

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] 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 8:00 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, 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

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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 an automatic paper towel dispenser is located near the sink in the Procedure Room.

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 8:09 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.0, dated 06-16-2025

Investigator's Brochure, Edition 3, NMIBC, dated 03-06-2026

Clinical Trial Supply Manual, Version 4.0, dated 03-2026

Prescribing Information, dated 03-2026

Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024

Research Modification Evaluation, Investigator's Brochure, Edition 2, NMIBC

Research Modification Evaluation, Investigator's Brochure, Edition 3, NMIBC

Research Modification Evaluation, Clinical Trial Supply Manual, Version 3.0

Research Modification Evaluation, Clinical Trial Supply Manual, Version 4.0

Research Modification Evaluation, Prescribing Information, dated 03-2026

Biological Risk Assessment and Summary, updated 08-18-2026

Site Map, Main Pharmacy, Vaccine Rm, BHW, Basement, dated 02-25-2026

Site Map, Cancer Center Clinic, Infusion Center, Basement, dated 02-25-2026

Site Inspection Checklist, expires 07-20-2028

Photos, Biohazardous Waste, all protocols, dated 09-14-2026

Photos, Procedure Rm, Cancer Ctr; Dosing Rm, Infusion Ctr, Basement, dated 09-14-2026

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 08-04-2026

Prior Meeting Minutes, Initial, dated 11-05-2025