INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 27, 2025**
Time:	12:00 pm Central Time
Location:	Zoom Teleconference
Institution:	Adult & Pediatric Urology, PC, Omaha, NE
Principal Investigator:	**Andrew Trainer, MD, FACS, CPI**
Protocol:	Ferring Pharmaceuticals A/S, **000425 (LUNAR)**
NCT Number:	NCT06668493
Meeting Type:	Initial 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 12:00 pm 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. 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: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 wash their hands with soap and water before exiting rooms with sinks, and use hand sanitizer before exiting rooms without sinks before proceeding to the nearest sink to wash with soap and water. The Committee recommended that the Site Inspection Checklist (#21) be revised accordingly.
2. The Committee recommended that a leak-proof tray be placed underneath cardboard biohazardous waste containers, and that a photo be sent to IBC Services when this has been done.
3. The Institutional Representative stated that both sharps and non-sharps waste go into the same container depicted in a site photo. 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 recommended that disposable eyewash bottles be kept away from sinks to minimize cross-contamination risks, and that a photo be provided to IBC Services when this has been done.
5. The Institutional Representative confirmed that if the dosing solution is drained into a syringe using a catheter after the required dwell time, the syringe would be disposed of as biohazardous waste.
6. The Institutional Representative confirmed that nothing is stored underneath operating tables.
7. The Institutional Representative confirmed that the study agent is prepared in the lab and is then taken to the dosing room via the route depicted on the Site Map.
8. The Institutional Representative confirmed that subjects are isolated in a post-op room dosing during the 30 minutes dwell time and that a Biohazard Sign will be placed on the door when the subject is inside.
9. The Institutional Representative noted that the plumbed eyewash station is located outside of the dosing rooms and is accessible to all persons.
10. The Institutional Representative confirmed that work surfaces are decontaminated with Super Sani-Cloth wipes, and that the reference to household bleach on the Site Inspection Checklist pertains to procedures from another study covered by the checklist.

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 12:35 pm Central Time.