INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, March 25, 2026**
Time:	9:00 am Central Time
Location:	Zoom Teleconference
Institution:	Urology Center of Iowa Research, Clive, IA
Principal Investigator:	**Brian Gallagher, MD**
Protocol:	Ferring Pharmaceuticals A/S, **000423 (ABLE-32)**
NCT Number:	NCT06510374
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 3b, Randomised, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk (IR) Non-Muscle Invasive Bladder Cancer (NMIBC)

1. Call to order:

The Meeting was called to order at 9:00 am 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:

The 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee 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 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.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 eye protection be used instead of, or in addition to, face shields since face shields will not provide complete eye protection and that site documents be revised accordingly.
2. The Committee recommended that Biosafety SOP Section 3.2 be revised to list eye protection and face shields separately.
3. The Committee recommended that Biosafety SOP Section 3.5.2 be revised to include details related to the terminal cleaning procedures used after a subject voids into the toilet (decontaminating the toilet and any high touch points, flushing with the lid down, etc.).
4. The Institutional Representative confirmed that the hard-sided biohazardous waste container in the preparation room is located near the countertop where the study agent is prepared. The Committee recommended that an updated photo, showing the location of the biohazardous waste container in relation to the countertop preparation area, be provided to IBC Services.
5. The Institutional Representative confirmed that access to the restroom where the subject voids after dosing is restricted to all other people until the subject has completed voiding and the restroom has been terminally cleaned.
6. The Institutional Representative confirmed that the wet contact for CaviWipes was extended to 5 minutes for decontaminating face shields.
7. The Institutional Representative confirmed that the study agent storage freezer is plugged into a regular outlet but that the temperature is monitored and study staff are alerted if it goes out of range.
8. The Institutional Representative confirmed that if the freezer temperature goes out of range, the study agent will be placed on dry ice until it can be properly stored in a freezer.

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 9:16 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 6.0, dated 06-16-2025
Clinical Trial Supply Manual, Version 3.0, dated 03-2025
Prescribing Information, ADSTILADRIN, dated 08-2024
Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024
Biological Risk Assessment and Summary, updated 11-17-2025
Site Map, dated 02-18-2026
Site Inspection Checklist, expires 02-23-2028
Photos, dated 02-24-2026
Biohazard Sign, ADSTILADRIN, dated 02-18-2026
SOP, Biosafety for ADSTILADRIN, dated 02-18-2026
Training, Shipping Certification, expires 2026
CV, Gallagher, B., signed 09-24-2025