INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, February 18, 2026**
Time:	3:00 pm Central Time
Location:	Zoom Teleconference
Institution:	Accellacare of Duly, Lisle, IL
Principal Investigator:	**Amit R. Patel, 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 3:01 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five 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:

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: 5 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.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 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. The Committee recommended that photos of the biohazardous containers in the biohazardous waste storage area be provided to IBC Services.
2. The Committee recommended that a comment be added to Site Inspection Checklist (#13) to indicate that needles are not used.
3. The Committee recommended that a photo of the study storage unit, labelled with a biohazard symbol, be provided to IBC Services.
4. The Committee noted that “Biohazard” is not checked in the “Equipment Utilization” section of the Biological Safety Cabinet (BSC) certification. The Committee recommended that this be checked the next time that the BSCs are certified and that the institution follow up with IBC Services on this.
5. The Institutional Representative confirmed that subjects will remain in the dosing room for the post-dosing dwell time.
6. The Institutional Representative confirmed that the plumbed eyewash is located in the Pharmacy Gown Room and that disposable eyewash bottles are also available in the Pharmacy. The Committee recommended that site documents 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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:17 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 6.0, dated 08-27-2025
Trial Supply Manual, Version 5.0, dated 10-10-2025
Prescribing Information, ADSTILADRIN, dated 08-2024
Research Modification Evaluation, Protocol, Version 3.0
Research Modification Evaluation, Protocol, Version 4.0
Research Modification Evaluation, Protocol, Version 6.0
Research Modification Evaluation, Trial Supply Manual, Version 2.0
Research Modification Evaluation, Trial Supply Manual, Version 3.0
Research Modification Evaluation, Trial Supply Manual, Version 4.0
Research Modification Evaluation, Trial Supply Manual, Version 5.0
Research Modification Evaluation, Prescribing Information, ADSTILADRIN
Biological Risk Assessment and Summary, updated 01-14-2026
Site Map, dated 07-10-2025
Site Inspection Checklist, expires 06-26-2027, updated 02-05-2026
Photos, dated 02-12-2026
Biohazard Sign, dated 07-02-2025
Biohazard Sign for Bathroom, dated 07-02-2025
Biological Safety Cabinet Certification, dated 01-12-2026

SOP, Biosafety for ADSTILADRIN, dated 08-07-2025
Training, Shipping Certification, expires 01-30-2027
CRRF, received 10-15-2025
Prior Meeting Minutes, Initial, dated, 01-03-2025