

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, September 4, 2025
Time: 11:00 am Pacific Time
Location: Zoom Teleconference
Institution: Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator: Jennifer Linehan, MD
Protocol: [REDACTED] 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 11:00 am Pacific 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 were five 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: 4

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that the Sponsor recently approved the use of closed system transfer devices (CSTDs) for study agent preparation, which will be used instead of the vented vial adapters. The Committee recommended that Biosafety SOP Section 3.3 be revised accordingly.
2. An Institutional Representative confirmed that a private bathroom is available for subject use if they need to void after the study agent is withdrawn from the renal pelvis and that access to the bathroom is restricted until the subject leaves and it has been terminally cleaned. The Committee recommended that Biosafety SOP Section 3.5 be revised to include this information.
3. An Institutional Representative confirmed that subjects will be provided with post-dosing instructions to avoid the use of public restrooms for 2 days post-dosing. The Committee recommended that Biosafety SOP Section 3.5 be revised to include this information.
4. The Committee recommended that Biosafety SOP Sections 3.6.1, 3.6.2 and 5.1.4.i be revised with a wet contact of 3 minutes for Peridox RTU.
5. The Committee recommended that Biosafety SOP Section 5.1.4.i be revised to remove "overlay the spill with one of the following".
6. The Committee noted that the Instructions for Use for Peridox RTU indicate that wipes should be used and recommended that the site contacts the manufacturer to confirm that paper towels are acceptable.
7. The Committee noted that IATA/DOT Shipping Training Certification will expire in November 2025 and recommended that the training be renewed prior to the expiration date and an updated certificate be provided to IBC Services.
8. An Institutional Representative confirmed that the yellow sharps container in the preparation room is used for disposal of used personal protective equipment (PPE) and sharps, and the black hazardous waste container is used for bulk waste. The Committee recommended that the Photos document be updated to reflect this.
9. An Institutional Representative confirmed that disposable eye protection is primarily used but that reusable eye protection is available as a back-up.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:19 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 2.0, dated 05-31-2024

Investigator's Brochure, Edition 1.0, dated 05-29-2024

Trial Supply Manual, Version 1.0, dated 07-08-2024

Biological Risk Assessment and Summary, dated 11-05-2024

Site Map, Saint John's Cancer Institute, 4th Floor Inpatient, dated 08-24-2025

Site Map, Pharmacy, Waste, Basement, dated 08-12-2024

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Site Map, Cancer Center Clinic, Infusion Center, basement, dated 03-26-2025

Site Inspection Checklist, expires 08-06-2026, updated 08-13-2025

Photos, dated 08-25-2025

Biohazard Sign, ADSTILADRIN dated 08-21-2025

Biological Safety Cabinet Certification, dated 07-24-2025

SOP, Biosafety for ADSTILADRIN, dated 08-25-2025

Training, Shipping Certification, expires 11-06-2025

CV, Linehan, J., signed 05-14-2024