INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, November 14, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Great Lakes Physicians PC dba Western New York Urology Associates, Cheektowaga, NY
Principal Investigator:	**John Rutkowski, 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 10:00 am 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 one local member unaffiliated with the institution. Also present was one Institutional Representative 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:

The 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: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair provided an overview of 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: 4 NO: 0 ABSTAIN: 0

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 Institutional Representative confirmed that a catheter will be used to drain the contents of the bladder into a container, and subjects will only void into toilet after the bladder is drained if necessary. The Committee recommended that Biosafety SOP Section 3.5 be revised accordingly.
2. The Committee discussed that Site Inspection Checklist, Items #4-9 were missing from the Site Inspection Checklist, expires 10-14-2027. The Institutional Representative confirmed that the answers to Items #4-9 in Site Inspection Checklist, dated 08-08-2024, and reviewed by the Committee last year remain accurate.
3. The Committee recommended that Site Inspection Checklist, expires 10-14-2027 be revised to include Items #4-9 using the information from Site Inspection Checklist, dated 08-08-2024.
4. The Institutional Representative confirmed that the Site Map accurately depicts the two dosing rooms and that these are two separate rooms, each with a door that closes and a sink for handwashing.
5. The Committee recommended that photos of each dosing room be provided to IBC Services.
6. The Committee recommended that Slide #3 in the Photos document be deleted as the sink shown is not located in the storage room.
7. The Committee recommended that a photo of the entrance door to the storage room, labeled with a biohazard symbol, be provided to IBC Services.
8. The Institutional Representative confirmed that prefilled disposable eyewash bottles are available in the preparation and dosing rooms.
9. The Institutional Representative confirmed that no subjects have been enrolled in the study.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 10:12 am Eastern Time.