ascent-05

Patient Information

Model(s) Portrayal

This brochure contains information about the ASCENT-05 Study for patients with early-stage triple negative breast cancer.

This information should help you decide whether you, or someone you know, may want to take part in the study.

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an experimental treatment, such as:

- Does it work?
- How safe is it?
- What are the side effects?

- Clinical research studies play a key role in the fight against cancer. Through these studies, we can explore new and potentially better ways of identifying, diagnosing, and treating cancer, with the goal of improving outcomes for patients affected by this disease now and in the future.
- Speak to your medical team to make sure you understand all your options before you decide whether to join a clinical research study.

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Choosing whether to take part in a clinical research study is an important decision. If you have any questions, you can contact the study team using the information provided in this brochure.

About the study drug

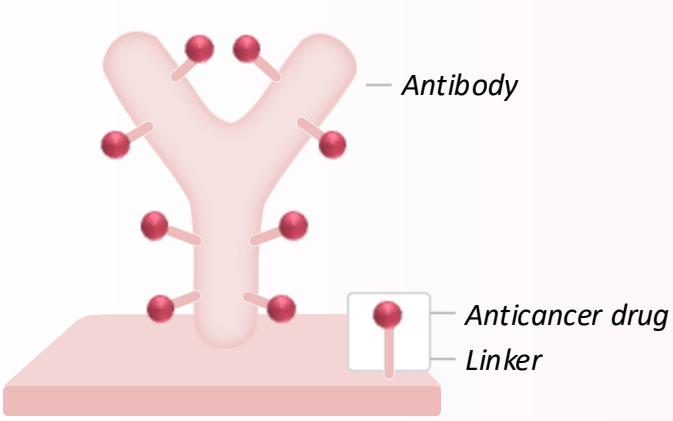
Sacituzumab govitecan (SG) is a more recent type of investigational treatment called an antibody–drug conjugate (ADC).

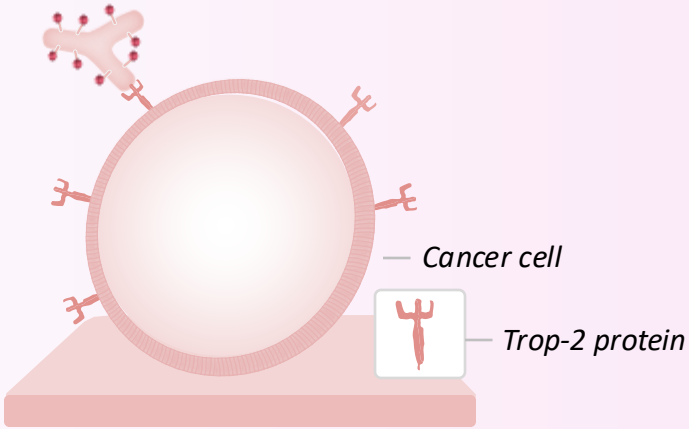
- Unlike traditional chemotherapy, ADCs are designed to target and attach to the surface of cancer cells that display certain type of protein markers on its surface to deliver anti-cancer drug directly to the cancer.
- Types of cancer such as breast cancer has more Trop-2 proteins than normal healthy cells.
- SG is designed to bind selectively to cells with Trop-2 proteins on cancer cells.

How SG is designed to work:

SG is Y-shaped and is designed to carry cancer-fighting medicine to cancer cells that have Trop-2 proteins

Tumor Cells in certain cancers have a higher amount of Trop-2 proteins for SG to link to





About the study drug

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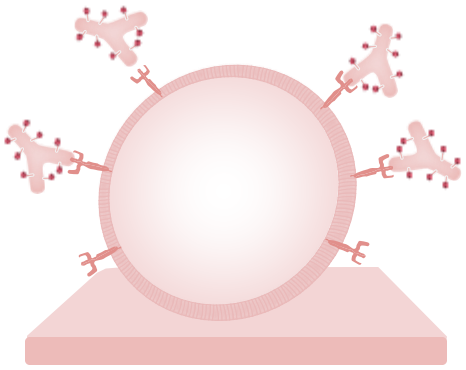
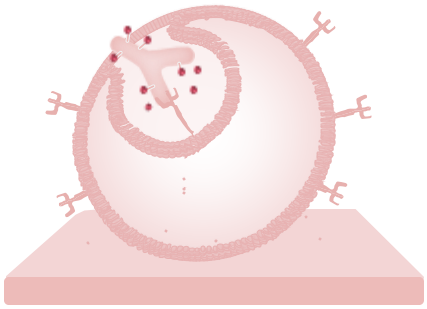
How SG is designed to work:

SG attaches to Trop-2



Once attached, SG enters the cancer cell



Once SG enters, the anticancer medicine is released, killing the cell. SG can also have an effect to other cancer cells in the surrounding environment

About the ASCENT-05 Study

This study is for patients who have early-stage triple negative breast cancer (TNBC) with residual (remaining in breast or lymph nodes) disease after completing their chemotherapy and surgery.

TNBC is when tumor tissue test negative for all 3 markers (estrogen, progesterone, and HER2) hence the name triple-negative breast cancer. Without these markers being expressed, treatment for TNBC is more limited than other types of breast cancer and may require a different approach.

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About the ASCENT-05 Study

The goal of this study is to see if the experimental treatment, sacituzumab govetican in combination with pembrolizumab, can improve outcomes and delay the return of disease in patients with high-risk early TNBC, when compared to pembrolizumab alone or pembrolizumab in combination with capecitabine (which is the current standard of care).

On ASCENT-05, researchers will compare the experimental treatment with standard of care to see what effect the experimental treatment has on:

- the time it takes for the cancer to come back (recurrence)
- the patients' survival once their cancer comes back
- patients' quality of life
- the patient's safety
- how well the body handles taking it

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About 1514 patients from around the world are expected to join this study.

About the Study Treatment Options in ASCENT-05

You will be randomly assigned to either 1 of the 2 study treatment groups for a **total of 8 cycles**. Both you and the study doctor will know which study treatment group you are in.

Group 1 patients will receive experimental treatment of **SG with pembrolizumab**

Days	1	2	3	4	5	6	7	8

*You will receive an intravenous infusion of SG on **Days 1 and 8** of each 21-days cycle. The infusion may take up to **3 hours and 15 minutes**, and then may take 1-2 hours for remaining cycles.*

*Only on day 1, SG infusions will be followed by a pembrolizumab infusion. This infusion may take up to **30 minutes**.*

Group 2 patients will receive a standard of care option. The option will be selected by your doctor based on what is best for your health:

Pembrolizumab alone (option 1)

You will receive an intravenous infusion of pembrolizumab on Day 1 of each 21-day cycle. This infusion may take up to **30 minutes**.

Pembrolizumab with capecitabine (option 2)

You will receive an intravenous infusion of pembrolizumab on Day 1 of each 21-day cycle.

This infusion may take up to **30 minutes**.

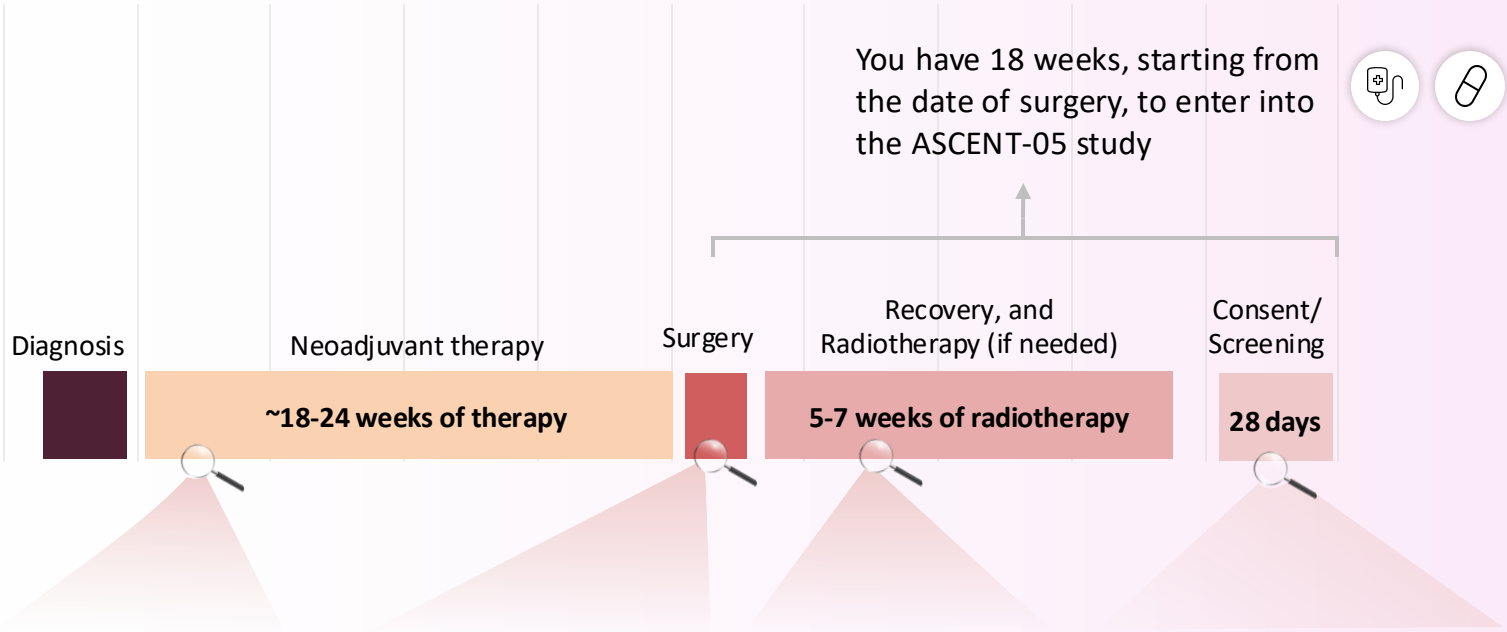
You will start taking capecitabine by mouth twice a day for **2 weeks** (Days 1-14).

