

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 20, 2025
Time: 9:00 am Eastern Time
Location: Zoom Teleconference
Institution: Georgia Urology, Atlanta, GA
Principal Investigator: Daniel Canter, 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 9:04 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present was one Institutional Representative and 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:

The Institutional Representative could not confirm whether a notice of the meeting was publicly posted. The Committee recommended that the notice of the meeting 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: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair provided an overview of 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.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

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

Points of Discussion:

1. The Committee discussed how the site ensures compliance with the requirement that the study agent be administered within six hours of preparation. The Institutional Representative confirmed that, as a standard practice, study agents are not prepared until the subject has arrived on-site. The Committee recommended that the Institution confirm with IBC Services that this practice is also followed for this protocol.
2. The Committee recommended that a photo of the internal transport container be provided to IBC Services.
3. The Committee recommended that the Site Inspection Checklist be revised to indicate that special provisions or restrictions for entry are required.
4. The Institutional Representative confirmed that the main number on the Biohazard Sign is monitored 24/7. The Committee recommended that the sign be revised to reflect this.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:17 am Eastern Time.