INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, October 20, 2026**
Time:	10:00 am Central Time
Location:	Zoom Teleconference
Institution:	Urology Austin, PLLC, Austin, TX
Principal Investigator:	**Brian Mazzarella, 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 10:13 am 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 two 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. 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 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

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 confirmed that both the Atrium and Radam locations will be used for this study based on the sub-investigators' availability and the ability to prepare the study agent on a countertop.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:19 am 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, US sites only
Trial Supply Manual, Version 7.0, dated 02-2026
Research Modification Evaluation, Protocol, Version 6.0, US Sites
Research Modification Evaluation, Protocol, Version 7.0, US and Canada
Research Modification Evaluation, Prescribing Information, dated 03-2026
Research Modification Evaluation, Trial Supply Manual, Version 5.0
Research Modification Evaluation, Trial Supply Manual, Version 7.0
Biological Risk Assessment and Summary, updated 08-18-2026
Site Map, Atrium, dated 10-01-2026
Site Map, Radam, dated 10-21-2025
Site Inspection Checklist, Radam, expires 12-01-2026, updated 07-30-2026
Site Inspection Checklist, Atrium, expires 12-01-2026, updated 07-30-2026
Photos, Atrium, dated 09-29-2026
Photos, Radam, dated 01-15-2025
Biohazard Sign, ADSTILADRIN, Atrium, dated 09-19-2025
Biohazard Sign, ADSTILADRIN, Radam, dated 09-19-2025
SOP, Biosafety for ADSTILADRIN, Atrium, dated 02-26-2026
SOP, Biosafety for ADSTILADRIN, Radam, dated 02-26-2026
Training, Shipping Certification, expires 08-25-2027
CRRF, dated 07-06-2026
Prior Meeting Minutes, Initial dated 10-17-2025