

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, August 28, 2025
Time: 12:00 pm Central Time
Location: Zoom Teleconference
Institution: Urology Associates, P.C., Nashville, TN
Principal Investigator: Gautam T. Jayram, 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 12:02 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four 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: 4

NO: 0

ABSTAIN: 0

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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 Biosafety SOP Section 3.5 be revised to indicate that access to the bathroom where the subject voids will be restricted during the 15-minute bleach dwell time and until the bathroom has been terminally cleaned.
2. The Committee recommended that the bleach dwell time in Biosafety SOP Section 3.6.2 be changed to 15 minutes to match the dwell time listed in Biosafety SOP Section 3.5.
3. The Committee recommended that the Biosafety SOP be revised to remove all references to CaviCide for decontamination and spill clean-up since it is not effective against non-enveloped viruses. An Institutional Representative confirmed that Clorox Clean Up with Bleach would be used for these activities.
4. The Committee recommended that Site Inspection Checklist, Item 13 be revised to remove the comment regarding the closed [REDACTED] Protocol.
5. An Institutional Representative confirmed that the plumbed eyewash station is flushed weekly and that a log of this action is maintained.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:14 pm Central Time.