



Committed to hope.
Dedicated to patient lives.
The future of bladder
cancer research
is here.

A quick reference guide for potential ABLE-22 study participants

Thank you for your interest in the ABLE-22 clinical research study. This sheet provides more details about the study. If you have any questions or would like to know more, please visit **ABLEclinicalstudies.Ferring.com/able22/** or call the local study site at the number at the end of this document.

What is the ABLE-22 study?

Nadofaragene firadenovec is currently approved by the United States Food and Drug Administration (FDA) under the tradename ADSTILADRIN® for the treatment of high-risk non-muscle invasive bladder cancer (NMIBC) that has not responded to Bacillus Calmette-Guerin (BCG) treatment. This study is evaluating the study drug, nadofaragene firadenovec, to find out how effective and tolerable it is when administered alone and in combination with chemotherapy or immunotherapy in adults with high-grade NMIBC.

A study drug contains a substance that is being tested in clinical studies. However, every study drug is reviewed by a government health authority, such as the United States FDA, and an ethics committee for testing in people.

Why is the ABLE-22 study important?

Some people with high-grade NMIBC may not respond to available therapies such as BCG immunotherapy, a treatment that helps the immune system fight cancer.

Clinical studies like this one aim to find new and better ways of preventing, diagnosing, and treating disease. Study participants can help us in this important research. Thank you for considering participation in this study.

How is the study drug being tested?

If you are eligible to participate, you will be randomly assigned to 1 of the following groups (arms) during the study:

- **Arm 1:** will receive nadofaragene firadenovec
- **Arm 2:** will receive nadofaragene firadenovec plus chemotherapy
- **Arm 3:** will receive nadofaragene firadenovec plus immunotherapy

You, the study doctor, and study staff will be aware of your study group assignment.

Nadofaragene firadenovec, chemotherapy, and immunotherapy will be administered at visits to the study site. Nadofaragene firadenovec and chemotherapy are both given directly into the bladder through a urinary catheter. Immunotherapy is given through an intravenous (IV; into a vein) infusion.

Who is this study enrolling?

To be eligible for this study, you must:

- Be at least 18 years of age
- Be diagnosed with high-grade NMIBC
- Have received and not responded to at least 2 courses of BCG immunotherapy for NMIBC

This is not a complete list of study requirements. The study doctor will review the full requirements for this study with you.

How long will I be in this study?

You will be in this study for up to 36 months, which includes a study treatment period (up to 24 months) and a follow-up period (up to Month 36).

How will my health be monitored in the ABLE-22 study?

During the study, you will visit the study site regularly for several types of tests and assessments. In between the site visits, your health may also be monitored through phone calls. Tests and assessments may include:



Physical examinations



Urinary symptom assessments



Electrocardiogram (ECG) heart tests



Laboratory tests (blood and urine sample collections)



Cystoscopy (procedure to examine the bladder and urethra)



Bladder biopsy

Not all of these activities will occur at every visit.

What are my costs to take part in this study?

You will receive all study-related procedures, nadofaragene firadenovec, and chemotherapy or immunotherapy at no cost. Certain participants may also be eligible for compensation for study-related travel expenses.

What are the benefits and risks of being in this study?

There is no guarantee that this study will improve a person's health. However, participants will be helping others by contributing to medical research about high-grade NMIBC. The results of this study may make a difference in the future care of individuals with NMIBC. Any study has risks, which may include things that could make participants feel sick or uncomfortable. Participants may experience side effects related to nadofaragene firadenovec, chemotherapy, and immunotherapy while participating in the study. The study team will review potential risks with you before participation and during the study.

Can I decide not to be in the study?

Taking part in a clinical study is voluntary. If you are eligible to participate, you may choose to join the study but leave at a later date for any reason at any time. Regardless of whether you choose to participate or leave the study early, your future healthcare won't be affected.

How can I learn more about the ABLE-22 study?

For more information, please visit ABLEclinicalstudies.Ferring.com/able22/ or call our local study site at the number below. The study team can schedule a screening appointment to explain the study in detail.

Study site phone number:

