



## What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a medical strategy, device, drug, or therapy is safe and effective for people. These studies are important because they help identify which medical approaches work best for specific illnesses in specific groups of people.

Participation in clinical research is voluntary, and participants can leave a study at any time. If you decide to join the LEGEND study, there is no guarantee that the study drug will improve your bladder cancer, but what researchers learn may lead to better cancer medications in the future.

For more information about the  
LEGEND study, contact:



## Do you have bladder cancer that is high risk OR has not responded to therapy?

You may be able to join the LEGEND study, which is testing a gene therapy in people with non-muscle invasive bladder cancer (NMIBC).

LEGEND



## What is the LEGEND study?

The LEGEND study is a clinical research study designed to test whether the study drug can safely help the body destroy cancer cells and delay or prevent bladder removal for people with NMIBC.

## What is the study drug?

The investigational\* study drug is a type of gene therapy. It includes tiny pieces of DNA, called genes, that are intended to give your immune system new instructions on how to recognize and fight cancer cells. The study drug is a *non-viral* gene therapy, which means it does not use a modified virus to get into cells and deliver the DNA, like many other gene therapies.

Study participants will receive the study drug as a liquid solution directly into the bladder through a temporary tube called a catheter.

\**Investigational* means the study drug has not been approved by the US Food and Drug Administration (FDA), or the regulatory authority in any country, to be used outside of clinical research.

## Who can join the study?

You may be able to join the LEGEND study if you meet the following study requirements:

- 18 years of age or older
- Diagnosed with NMIBC (bladder cancer that has not extended into the bladder muscle) that is considered high risk OR that did not respond to, or returned after, BCG therapy (Bacillus Calmette-Guerin), which is an immunotherapy drug infused in the bladder and sometimes used to treat NMIBC

Other study requirements will apply.



## What can study participants expect?

If you join the LEGEND study, your active participation may last up to 144 weeks (about 2 years and 9 months). If you stop taking the study drug before this, you may have up to a year of follow-up. The study is divided into the following periods:



### Screening (up to 4 weeks)

- You will have study tests and procedures to find out if you can be in the study.



### Study Drug (up to 144 weeks)

- You will receive at least 1 cycle, and as many as 12 cycles, of the study drug. One cycle is 12 weeks.
- **Initial Study Drug Period** (Cycles 1 to 4): You will receive the study drug once a week for the first 2 weeks of each cycle and once again in the fifth and sixth week of each cycle.
- **Study Drug Maintenance Period** (Cycles 5 to possibly 12): If the cancer has not come back at the end of the first 4 cycles, you will continue for Cycles 5 to 8. You will receive the study drug once a week for the first 2 weeks of each cycle.  
  
If the cancer has not come back after 8 cycles, your study doctor may discuss either continuing for 4 more cycles (12 cycles total) or entering the Follow-up Period. If you choose Follow-up, you will have visits every 12 weeks while the cancer has not come back.
- You will have regular study visits for tests and procedures, including a cystoscopy, urine cytology, and/or a bladder biopsy, near the end of each cycle to find out the status of the cancer and whether you can continue with the next cycle.



### Follow-up (up to 1 year)

- If the cancer comes back, you will receive a phone call every 3 months rather than the study visits.