

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, March 26, 2026
Time: 12:00 pm Central Time
Location: Zoom Teleconference
Institution: Urology Austin, PLLC, Austin, TX
Principal Investigator: Brian Mazzearella, 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 12:01 pm Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present was one Institutional Representative 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 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 of 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: 5

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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 plumbed eyewash stations be flushed weekly and that a log of this action be maintained.
2. The Institutional Representative confirmed that the study agent-specific Biohazard Sign is posted on the dosing room doors during subject dosing.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:11 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.0, dated 06-16-2025

Clinical Trial Supply Manual, Version 3.0, dated 03-2025

Prescribing Information, ADSTILADRIN, dated 08-2024

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

Biological Risk Assessment and Summary, updated 11-17-2025

Site Map, Radam, dated 10-21-2025

Site Map, Atrium, dated 10-21-2025

Site Inspection Checklist, Radam, expires 12-01-2026, updated 02-26-2026

Site Inspection Checklist, Atrium, expires 12-01-2026, updated 02-26-2026

Photos, Radam, dated 01-15-2025

Photos, Atrium, dated 01-16-2025

Biohazard Sign, ADSTILADRIN, Radam, dated 09-19-2025

Biohazard Sign, ADSTILADRIN, Atrium, dated 09-19-2025

SOP, Biosafety for ADSTILADRIN, Radam, dated 02-26-2026

SOP, Biosafety for ADSTILADRIN, Atrium, dated 02-26-2026

Training, Shipping Certification, expires 08-25-2027

CV, Mazarella, B., signed 04-04-2024