

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 1, 2026  
**Time:** 12:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Wichita Urology Group, Wichita, KS  
**Principal Investigator:** Philippe Nabbout, MD  
**Protocol:** Ferring Pharmaceuticals A/S, 000423 (ABLE-32)  
**NCT Number:** NCT06510374  
**Meeting Type:** Continuing 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 12:03 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 were 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 was not present to confirm that notice of the meeting was publicly posted. The Committee recommended that the Institution confirm with IBC Services if notice of this meeting was publicly posted and to forward any comments from the public regarding this review.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

### 8. Determination for biosafety level and period of IBC oversight:

The Committee previously 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 reaffirmed this determination.

The Committee previously 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. The Committee reaffirmed this determination.

### 9. 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

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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 discussed the use of the laminar flow clean bench for study agent preparation and recommended that the Institution confirm that it is still being used with the unit turned off as it would be hazardous to prepare study agent with the unit on since it sends aerosols directly towards the user and into the room.
2. The Committee recommended that Biosafety SOP Section 3.3 be revised to include that use of the laminar flow clean bench for study agent preparation with the unit turned on is hazardous as it will send aerosols directly towards the user and into the room.
3. The Committee recommended that a sign be posted on the laminar flow clean bench to remind study staff that it must be turned off during study agent preparation.
4. The Committee recommended that site documents be revised to replace “hood” with “laminar flow clean bench.”
5. The Committee recommended that Biosafety SOP Section 3.5 be revised to note that men should remain seated while urinating during the first two days after dosing to minimize the risk of splashing.
6. The Committee recommended that the Institution confirm subjects will remain in the dosing room during the one-hour study agent dwell time.
7. The Committee recommended that the Institution confirm that there is sufficient absorbent material placed underneath the subject during study agent dosing to absorb the entire contents of the subject’s bladder.
8. The Committee discussed disposal of study agent vials into a sharps container and determined this to be acceptable.

### **11. Site requirements:**

The Chair did not review training and communication requirements for maintaining IBC approval as an Institutional Representative was not present.

### **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 12:19 pm Central Time.

**15. Post-meeting notes:** An Institutional Representative joined the subsequent continuing review meeting and verified that a public posting for the meeting was made and that no public comments or questions were received. The Institutional Representative confirmed discussion points 1, 6, and 7 listed above at the subsequent meeting and confirmed that there is already a sign posted on the laminar flow clean bench.

### **Documents reviewed:**

Agenda

Protocol, Version 6.0, dated 06-16-2025

Prescribing Information, dated 03-2026

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

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

Research Modification Evaluation, Protocol, Version 6.0

Research Modification Evaluation, Clinical Trial Supply Manual, Version 4.0

Research Modification Evaluation, Clinical Trial Supply Manual, Version 3.0

Research Modification Evaluation, Prescribing Information, dated 03-2026