INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, May 1, 2026**
Time:	11:00 am Central Time
Location:	Zoom Teleconference
Institution:	The Conrad Pearson Clinic, PC, Germantown, TN
Principal Investigator:	**Ravi Chauhan, MD**
Protocol:	Ferring Pharmaceuticals A/S, **000434 (ABLE-22)**
NCT Number:	NCT06545955
Meeting Type:	Initial 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 11:22 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 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. 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. An Institutional Representative confirmed that the plumbed eyewash station in the Nurse's Station Room is within a 10 second walk of all dosing rooms.
2. The Committee recommended that the Institution purchase prefilled disposable eyewash bottles designed for specifically flushing eyes in the event of an eye exposure. These bottles typically come in volumes of 16 or 32 ounces. An Institutional Representative agreed to this arrangement.
3. An Institutional Representative confirmed that after an instillation, the contents of the bladder may be removed via a catheter into a container or the subject may void the contents of their bladder directly into a urinal container.
4. An Institutional Representative confirmed that the two types of containers have lids which seal and that these are the discarded into the biohazardous waste stream.
5. The Committee recommended that Biosafety SOP Section 3.5.2 be revised to indicate that bleach will be added to the urinal container after voiding to prevent splashes of the bleach onto skin.
6. The Committee recommended that Biosafety SOP Section 3.5.2 be revised to indicate that the containers will be sealed with a lid and then disposed of into the biohazardous waste stream.

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 11:26 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 7.0, US and Canada, dated 01-23-2026
Prescribing Information, ADSTILADRIN, dated 08-2024
Trial Supply Manual, Version 7.0, dated 02-2026
Biological Risk Assessment and Summary, updated 04-17-2026
Site Map, dated 02-25-2026
Site Inspection Checklist, expires 03-12-2028
Photos, dated 02-25-2026
Biohazard Sign, ADSTILADRIN, dated 02-25-2026
SOP, Biosafety for ADSTILADRIN, dated 02-25-2026
Training, Shipping Certification, expires 09-16-2027
CV, Chauhan, R., signed 02-25-2026