INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, November 4, 2025**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	WakeMed, Raleigh, NC
Principal Investigator:	**Matthew D. Lyons, MD, FACS**
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 1:59 pm 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 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.

Point of Discussion:

1. An Institutional Representative confirmed that the Principal Investigator (PI) has previous clinical research experience. The Committee recommended that an updated CV, or an addendum to the CV, that lists the PI's clinical research experience be provided to IBC Services.

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 5.2.4 be revised to indicate that the affected eye is rinsed thoroughly, for up to 15 minutes.
2. An Institutional Representative confirmed that the biohazardous waste containers noted in the Photos document as being blue are black in color and are used for disposal of drugs that require destruction. The Committee recommended that the containers be labeled with a biohazard symbol if they are used for disposal of the study agent.
3. An Institutional Representative confirmed that the [redacted] phone number listed on the Biohazard Sign is monitored 24/7. The Committee recommended that the sign be revised to reflect this.
4. The Committee recommended that the Biohazard Sign be printed on red or orange colored paper, per best biosafety practices.
5. An Institutional Representative confirmed that a sharps container is located inside the biological safety cabinet for immediate disposable of used study agent vials and vented vial adapters.
6. The Committee noted that vented vial adapters, rather than needles, are used for study agent preparation.
7. The Committee noted that face shields used when handling the study agent could be disposed of as biohazardous waste rather than in the yellow chemotherapy waste bins as it would be more cost-effective.
8. An Institutional Representative confirmed that the cardboard biohazardous waste boxes are lined with a thick red plastic bag and are the standard container supplied by the licensed biohazardous waste hauler. The Committee determined this to be acceptable.
9. An Institutional Representative confirmed that the gray trash can in the biohazardous waste storage area is used for regular trash

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 2:20 pm Eastern Time.