INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, May 26, 2026**
Time:	10:00 am Central Time
Location:	Zoom Teleconference
Institution:	The Urology Center, PC, dba UroHealth Partners, Omaha, NE
Principal Investigator:	**Andrew Trainer, MD, FACS, CPI**
Protocol:	Ferring Pharmaceuticals A/S, **000425 (LUNAR)**
NCT Number:	NCT06668493
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2, Single-arm, Open-Label Trial to Evaluate the Safety and Efficacy of Nadofaragene Firadenovec Instilled to the Renal Pelvis in Adult Subjects with Low-grade Upper Tract Urothelial Carcinoma (LG-UTUC)

1. Call to order:

The Meeting was called to order at 10:12 am Central 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 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: 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 staff members use hand sanitizer prior to exiting the dosing room and then wash their hands in the closest available sink. The Committee recommended that Site Inspection Checklist Item 21 be revised to indicate “Yes”.
2. An Institutional Representative confirmed that a lipped tray has been placed under the cardboard biohazardous waste box in the biohazardous waste storage room. The Committee recommended that the Photos document be updated to reflect this.
3. The Committee recommended that sharps and non-sharps waste be segregated to reduce the likelihood of needlesticks, and that a photo of the non-sharps waste container be provided to IBC Services.
4. The Committee noted that bleach should not be stored underneath sinks since closed contains of bleach can still emit off-gases which will over time erode metal plumbing.
5. The Committee noted that staff members should not exit the dosing room without removing personal protective equipment per Infection Prevention regulations.

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 10:20 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 08-25-2025
Investigator's Brochure, Edition 1.0, dated 05-29-2024
Trial Supply Manual, Version 1.0, dated 07-08-2024
Research Modification Evaluation, Protocol, Version 4.0
Biological Risk Assessment and Summary, updated 01-26-2026
Site Maps, dated 04-15-2026
Site Inspection Checklist, expires 02-10-2027, updated 05-01-2026
Photos, dated 04-15-2026
Biohazard Sign, ADSTILADRIN, dated 04-22-2024
SOP Biosafety for ADSTILADRIN, dated 04-15-2026
Training, Shipping Certification, expires 04-28-2027
CRRF, dated 03-02-2026
Prior Meeting Minutes, Initial, dated 06-27-2025