

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Monday, November 24, 2025**
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: CAMC Institute for Academic Medicine, Charleston, WV
Principal Investigator: **Michael Stencel, DO**
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 12:01 pm Eastern 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 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: 3

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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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 stated that both safety and non-safety needles are available for use onsite. The Committee found this to be acceptable.
2. An Institutional Representative stated that there is one plumbed eyewash onsite, and it is not located in the preparation or dosing rooms. The Committee recommended that disposable eyewash bottles be purchased for the preparation and dosing rooms and that site documents be revised to indicate this.
3. An Institutional Representative confirmed that the refrigerator in the [REDACTED] will not be used to store the study agent. The Committee recommended that the photo of the refrigerator be removed from the site photos.
4. The Committee recommended that a biohazard sign be posted at the entrance to all areas where the study agent is handled and that photos of the posted signage be provided to IBC Services.
5. The Committee recommended that all biohazardous waste containers be lidded when not in use.
6. The Committee recommended that a small sharps container be placed inside the Biological Safety Cabinet (BSC) and that site documents be revised to reflect this.

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 12:19 pm Eastern Time.