Committed to hope.
Dedicated to patient lives.

The future of bladder cancer research is here.

A quick reference guide for potential ABLE-32 study participants.

Thank you for your interest in the ABLE-32 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/able32/** or call the local study site at the end of this document.

What is the ABLE-32 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-Guérin (BCG) treatment. This study is evaluating the investigational study drug, nadofaragene firadenovec to find out how effective and tolerable it is in preventing intermediate risk NMIBC from returning after removal.

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-32 study important?

No treatments for intermediate risk, non-muscle invasive bladder cancer (NMIBC) are currently approved by the FDA or any other health authority.

Clinical studies like this one aim to find new and better ways of preventing, diagnosing, and treating the 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, your study doctor will first perform a transurethral resection of bladder tumor (TURBT) to remove the tissue from your bladder that could be cancer. After this procedure, you will be randomly assigned to 1 of the following groups (arms) during the study:

- **Arm 1:** receive nadofaragene firadenovec (study drug)
- **Arm 2:** observation (no study drug; standard treatment)

Arm 1 participants will receive the study drug once every 3 months at the clinic visits during the 2-year study treatment period unless the cancer returns. The study drug will be given directly into the bladder through a urinary catheter.

Arm 2 participants will come to the clinic twice every 3 months during the first 2 years and will be provided standard treatment. If you are in Arm 2 and if your cancer returns within the first 2 years, you will be given the option of receiving the study drug once every 3 months at clinic visits for up to 2 years.

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Who is this study enrolling?

To be eligible for this study, you must:

- Be at least 18 years of age
- Be diagnosed with intermediate risk 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 5 years, which includes a study treatment period (up to 2 years) and a follow-up period (3 years).

How will my health be checked in the ABLE-32 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 checked 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 and the study drug 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 intermediate risk 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 the study drug (if applicable) 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-32 study?

For more information, please visit **ABLEclinicalstudies.Ferring.com/able32/** 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:

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