October 20, 2026

Brian Mazzarella, MD
Urology Austin, PLLC

Dear Dr. Mazzarella,

SUBJECT: **INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION**

Sponsor:	Ferring Pharmaceuticals A/S
Protocol:	**000434 (ABLE-22),** Version 7.0, US and Canada, dated 01-23-2026
Title:	A phase 3, randomised, multi-centre, open-label trial to evaluate the safety and efficacy of intravesical nadofaragene firadenovec alone or in combination with chemotherapy (gemcitabine and docetaxel) or immunotherapy (pembrolizumab) in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC).

The WCG-administered Institutional Biosafety Committee (IBC) for Urology Austin, PLLC has reviewed this research and made the following determination:

Meeting Date:	**October 20, 2026**
Meeting Type:	**Continuing Review of Protocol and Site**
IBC Determination:	☒ **Approved** ☐ **Disapproved** ☐ **Conditionally Approved** ☐ **Tabled** Applicable Section of the NIH Guidelines: III-C-1
Approval Expiration Date:	**October 31, 2027**
Biosafety Level:	**BSL-2**
IBC Oversight Period:	**3 months after the last subject's final dose**

If you have changes to your research to submit, please complete an IBC Change in Research Form and submit the completed form to IBCServices@wcgclinical.com.

cc: Dawn Montoya, Urology Austin, PLLC
Emma Hebert, Urology Austin, PLLC
Christine Chau, Urology Austin, PLLC
Spencer Kalk, Syneos Health
Amanda Carver, Syneos Health
Kathryn Arnold, Syneos Health
Ionna Pritsiveli, Syneos Health
Emma Elison, Ferring Pharmaceuticals A/S
Study File

ALL IBC-APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Report the following site-specific information to the IBC within 5 days:
    a. Violations of the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines).
    b. New information bearing on the NIH Guidelines.
    c. Significant research-related accidents and/or illnesses.
    d. Research-related spills, exposures, and/or laboratory-acquired infections.
    e. Loss of containment.
    f. Suspension or termination of the study by the sponsor, investigator, or institution.
    g. Unresolved complaints related to biosafety.

2. Training:
    a. Be adequately trained in good microbiological techniques and IBC-approved standard operating procedures.
    b. Instruct and train the research staff in:
        i. The practices and techniques required to ensure safety;
        ii. The procedures for dealing with accidents, spills, and/or exposures.
    c. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested.

3. Safety:
    a. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed.
    b. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken.
    c. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
    d. Remain in communication with the IBC throughout the conduct of the project.

4. Accountability:
    a. Correct work errors and conditions that may result in the loss of containment of recombinant or synthetic nucleic acid molecules.
    b. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules.
    c. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
    d. Notify WCG IBC Services and obtain IBC approval before making any changes to the protocol, facilities, practices, and key study staff associated with the research.

The NIH Guidelines require that the IBC conduct periodic reviews of approved research. You will receive Continuing Review Report Forms from WCG IBC Services. These reports must be returned in a timely manner, even if research at your site has not yet begun.