INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, September 23, 2026**
Time:	8:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Saint John's Cancer Institute, Santa Monica, CA
Principal Investigator:	**Jennifer Linehan, MD**
Protocol:	[redacted], **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 8:09 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, the Principal Investigator, 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. 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.

Point of Discussion:

1. An Institutional Representative confirmed that the study agent is typically prepared on the countertop in one of the Operating Rooms rather than inside a biological safety cabinet in the Vaccine Room, as the required dose volume is determined immediately prior to administration.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and 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 8:14 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 6.0, dated 05-19-2026
Investigator's Brochure, Edition 2, UTUC, dated 04-24-2026
Trial Supply Manual, Version 6.0, dated 03-2026
Research Modification Evaluation, Protocol, Version 4.0
Research Modification Evaluation, Protocol, Version 6.0
Research Modification Evaluation, Investigator's Brochure, Edition 2, UTUC
Research Modification Evaluation, Trial Supply Manual, Version 2.0
Research Modification Evaluation, Trial Supply Manual, Version 3.0
Research Modification Evaluation, Trial Supply Manual, Version 4.0
Research Modification Evaluation, Trial Supply Manual, Version 5.0
Research Modification Evaluation, Trial Supply Manual, Version 6.0
Biological Risk Assessment and Summary, updated 09-08-2026
Research Modification Evaluation, Site location Changes, dated 03-27-2026
Site Map, Main Pharmacy, Vaccine Rm, BHW, Basement, dated 02-25-2026
Site Map, ORs 2nd floor, dated 03-27-2026
Site Inspection Checklist, expires 07-20-2028
Photos, Biohazardous Waste, all protocols, dated 09-14-2026
Photos, ORs x2, 2nd floor, dated 03-27-2026
Photos, Main Pharm, Vacc. Rm, Satellite Pharm, dated 09-14-2026
Biohazard Sign, ADSTILADRIN dated 08-21-2025
Biological Safety Cabinet Certification, expires 12-2026
SOP, Biosafety for ADSTILADRIN, dated 03-27-2026
Training, Shipping Certification, expires 12-09-2027
CRRF, dated 06-22-2026
Prior Meeting Minutes, Initial, dated 09-04-2025