Thank you

for your interest in the ABLE-22 study for adults with high-grade NMIBC.

For more information,
please scan the QR code or contact:

[Study site contact information]

Alternatively, visit the study website at:
ABLEclinicalstudies.Ferring.com/able22/

FERRING PHARMACEUTICALS

ABLE-22

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IRB Approved at the
Protocol Level
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ABLE-22

Committed to hope. Dedicated to patient lives.

The future of bladder cancer research is here.

Ask your doctor if you are eligible for the ABLE-22 clinical research study.

What is a clinical study?

A clinical study is a research study involving volunteers (also called participants) that is intended to add to medical knowledge of a disease or condition, in this case, bladder cancer.

What is a study drug?

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

Why is the ABLE-22 study important?

Some people with high-grade non-muscle invasive bladder cancer (NMIBC) may not respond to available therapies such as Bacillus Calmette-Guerin (BCG) immunotherapy, a treatment that helps the immune system fight cancer.

This study is evaluating a study drug called nadofaragene firadenovec. Nadofaragene firadenovec is currently approved by the United States FDA under the tradename ADSTILADRIN® for the treatment of high-risk NMIBC that has not responded to BCG treatment. Clinical studies like this one aim to find new and better ways of preventing, diagnosing, and treating disease. Being part of discovering new health information may help others in the future.

What is the purpose of this study?

This study is evaluating 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.

Who can participate in the ABLE-22 study?

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 with you.

How long will this study last?

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

What can I expect if I decide to participate?

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

Arm 1:	Arm 2:	Arm 3:
will receive nadofaragene firadenovec	will receive nadofaragene firadenovec plus chemotherapy	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 the study visits. 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.

Laboratory tests, cystoscopy (procedure to examine the bladder and urethra), heart tests, bladder biopsies, and other assessments and questionnaires will be conducted as part of this study.

What are the 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 risks are involved for study participants?

There are possible risks involved with any clinical study. The research staff will review the risks with you, and you will be closely monitored by the research staff throughout the clinical study.

Why should I take part in this study?

Participation in a clinical study is voluntary. Clinical studies are important for medical advances. By participating in the study, you may:

- Be closely monitored through regular visits with your study doctor to check your condition
- Be a part of discovering new health information that may help others in the future