TroFuse 036

ONCOLOGY CLINICAL TRIALS GOG-3123/ ENGOT-cx22

Learn about a clinical trial for **Cervical Cancer**

In this brochure, you will learn about **cervical cancer** and a clinical trial for this disease. In this trial, researchers are trying to find out if the investigational trial drug sacituzumab tirumotecan (sac-TMT) given with other treatments:

- Is safe
- Helps stop cervical cancer from spreading or growing
- Helps people live longer

You can also use this brochure to talk with your doctor about this trial.



Table of Contents

- What is Cervical Cancer?
  - What are my treatment options?
- What is a clinical trial?
- All about this clinical trial
  - What is the goal of this trial?
  - What is the treatment being studied?
  - About sac-TMT
- Who can join this trial?
- If I am able to join, how long will I be in the trial?
- What will happen during trial visits?
- What study treatment will I get?
- Notes

What is Cervical Cancer?

The cervix is a cylinder-shaped neck of soft tissue, which connects the body of the uterus to the vagina. Cervical cancer starts in the cells of the cervix and can develop over time. Most often normal cells in the cervix gradually develop pre-cancerous changes first. These changes can be detected by the Pap test and if treated, can prevent cancer from developing. However, in some cases the pre-cancerous cells turn into cancer. The most common type of cervical cancer is squamous cell carcinoma.

What are my treatment options?

If you have cervical cancer, your care team will talk about your treatment options with you and those close to you.

Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far

- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms
- Features of your cancer cells (called biomarkers) that may help guide your treatment

Your care team may offer you 1 or more of these treatments:

- **Local therapies** – treatment directed at the site of the cancer to destroy it
- **Targeted therapy** – treatment that works on specific cells to stop them from growing
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Radiation therapy** – treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Palliative care** – also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat cervical cancer, but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove all or part of the cancer
- **Watchful waiting** – your care team might wait and watch the cancer before they use any treatment (also called active surveillance)
- **Clinical trials**, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if an investigational trial drug, called sacituzumab tirumotecan (sac-TMT), given with other treatments:

- Is safe
- Helps stop cervical cancer from spreading or growing
- Helps people live longer

In this trial, researchers are studying the investigational combination of sac-TMT and pembrolizumab with or without bevacizumab compared to standard of care alone. Everyone in this trial will get standard of care treatments for this type of cervical cancer, either before they join the trial or as part of the trial.

- **Pembrolizumab** is an immunotherapy, which is a medicine that helps your immune system fight the cancer.
- **Bevacizumab** is a targeted therapy, which is a treatment that works on specific cells to stop them from growing.

Researchers don't know if sac-TMT may work to help treat cervical cancer.

What treatment is being studied?

The investigational trial drug is sacituzumab tirumotecan, also known as sac-TMT or MK2870.

About sacituzumab tirumotecan:

Sacituzumab tirumotecan (sac-TMT) is a type of investigational targeted therapy known as antibody drug conjugate (ADC) that may destroy cancer cells.

Unlike traditional chemotherapy, ADCs have 3 parts:

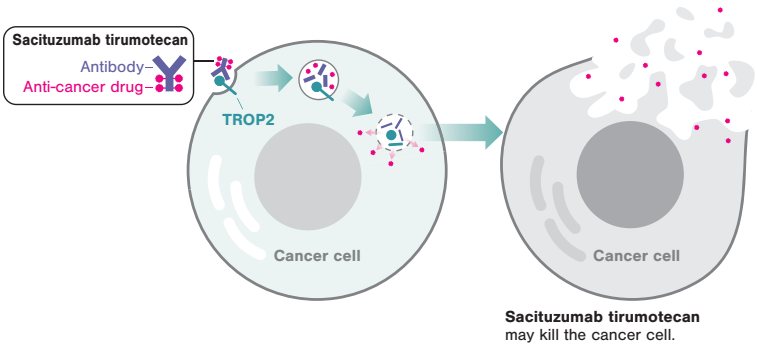
- **A monoclonal antibody:** A protein that binds to a specific protein or receptor found on certain types of cells, including cancer cells. In this case, the specific receptor is TROP2.
- **An anti-cancer drug:** A type of drug that is meant to kill cancer cells
- **Linker:** Connects the anti-cancer drug to the monoclonal antibody.

How sacituzumab tirumotecan works:

1. TROP2 receptors are involved in how tissues in the body grow. These are more common in cancer cells.
2. The monoclonal antibody in sacituzumab tirumotecan (trial drug) finds and binds to the TROP2 receptors on cancer cells.
3. TROP2 moves sacituzumab tirumotecan into the cancer cell where the anti-cancer drug is released.
4. Once inside the cancer cell, the anti-cancer drug may kill the cancer cell.

This is what scientists know or assume about how the trial drug works.

Another way to think about sacituzumab tirumotecan



Who can join this trial?

There are eligibility criteria that will determine if you qualify for participation.

For example, you must:

- Have one of these types of cervical cancer:
  - ➤ Squamous cell carcinoma
  - ➤ Adenosquamous carcinoma
  - ➤ Adenocarcinoma cervical cancer
- Have not had prior systemic anticancer treatment. However, prior use of chemoradiotherapy or induction chemotherapy prior to radiotherapy in the locally advanced setting is allowed.
- Have persistent, recurrent, or metastatic cervical cancer.
- Has tumor PD-L1 expression of CPS ≥1

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- What type of cancer you have
- How well you tolerate the study treatments



Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the study drugs are working for you.

During your trial visits, you may get:

- Your trial treatments
- Blood and urine tests
- Physical exams
- Imaging scans such as CT scans or MRIs (scans that help the doctor see cancer inside your body)

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

What treatments will I get?

The treatments you get depends on the part of the trial and which group you are assigned to.

If you are one of the first 20 participants to join the study, you will be in the safety run-in part of the trial. In this part, researchers will give participants the investigational combination of sacituzumab tirumotecan with pembrolizumab and bevacizumab.

The treatment after the safety run-in will consist of two parts:

In the first part of treatment, you will get chemotherapy and pembrolizumab. You may also get bevacizumab. If the cancer responds (gets smaller or goes away), you will continue to the second part. If the patient does not respond, you may be eligible for the subsequent treatment arm receiving sac-TMT +/- pembrolizumab.

In the second part, you will be randomly assigned to 1 of 2 groups:

- **Group A** will get sac-TMT and pembrolizumab, with or without bevacizumab
- **Group B** will get pembrolizumab with or without bevacizumab.

A computer will decide which group you are put in. You have an equal chance of getting put in each group.

Thank you for learning about cervical cancer and this clinical trial

You can use this brochure to talk with your doctor about this trial.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit **www.merckoncologyclinicaltrials.com**
- Scan this QR code:

MERCK GOG FOUNDATION ENGOT European Network of Gynaecological Oncological Trial groups

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