

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, 000434 (ABLE-22)
NCT Number: NCT06545955
Meeting Type: Continuing Review of Protocol and Site
Title: A phase 3, randomised, multi-centre, open-label trial to evaluate the safety and efficacy of intravesical nadofaragene firadenovec alone or in combination with chemotherapy (gemcitabine and docetaxel) or immunotherapy (pembrolizumab) in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC).

1. Call to order:

The Meeting was called to order at 12:19 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. 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.

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 noted that it would be hazardous to prepare the study agent with the unit turned on since it sends aerosols directly towards the user and into the room. The Institutional Representative confirmed that the laminar flow clean bench is turned off during study agent preparation.
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 Institutional Representative confirmed that a sign is 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 Institutional Representative confirmed that the study agent is not on site. The Committee recommended that the CRRF be revised to reflect this.
7. The Institutional Representative confirmed that subjects will remain in the dosing room during the one-hour study agent dwell time.
8. The Institutional Representative confirmed that there is sufficient absorbent material placed underneath the subject during study agent dosing to absorb the entire contents of the subject's bladder.
9. The Committee discussed disposal of study agent vials into a sharps container and determined this to be acceptable.

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 12:29 pm Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 7.0, US and Canada, dated 01-23-2026

Prescribing Information, dated 03-2026

Trial Supply Manual, Version 7.0, dated 02-2026

Research Modification Evaluation, Protocol, Version 7.0

Research Modification Evaluation, Protocol, Version 6.0

Research Modification Evaluation, Prescribing Information, dated 03-2026

Research Modification Evaluation, Trial Supply Manual, Version 7.0

Research Modification Evaluation, Trial Supply Manual, Version 5.0

Research Modification Evaluation, Trial Supply Manual, Version 4.0

Research Modification Evaluation, Trial Supply Manual, Version 3.0

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Research Modification Evaluation, Trial Supply Manual, Version 2.0
Biological Risk Assessment and Summary, updated 05-21-2026
Site Maps, dated 04-11-2024
Site Inspection Checklist, expires 05-28-2028, updated 05-29-2026
Photos, dated 05-17-2024
Biohazard Sign, ADSTILADRIN, dated 05-17-2024
SOP, Biosafety for ADSTILADRIN, dated 05-29-2026
Training, Shipping Certification, expires 06-19-2027
CRRF, dated 03-26-2026
Prior Meeting Minutes, Continuing, dated 06-17-2025