics was the initial sponsor, later acquired by Gilead)

Gilead Study Number: IMMU-132-13

Date of Study: January 2021 to July 2025

Short Study Title: Study of Sacituzumab Govitecan Versus Physician's Choice of Treatment in Participants With Urothelial Cancer That Cannot be Removed or has Spread

Study Nickname: TROPiCS-04

Date of this Plain Language Summary: February 2026

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**.

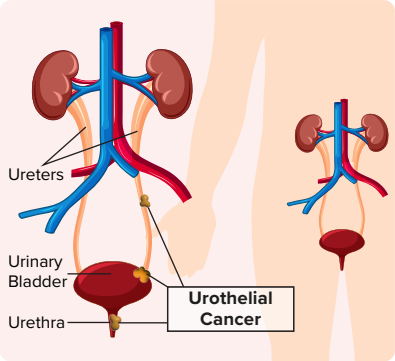
Immunomedics, Inc. sponsored this study and was later acquired by Gilead Sciences. This summary is prepared for study participants and the general public.

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 is Urothelial Cancer?

Urothelial cancer (UC) is a cancer that starts in the renal pelvis, ureters, bladder, or urethra. These are the parts of the urinary or the waste-removal system of the body. Renal pelvis is a funnel shaped part of the kidney that collects urine to pass to the ureters. Ureters are the tubes that carry urine from the kidneys to the bladder. The bladder is a sac that stores urine before it is removed through the urethra. UC occurs when the urothelial cells—cells on the surface of these body parts, grow out of control and affect the normal working of the urinary system.

Chemotherapy has been the standard treatment for people with UC. **Chemotherapy** is a combination of medicines that can kill cancer cells. However, these treatments may not be suitable for everyone or may not work for some people. Sometimes, the cancer grows outside the area where it started. This is called **locally advanced** cancer. When the cancer grows and spreads to other parts of the body, it is called **metastatic** cancer. At times, these locally advanced and metastatic cancer cells go deep into the organ or blood vessels and cannot be removed by surgery. This is called **unresectable cancer**. Therefore, the researchers are looking for an effective and safe treatment option for patients who did not benefit did not benefit from prior therapy or their UC progressed after treatment.

Sacituzumab govitecan (SG) is an approved medicine for certain types of breast cancer. It 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 and deliver drugs directly to the cancer cells. This drug stops cancer cells from growing and spreading.

In this study, researchers compared SG with approved treatments doctors chose, called Treatment of Physician's Choice (TPC). These treatments included paclitaxel, docetaxel, and vinflunine—common chemotherapy drugs used for UC.

This is a **Phase 3** clinical study. This means that researchers looked at how SG worked in a large group of people with UC.

What was the purpose of the study?

The purpose of this study was to check if the participants with locally advanced or metastatic UC who took SG lived for a longer time (**overall survival**) compared to those who were treated with TPC.

Overall survival was measured as the length of time participants stayed alive after joining the study. Overall survival is measured to see how effective the drug is in increasing survival chances in people with cancer.

The main question the researchers wanted to answer in this study was:

How long did the participants live after joining the study (overall survival)?

Researchers also wanted to know the side effects that participants had during the study.

Who took part in the study?

711 participants with metastatic or locally advanced, unresectable UC around the world took part in this study.

People could take part in the study if they:

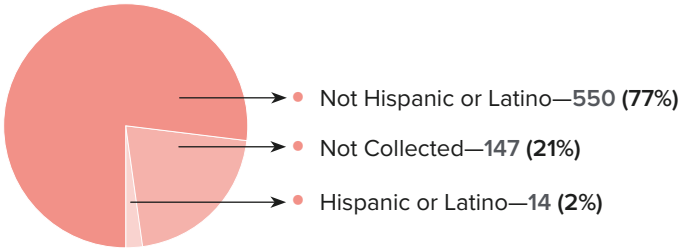
- Were at least 18 years of age
- Had confirmed metastatic or locally advanced, unresectable UC
- Had received treatment for UC before, that was not helping

The study participants were between the ages of **30** and **89** years.

