

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 24, 2026
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: Urology Associates, P.C. - Nashville, Nashville, TN
Principal Investigator: Gautam Jayram, MD
Protocol: Ferring Pharmaceuticals A/S, 000434 (ABLE-22)
NCT Number: NCT06545955
Meeting Type: Continuing Review of Protocol and Site
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).

1. Call to order:

The Meeting was called to order at 10:02 am Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Three voting members were present, including one local member unaffiliated with the institution. Also present was IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative was not present to confirm that a notice of the meeting was publicly posted. The Committee recommended that the Institution confirm with IBC Services whether the public posting was made and if any comments or questions from the public were received. If the notice of the meeting was not publicly posted, the Committee recommended that it be publicly posted for one week from today and that any questions or comments received be forwarded to IBC Services.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 3 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for ADSTILADRIN (nadofaragene firadenovec), since it consists of a recombinant replication-defective adenoviral vector administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of ADSTILADRIN (nadofaragene firadenovec) locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

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9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3

NO: 0

ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee recommended that Site Inspection Checklist, Item #13 be revised to uncheck "N/A" for the use of safety needles.

11. Site requirements:

The Chair did not review training and communication requirements for maintaining IBC approval as an Institutional Representative was not present.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:09 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 7.0, US and Canada, dated 01-23-2026

Trial Supply Manual, Version 7.0, dated 02-2026

Prescribing Information, dated 03-2026

Research Modification Evaluation, Protocol, Version 6.0, US Sites

Research Modification Evaluation, Protocol, Version 7.0, US and Canada

Research Modification Evaluation, Trial Supply Manual, Version 5.0

Research Modification Evaluation), Trial Supply Manual, Version 7.0

Research Modification Evaluation, Prescribing Information, ADSTILADRIN

Biological Risk Assessment and Summary, updated 05-21-2026

Site Map, dated 07-31-2025

Site Inspection Checklist expires 07-10-2028

Photos, dated 07-31-2025

Biohazard Sign, ADSTILADRIN, dated 08-10-2025

SOP, Biosafety for ADSTILADRIN, dated 08-29-2025

Training, Shipping Certification, expires 03-03-2027

CRRF, dated 06-03-2026

Prior Meeting Minutes, Initial, dated 08-28-2025