

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, May 11, 2026
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: McGill University Health Centre, Montreal, Quebec
Principal Investigator: Wassim Kassouf, MD, CM, FRCSC
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 2:00 pm Eastern 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.

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices. The Committee did not have any comments or questions on the proposed facilities and practices.

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 2:07 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 6.0, dated 06-16-2025

Prescribing Information, ADSTILADRIN, dated 08-2024

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

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

Biological Risk Assessment and Summary, updated 04-17-2026

Site Map, Onc. Pharm., D01.1618, dated 03-16-2026

Site Map, 4th floor C04.35, dated 03-16-2026

Site Map, Biohazardous Waste Storage, dated 03-16-2026

Site Inspection Checklist, McGill University Health Centre, expires 08-13-2026, updated 05-04-2026

Photos, Oncology Pharmacy, D01.1618, dated 03-12-2026

Photos, 4th floor C04.35 and Waste, dated 05-05-2026

Biohazard Sign, ABLE, dated 04-01-2026

SOP, Biosafety for ADSTILADRIN, dated 05-05-2026

Training, Shipping Certifications, ABLE studies, expire 09-24-2027, 07-14-2027

CV, Kassouf, W., signed 03-12-2026