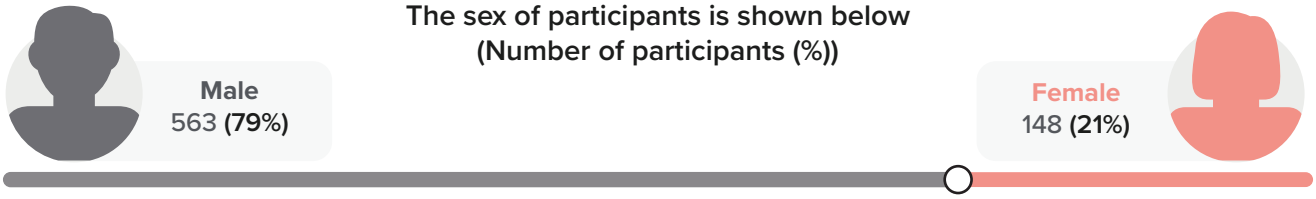
The participants from each country are shown below (Number of participants (%)).

France	150 (21%)	Taiwan	10 (1%)
Spain	88 (12%)	United States	10 (1%)
China	83 (12%)	Georgia	9 (1%)
South Korea	65 (9%)	Israel	9 (1%)
United Kingdom	55 (8%)	Portugal	7 (below 1%)
Italy	47 (7%)	Singapore	5 (below 1%)
Belgium	42 (6%)	Sweden	5 (below 1%)
Greece	30 (4%)	Ireland	3 (below 1%)
Australia	28 (4%)	Bulgaria	2 (below 1%)
Germany	26 (4%)	Croatia	2 (below 1%)
Canada	19 (3%)	Switzerland	2 (below 1%)
Austria	11 (2%)	Turkey	2 (below 1%)
Hong Kong	1 (below 1%)		

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



The sex of participants is shown below (Number of participants (%))



What happened during the study?

This was an **open-label**, **randomized**, and **controlled** study.

Open-label means the participants, the doctors, and study staff knew the treatment the participants received.

Randomized means the researchers used a computer program to assign participants into treatment groups by chance. This makes sure the study is fair. The participants were assigned into 2 groups to receive treatment. Each participant had an equal chance of getting SG or TPC. This is called 1:1 randomization.

Controlled means a known effective treatment (TPC) was compared to the investigational (test) drug, SG.

Participants were assigned to 1 of the 2 groups below to receive treatment in **cycles**. A **cycle** is the time between one round of treatment until the start of the next. Each cycle consisted of 21 days.

SG Group

Participants in this group received SG 10 mg/kg of weight, as a slow injection into a vein (intravenous (IV) infusion), on Day 1 and Day 8 of every 21-day cycle.

