INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 26, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Lakeland Regional Health - Hollis Cancer Center, Lakeland, FL
Principal Investigator:	**Peter Hinds, 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 11:00 am Eastern 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 were two 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. 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: 3 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. An Institutional Representative confirmed that the subject's bladder will be drained via a catheter into a catheter bag after dosing and that the contents of the bag will be decontaminated by adding to a container containing 8 mL of household bleach. The Committee discussed that the catheter bag could be disposed of directly into a leak-proof biohazardous waste container but determined that bleaching the contents of the catheter bag was also acceptable. The Committee recommended that Biosafety SOP Section 3.5.1 be revised to accurately reflect how the voided bladder contents will be handled.
2. An Institutional Representative confirmed that the subject bathroom, located in the patient waiting area, will be restricted for use until after the voided bladder contents have been decontaminated with bleach for the required 15-minute dwell time.
3. The Committee recommended that the black hazardous containers in the Pharmacy be labeled with a biohazard symbol if they are used for disposal of biohazardous waste. The Committee discussed that the yellow, biohazard-labeled, chemotherapy waste containers or a red biohazardous waste container could be used for disposal of biohazardous waste.
4. The Committee recommended that an overall room photo of the interior of the biohazardous waste storage room be provided to IBC Services.
5. An Institutional Representative confirmed that the water jug, as shown in the Dosing Room photo, will be removed from the room, and that disinfecting wipes are available in the room.

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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:16 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 6.0, dated 06-16-2025
Clinical Trial Supply Manual, Version 4.0, dated 03-2026
Prescribing Information, dated 03-2026
Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024
Biological Risk Assessment and Summary, updated 05-21-2026
Site Map, dated 05-12-2026
Site Inspection Checklist, expires 04-09-2028
Photos, dated 04-28-2026
Biohazard Sign, ADSTILADRIN, dated 05-11-2026
Biological Safety Cabinet Certification, expires 08-2026
SOP, Biosafety for ADSTILADRIN, dated 05-12-2026
Training, Shipping Certifications, expire 12-09-2026, 09-17-2027
CV, Hinds, P., signed 06-21-2024