

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, December 30, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Southeastern Regional Medical Center, Inc. dba City of Hope Atlanta, Newnan, GA
Principal Investigator: Farhang Rabbani, MD
Protocol: Ferring Pharmaceuticals A/S, 000423 (ABLE-32)
NCT Number: NCT06510374
Meeting Type: Continuing 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 10:19 am Eastern 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 seven 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously 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 reaffirmed this determination.

The Committee previously 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. The Committee reaffirmed this determination.

9. 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

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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. The Committee noted that the biological safety cabinets (BSCs) were due to be recertified in November per the 6-month expiration date listed on the certification reports. An Institutional Representative could not confirm whether the BSCs are certified on a 6-month or 12-month schedule.
2. The Committee recommended that the Institution confirm whether the BSCs are certified on a 6-month or 12-month schedule and provide current certification reports to IBC Services when they are available.
3. The Committee recommended that site documents be revised to indicate that the BSCs have been certified within the last 12 months.
4. The Committee recommended that the Biohazard Sign be revised to include the 24/7 Inpatient Pharmacy phone number as an alternate phone number.
5. An Institutional Representative confirmed that prefilled disposable eyewash bottles will be available in the dosing rooms. The Committee recommended that site documents be revised to reflect this.
6. An Institutional Representative confirmed that red biohazardous waste containers are used for the disposal of used PPE and other non-sharp items and that yellow waste containers are used to dispose of chemotherapy waste.
7. An Institutional Representative confirmed that a photo of the contents of the Chemo Spill Kit had been provided to IBC Services and indicated that it would be re-sent since the photo was not included in the current site documents.

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

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 10:23 am Eastern Time.