INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, September 10, 2025**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Michigan Institute of Urology, PC, Troy, MI
Principal Investigator:	**Jason Hafron, 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 11:28 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 were three Institutional Representatives 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:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

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

10. Review of proposed facilities and practices:

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

Points of Discussion:

1. An Institutional Representative confirmed that the Biological Safety Cabinet (BSC) is scheduled for recertification on 09-17-2025.
2. The Committee recommended that the Institution submit the new BSC Certification document to IBC Services when it becomes available from the certifying company.
3. An Institutional Representative confirmed that a solidifier is not added to the biohazardous waste container. Instead, a urine bag used to collect the post-dosing bladder contents via a catheter. The urine bag is then placed in a biohazard-labeled sealable bag, which then disposed of into a hard-sided biohazardous waste container. The Committee recommended that Biosafety SOP Dosing section E.b be revised accordingly.

11. Site requirements:

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

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 11:33 am Eastern Time.