INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, November 5, 2025**
Time:	9:00 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:	Initial 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 9:00 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 three 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.

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 Committee recommended that Biosafety SOP Section 3.5.2 be revised to indicate that if the subject voids in the private bathroom after the study agent is withdrawn from the bladder, the urine will be decontaminated with bleach, with a 15-minute dwell time, as part of the terminal cleaning.
2. The Committee recommended that Biosafety SOP Section 3.5.2 be revised to indicate that subjects should add 4 oz of household bleach to the toilet bowl after urinating, rather than before urinating.
3. An Institutional Representative confirmed that plumbed eyewash stations are flushed weekly.
4. An Institutional Representative confirmed that the study agent would primarily be prepared in the biological safety cabinet, but study staff also wanted the option to prepare it on a countertop in the dosing room.

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 9:12 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 6.0, dated 06-16-2025
Clinical Trial Supply Manual, Version 2.0, dated 09-26-2024
Prescribing Information, ADSTILADRIN, dated 08-2024
Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024
Biological Risk Assessment and Summary, updated 07-29-2025
Site Map, Cancer Center Clinic, Infusion Center, basement, dated 10-24-2025
Site Map, Pharmacy, Waste, Basement, dated 08-12-2024
Site Inspection Checklist, expires 08-06-2026, updated 10-21-2025
Photos, dated 10-22-2025
Biohazard Sign, ADSTILADRIN dated 08-21-2025
Biological Safety Cabinet Certification, dated 07-24-2025
SOP, Biosafety for ADSTILADRIN, dated 10-29-2025
Training, Shipping Certification, expires 04-16-2026
CV, Linehan, J., signed 05-14-2024