INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Friday, August 28, 2026** |
| **Time:** | 9:00 am Eastern Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Hackensack Meridian Health, Hackensack, NJ |
| **Principal Investigator:** | **Nitin Yerram, MD** |
| **Protocol:** | Hackensack Meridian Health, **NATIVE Trial** |
| **NCT Number:** | N/A |
| **Meeting Type:** | Initial Review of Protocol and Site |
| **Title:** | A Pilot Study of Nadofaragene Firadenovec-vncg in Treatment-Naive Patients with Newly Diagnosed High-Risk Non-Muscle Invasive Bladder Cancer (NATIVE Trial) |

**1. Call to order:**

The Meeting was called to order at 9:10 am Eastern Time.

**2. Introductions and orientation:**

Introductions were made and the Chair oriented members to the meeting procedures.

**3. Declaration of quorum:**

Six voting members were present, including two local members unaffiliated with the institution, and the Institution's Biosafety Officer. 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:**

The Biosafety Officer 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: 6 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 Biosafety SOP Section 3.3. be revised to include that study agent vials will be thawed prior to preparation.
2. The Committee discussed that Biosafety SOP Section 3.5.1 indicates that subjects will be instructed to void at home after dosing and noted that there is likely to be a high concentration of study agent in the initial bladder void. The Committee recommended that after dosing, the subject's bladder contents be drained via catheter into a container containing bleach or that subjects void into a toilet in the clinic containing bleach and that the bladder contents in the container or toilet are allowed to sit for 15 minutes prior to discarding or flushing. The Committee recommended Biosafety SOP Section 3.5.1. be revised accordingly.
3. The Committee noted that the biological safety cabinet (BSC) certifications are due for recertification next month (September 2026).

**11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer Institutional Representatives.

**12. Vote on the Site:**

The Committee voted for the following determination on the Site:

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|---|---|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 6 NO: 0 ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 9:17 am Eastern Time.

**15. Post-meeting notes:** None.

**Documents reviewed:**
Agenda
Protocol, Version 1.0, dated 06-04-2026
Investigator's Brochure, Edition 3, dated 03-06-2026
Prescribing Information, dated 03-2026
Storage and Stability Requirements, dated 05-01-2026
Biological Risk Assessment and Summary, dated 06-23-2026
Site Map, 360 Essex St, dated 11-18-2025
Site Map, Cancer Center Pharmacy, dated 04-16-2025
Site Map, Cancer Center Loading Dock, dated 01-19-2022
Site Inspection Checklist, 360 Essex Street, expires 11-08-2027, updated 06-03-2026
Site Inspection Checklist, JTCC Cancer Center, expires 04-15-2027, updated 08-19-2026
Biohazard Sign, Yerram, ADSTILADRIN, dated 08-19-2026
Biological Safety Cabinet Certifications, JTCC Pharmacy, expire 09-2026
Biosafety Guidelines, Biosafety for ADSTILADRIN, dated 08-19-2026
Training, Shipping Certifications, expire 10-2026, 11-2026, 12-2026, 2027
CV, Yerram, N., signed 05-23-2024