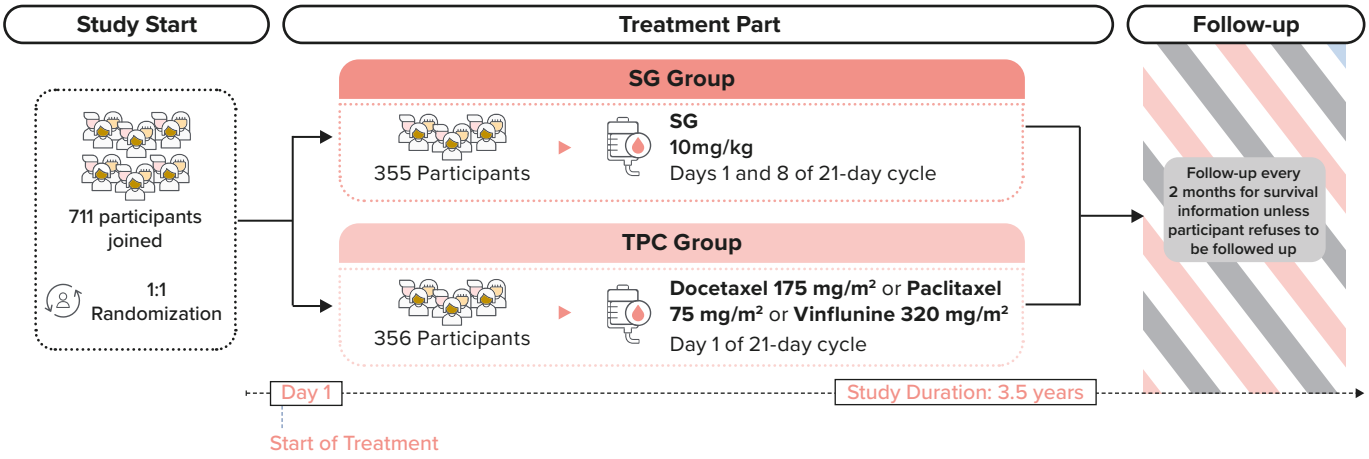
TPC Group

Participants in this group received any 1 of the 3 standard treatments at the recommended dose per body surface area, as a slow injection into a vein (IV) on Day 1 of every 21-day cycle.

- Paclitaxel 175 mg/m^2 IV
- Docetaxel 75 mg/m^2 IV
- Vinflunine 320 mg/m^2 IV

The study doctor chose the best suited medicine based on participant's condition.

The graphics below show the treatment plan.



Out of 711 participants, 686 participants took at least 1 dose of study treatment—349 participants in the SG Group and 337 participants in TPC Group. All 686 participants continued the treatment until it was helping them and they could tolerate it. By the end of the study, all participants stopped treatment, mainly due to cancer worsening, unwanted side effects, or they chose to stop participation. The overall study period was 3 and a half years.

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 long did the participants live after joining the study (overall survival)?

Researchers compared overall survival in both groups using a statistical model. The average overall survival time was similar between the groups and showed only a small improvement of SG compared to TPC (10 months in SG group and 9 months in TPC group).

This study did not achieve its main goal. It could not clearly prove that SG helps people live much longer than TPC.

What side effects did participants have during the study?

Unwanted medical events can happen to the study participants when they take study treatment. In this summary, "**side effects**" are defined as unwanted medical events that the study doctors think might be caused by the study treatment. The researchers assessed if the side effects were **serious** or non-serious in nature.

A side effect 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 results from several studies are usually needed to help decide if a treatment actually caused a side effect.
This section only includes results from 686 participants who received the treatment—349 in the SG group and 337 in the TPC group. The table below shows how many participants had side effects during the study.

Overall Side Effects

	SG (Out of 349 participants)	TPC (Out of 337 participants)	Total (Out of 686 participants)
	Number of participants (%)		
How many participants had **any** side effects?	339 (97%)	296 (88%)	635 (93%)
How many participants had **any serious** side effects?	120 (34%)	60 (18%)	180 (26%)
How many participants **died** due to any serious side effects?	15 (4%)	5 (1%)	20 (3%)
How many participants **stopped treatment** due to any side effects?	39 (11%)	42 (12%)	81 (12%)

What were the serious side effects?

The table below shows serious side effects that occurred in at least 1% of all study participants.

Serious Side Effects	SG (Out of 349 participants)	TPC (Out of 337 participants)	Total (Out of 686 participants)
	Number of participants (%)		
Fever with a low number of white blood cells called neutrophils (Febrile neutropenia)	37 (11%)	14 (4%)	51 (7%)
Frequent loose watery stools (Diarrhea)	28 (8%)	5 (1%)	33 (5%)
Low number of white blood cells called neutrophils (Neutropenia)	26 (8%)	9 (2%)	35 (5%)
An infection in the blood causing the body to overreact and harm its own organs accompanied with low levels of white blood cells called neutrophils (Neutropenic sepsis)	10 (3%)	2 (below 1%)	12 (2%)
Fever (Pyrexia)	7 (2%)	2 (below 1%)	9 (1%)
Vomiting	7 (2%)	2 (below 1%)	9 (1%)
Low number of red blood cells (Anaemia)	7 (2%)	1 (below 1%)	8 (1%)
Infection in the blood that causes the body to overreact and harm it's own organs (Sepsis)	5 (1%)	3 (below 1%)	8 (1%)
A life-threatening condition that happens when the sepsis causes blood pressure drop to a dangerously low level (Septic shock)	7 (2%)	1 (below 1%)	8 (1%)
Feeling less hungry (Decreased appetite)	3 (below 1%)	4 (1%)	7 (1%)
An infection in parts of urinary system—kidneys, ureters, bladder and urethra (Urinary tract infection)	1 (below 1%)	6 (2%)	7 (1%)

The table below shows all the serious side effects that caused death in the study.

