INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, September 19, 2025**
Time:	9:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	AdventHealth Denver, Denver, CO
Principal Investigator:	**Lawrence Karsh, MD**
Protocol:	Ferring Pharmaceuticals A/S, **000434 (ABLE-22)**
NCT Number:	NCT06545955
Meeting Type:	Initial 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 9:19 am Mountain Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three 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: 3 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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 a 24/7 monitored phone number be added to the Biohazard Sign.
2. An Institutional Representative confirmed that the reusable eye protection consists of protective glasses with side shields rather than goggles. The Committee recommended that site documents be revised accordingly.
3. An Institutional Representative confirmed that the [redacted] has two main entrance doors, as depicted in Slide 2 of the Photos document, and an additional entrance door into the [redacted] room within the [redacted], which is depicted in Slide 3 of the Photos document. The Committee recommended that the photos be updated to include this descriptive information.
4. An Institutional Representative confirmed the following regarding biohazardous waste:
    a. Gray and beige biohazardous waste containers in the [redacted] are not lined with a bag and the entire container is removed and replaced by Environmental Services when full. The Committee recommended that site documents be revised to include this information.
    b. Red biohazardous waste containers in the dosing rooms are lined with a yellow chemotherapeutic waste bag.
    c. The yellow chemotherapeutic waste bags are removed from the biohazardous waste containers in the dosing rooms and transported to the [redacted] where they are placed inside the large, hard-sided yellow waste containers.

    The Committee recommended that site documents be revised to include this information.
5. An Institutional Representative confirmed that the bracket for the door interlock on the Compounding Aseptic Containment Isolator (CACI) has been ordered but that the unit can still be used to safely prepare the study agent.
6. An Institutional Representative confirmed that the Biohazard Sign will be posted at the entrance to areas where study agent is handled once the study agent is on-site.

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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:23 am Mountain Time.