INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Thursday, September 10, 2026** |
| **Time:** | 10:00 am Central Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Southern Urology, LLC, Lafayette, LA |
| **Principal Investigator:** | **Jason Bourque, MD** |
| **Protocol:** | Ferring Pharmaceuticals A/S, **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 10:02 am Central 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.

**Point of Discussion:**

1. An Institutional Representative stated that study agent vials are thawed at room temperature. The Committee recommended that Biosafety SOP Section 3.3 be revised to reflect this.

**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 10:12 am Central 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
Prescribing Information, dated 03-2026
Clinical Trial Supply Manual, Version 4.0, dated 03-2026
Supporting Information to ADSTILADRIN Prescribing Information, dated 03-01-2024
Biological Risk Assessment and Summary, updated 08-18-2026
Site Maps, dated 08-11-2026
Site Inspection Checklist, expires 08-26-2028
Photos, dated 08-10-2026
Biohazard Sign, ADSTILADRIN, dated 08-27-2026
SOP, Biosafety for ADSTILADRIN, dated 08-27-2026
Training, Shipping Certifications, expire 06-2027, 04-2028, 06-2028
CV, Bourque, J., signed 06-15-2026