INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, July 18, 2025**
Time:	11:00 am Central Time
Location:	Zoom Teleconference
Institution:	Blessing Corporate Services, Inc, Quincy, IL
Principal Investigator:	**David Lieber, 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 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 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: 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 pre-filled disposable eyewash bottles be made available in the dosing room for immediate triage in the event of an exposure.
2. An Institutional Representative confirmed that Stericycle provides black containers for biohazardous waste. The Committee recommended that a biohazard symbol be placed on the biohazardous waste bins if they don't already contain one.
3. An Institutional Representative confirmed that needles are not used for preparation, but that a sharps container is available immediately outside of the biosafety cabinet (BSC).
4. The Committee noted that the BSC certification will expire in September. An Institutional Representative stated that the institution contracts with an external company to recertify BSCs every 6 months.
5. An Institutional Representative confirmed that the restroom used for disposal of bleached bladder contents is located next to the dosing room. The Committee found this to be acceptable.
6. An Institutional Representative confirmed that study agent instillation will be done using a catheter as described in prescribing information for ADSTILADRIN.
7. The Committee noted that a 10% solution of household bleach with a 15-minute dwell time is suitable to inactivate adenoviral vectors.
8. An Institutional Representative confirmed that MSDS references in Biosafety SOP Section 5.1 refer to the cleaning agents (i.e. bleach).
9. An Institutional Representative confirmed that subject assignments are not blinded, as the study includes an active arm and an observation-only control arm.
10. An Institutional Representative stated that staff with personal concerns about handling the study agent may self-identify and receive necessary accommodations per Institutional policy.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:34 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 5.0, dated 02-27-2025
Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024
Clinical Trial Supply Manual, Version 2.0, dated 09-26-2024
Prescribing Information, ADSTILADRIN, dated 08-2024
Biological Risk Assessment and Summary, updated 04-18-2025
Site Maps, dated 06-26-2025
Site Inspection Checklist, expires 06-19-2027
Photos, dated 06-26-2025
Biohazard Sign, dated 06-19-2025

Biological Safety Cabinet Certification, expires 09-2025
SOP, Biosafety for ADSTILADRIN, dated 06-26-2025
Training, Shipping Certification, expires 02-11-2027
CV, Lieber, D., signed 09-26-2023