You will have a **1-week** rest period before your next cycle of capecitabine.

What is required before considering ASCENT-05?

~ 1 year before study entry

Randomization



You will need to complete a minimum of 6 cycles or 18 weeks of chemotherapy prior to your breast cancer surgery

Your surgeon will take samples of tissue from your tumor in the breast and/or lymph node(s) and a pathologist will check to see if there are any live cancer cells left under a microscope. This will determine if you have residual disease and if further treatment is needed.

Depending how advance your disease is, you may need to complete up to 5-7 weeks of radiation therapy before to entering the ASCENT-05 study

Once you agreed to be part of this study, your study doctor will perform a series of medical procedures (*e.g. blood tests, physical exam)* to make sure this study is the right fit for you. The screening process will last no more than 28 days.

What should I expect if I do take part in ASCENT-05?

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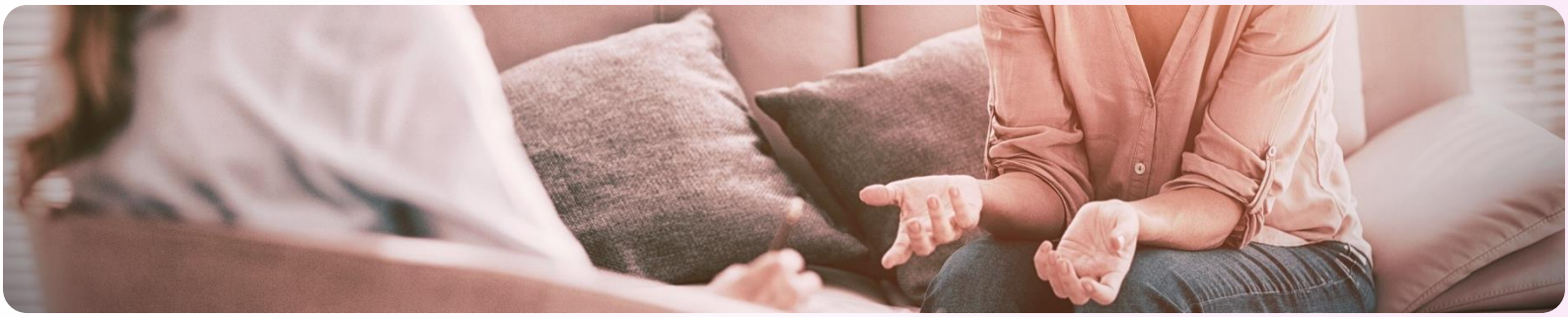

Screening period (up to 28 days)

If you agree to participate in this study and you have signed this informed consent form, you will be evaluated to see if you meet the criteria to participate in the study.

Study treatment period

You will receive on study adjuvant treatment 21-day cycles for 8 cycles

- Group 1
- Group 2

Disease Status Evaluation/Long-Term Follow Up

- Once you stopped or have completed study treatment, you will return for an end of treatment visit.
- You will be evaluated for you disease status evaluation (DSE) starting from date of randomization. DSE visits will be scheduled. For specifics, please discuss with your study doctor or study care team.
- If your disease has unfortunately returned, you will no longer be contacted to evaluate for your disease status evaluation visit.
- You will then be contacted annually or more frequently to follow up on your safety and well-being in person or through telephone.

What else do I need to consider?

- The study team will explain the possible benefits and risks of the study.
- You do not have to take part in the study if you do not want to.
- If you choose to take part in the study, you can stop participating at any time.
- You will not be paid to take part in this study, but you may be reimbursed for reasonable travel, parking or lodging during your participation.
- All study-specific related tests will be provided at no cost to you.
- A team of doctors and nurses will monitor your health carefully during the study.
- The study has been approved by an Institutional Review Board (IRB)/Ethics Committee (EC), which protects the rights, safety, and well-being of the patients.

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Contact Information

To learn more, visit:

https://www.gileadclinicaltrials.com/study?nctid=NCT05633654

General Contact Center:

Gilead Study Information Center

Monday – Friday, 5am – 6pm PT

Email: GileadClinicalTrials@gilead.com

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Study participation is voluntary, please contact your study doctor or study care team for more information on ASCENT-05

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Sponsored Gilead Sciences Inc. 333 Lakeside Drive Foster City, CA, 94404 USA

The images depicted contain models and are being used for illustrative purposes only.

Patient Pamphlets, 16 January 2025 [Version 2]