

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, July 14, 2025
Time: 11:00 am Central Time
Location: Zoom Teleconference
Institution: Urology Associates of Mobile, Mobile, AL
Principal Investigator: Charles White, 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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 sharps containers be either placed in stabilizers or attached to the wall.
2. The Committee noted that hydrogen peroxide and bleach solution are both listed as disinfecting agents for work surfaces on the Site Inspection Checklist (#19). An Institutional Representative stated that only Caviwipes¹ or Caviwipes will be used. The Committee recommended that site documents be revised accordingly to reflect this.
3. The Committee noted that the sponsor documents reference “universal precautions,” but “standard precautions” is the more widely used term.
4. An Institutional Representative stated that the study agent storage freezer is labeled with a biohazard symbol. The Committee recommended that a new photo of the freezer, showing the biohazard symbol, be provided to IBC Services.
5. An Institutional Representative confirmed that the Principal Investigator will administer the study agent and that study staff will prepare the study agent.
6. An Institutional Representative confirmed that prefilled disposable eyewash bottles are now available in the dosing room. The Committee recommended that site documents be revised accordingly 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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:15 am Central Time.