Serious Side Effects that Caused Death

	SG (Out of 349 participants)	TPC (Out of 337 participants)	Total (Out of 686 participants)
	Number of participants (%)		
An infection in the blood causing the body to overreact and harm its own organs accompanied with low levels of white blood cells called neutrophils (Neutropenic sepsis)	4 (1%)	0	4 (below 1%)
Infection in the blood that causes the body to overreact and harm it's own organs (Sepsis)	3 (below 1%)	0	3 (below 1%)
Bleeding in the digestive tract (Gastrointestinal hemorrhage)	0	2 (below 1%)	2 (below 1%)
A life-threatening condition that happens when the sepsis causes blood pressure drop to a dangerously low level (Septic shock)	2 (below 1%)	0	2 (below 1%)
Sudden episode of decreased kidney filtering function (Acute kidney injury)	1 (below 1%)	0	1 (below 1%)
Lung injury that allows fluid to leak into the lungs (Acute respiratory distress syndrome)	1 (below 1%)	0	1 (below 1%)
Fever in a person with low production of blood cells in the bone marrow (Febrile bone marrow aplasia)	0	1 (below 1%)	1 (below 1%)
Reduced physical health (General physical health deterioration)	0	1 (below 1%)	1 (below 1%)
Low number of white blood cells (Leukopenia)	1 (below 1%)	0	1 (below 1%)
Presence of fluid in the lungs, usually as a result of infection (Pneumonia)	0	1 (below 1%)	1 (below 1%)
Bacterial infection in the blood caused by the Pseudomonas bacteria (Pseudomonal sepsis)	1 (below 1%)	0	1 (below 1%)
Bacterial infection in the lungs (Pulmonary sepsis)	1 (below 1%)	0	1 (below 1%)
Lungs not working properly (Respiratory failure)	1 (below 1%)	0	1 (below 1%)

What were the non-serious side effects?

The table below shows the most common non-serious side effects that occurred in at least 13% of all study participants.

Most Common Non-Serious Side Effects

	SG (Out of 349 participants)	TPC (Out of 337 participants)	Total (Out of 686 participants)
	Number of participants (%)		
Low number of red blood cells (Anaemia)	158 (45%)	96 (28%)	254 (37%)
Hair loss (Alopecia)	134 (38%)	110 (33%)	244 (36%)
Loose watery stools (Diarrhea)	172 (49%)	44 (13%)	216 (31%)
Feeling sick to the stomach (Nausea)	143 (41%)	47 (14%)	190 (28%)
Extreme tiredness (Asthenia/Fatigue)	193 (56%)	133 (39%)	326 (48%)
Feeling less hungry (Decreased appetite)	78 (22%)	38 (11%)	116 (17%)
Low number of white blood cells called neutrophils (Neutropenia)	165 (47%)	44 (13%)	209 (30%)
Vomiting	72 (21%)	17 (5%)	89 (13%)

How has this study helped researchers?

The researchers learned more about how well SG worked and was tolerated in people with UC. It assessed the effectiveness of SG compared to standard of care treatment available at the time the study was done.

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 has ongoing 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: 2024-513870-23-00
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov Number: NCT04527991
Gilead Website www.gileadclinicaltrials.com	IMMU-132-13
Links to Publications About the Study	Powles T, et al. Ann Oncol. 2025;36(5):561-71 (This article is written in technical scientific language) Powles T, et al. Future Oncology. 2025; 21(28): 3593–3610 (This article is written in plain language)

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

Full Study Title: A Randomized Open-Label Phase III Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Subjects with Metastatic or Locally Advanced Unresectable Urothelial Cancer

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.

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