TroFuse 027

ONCOLOGY CLINICAL TRIALS Dose Escalation

Learn about a clinical trial for **intermediate-risk non-muscle invasive bladder cancer which is a type of bladder cancer called (IR NMIBC)**

In this brochure, you will learn about intermediate-risk non-muscle invasive bladder cancer (IR NMIBC) and a clinical trial for this disease. In this trial, researchers are evaluating the safety and tolerability of varying doses of an investigational trial drug.

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

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What is intermediate-risk non-muscle invasive bladder cancer (IR NMIBC)?

Cancer is when abnormal cells grow out of control. Cancer can start in any part of the body and can then spread to other areas of the body. If you are diagnosed with cancer, your doctor will likely do many tests which may include scans and a biopsy (sample of tissue) to find out the staging (Stage 0-IV) of the cancer.

Bladder cancer is a type of cancer in the inner layers of cells that line the urinary tract. It's often called bladder cancer because it most often happens in the bladder, but it can happen in other parts of the urinary tract too. The urinary tract is a set of organs that work together to remove urine (pee) from your body, which includes:

- Kidneys – organs that filter waste and extra water from blood to make urine
- Ureter – tube that carries urine from the kidney to the bladder

- Bladder – organ that stores urine
- Urethra – tube that empties urine from the bladder to leave the body

"Non-muscle invasive" bladder cancer (NMIBC) means the cancer has not spread to the muscle layer of the bladder lining. NMIBC has 3 risk categories, which describe how likely the cancer is to grow or come back. The 3 risk categories are:

- Low-risk – the cancer is less likely to grow or come back. It usually involves small, single tumors that haven't spread.
- Intermediate-risk – the cancer has a medium chance of growing or coming back. It might involve larger or multiple tumors, or tumors that have certain features making them more concerning than low-risk.
- High-risk – the cancer is more likely to grow or spread to deeper layers of the bladder or more likely to come back after treatment. It includes larger tumors, multiple tumors, or tumors that have features known to have more dangerous features.

What are my treatment options?

If you have IR NMIBC, 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

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. This includes surgery to remove part or all of the cancer or surgery combined with treatments given directly into the bladder (called intravesical therapy). These treatments include:
  - **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
- **Radical cystectomy** – surgery to remove the bladder
- **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 trial 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 find a safe and effective dose for the investigational trial drug when it is directly given into the bladder (intravesical delivery). Researchers are hoping to better understand the effect of the investigational trial drug and the appropriate dose for intravesical delivery.

What treatment is being studied?

The investigational trial drug is sac-TMT, Sacituzumab-tirumotecan (also called MK-2870).

About sacituzumab-tirumotecan:

Sacituzumab-tirumotecan (sac-TMT) is a type of targeted therapy known as antibody drug conjugate (ADC) that may destroy cancer cells. Unlike traditional chemotherapy, ADCs have 3 parts:

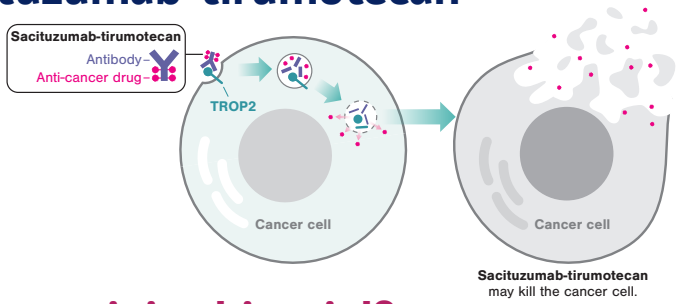
- **A monoclonal antibody:** A protein that binds to specific proteins or receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is TROP2.
- **An anti-cancer drug:** A type of drug that is meant to kill cancer cells.
- **Linker:** Connects the anti-cancer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

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 will qualify for participation.

For example, you must:

- Have history of low grade NMIBC that has come back
- Have a negative urine test for high-grade bladder cancer
- Be 18 years of age or older

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

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.

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

Everyone who joins will be in this trial for about 2 years. Your time in the study will start when you sign the informed consent document. It will end with your last contact with the trial staff.

How long you will be in the trial depends on:

- Your health
- How well you tolerate the study treatments

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 investigational trial drug is working for you. **During your trial visits, you may get:**

- The investigational trial drug
- Blood and urine collection/tests
- Physical exams
- Scans and procedures such as:
    - Surgery with the goal of removing your bladder cancer (called TURBT)
    - A test to check how your heart is beating (called electrocardiogram or ECG)
    - Scans to see and take pictures of the inside of your bladder and urinary tract (called CTU/MRU)

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?

All participants will receive one dose of the investigational trial drug, sacituzumab-tirumotecan, weekly for 6 total weeks. Your trial doctor will deliver the investigational trial drug directly into your bladder through a urinary catheter (a small tube). Each participant will only get one of the 4 varying doses of the investigational trial drug.

You, your trial doctor, and the trial staff will know what dose you are getting.

Thank you for learning about intermediate-risk non-muscle invasive bladder cancer (IR NMIBC) and this clinical trial

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

Your questions and notes:

You can use this space to write down notes or questions about this trial.

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To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Contact Merck by
  - ➤ Visiting **www.merckoncologyclinicaltrials.com**
  - ➤ Scanning this QR code:

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