INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, October 28, 2025**
Time:	10:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Colorado Clinical Research, Lakewood, CO
Principal Investigator:	**David J. Cahn, 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 10:04 am Mountain 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 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. 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.

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 Biosafety SOP Section 3.2 be revised to remove "CACI."
2. An Institutional Representative confirmed that the floor in the study agent storage room is carpeted but that the carpet is scheduled for removal by the end of the year. However, the study agent will most likely be stored onsite by then. The Committee recommended that plastic mats or runners be placed under the study agent storage freezer until the carpet is removed.
3. The Committee recommended that Site Inspection Checklist (#17) be revised to reflect that carpet is in the storage room and that Biosafety SOP, Section 5.1.4 be revised to indicate how carpets will be decontaminated in the event of a spill.
4. An Institutional Representative confirmed that full biohazardous waste containers are stored in the [redacted] until pick-up by the waste hauler. The Committee recommended that a biohazard sign be placed on the wall above the stored biohazardous waste containers in the [redacted].
5. The Committee recommended that Site Inspection Checklist (#21) be revised to indicate that study staff members use hand sanitizer prior to exiting the room when a sink is not available and then immediately wash hands with soap and water at the nearest sink.
6. An Institutional Representative stated that the study agent transport container is about 24x18 inches with latches on both sides and is easily transported by study staff.
7. An Institutional Representative stated that disposable eyewash bottles are now wall-mounted and will provide IBC Services with photos of this.
8. An Institutional Representative confirmed that subjects remain in the dosing room during dosing and for the entire dwell-time post dosing.
9. An Institutional Representative stated that the Biological Safety Cabinet (BSC) is easily accessible and that study staff stand while working inside the BSC.
10. An Institutional Representative stated that PDI Sani-Cloth Bleach Germicidal wipes are used to decontaminate work surfaces. The Committee found this to be acceptable.
11. An Institutional Representative stated that while service animals are allowed onsite, they are not in the dosing room or other areas where the study agent is handled. The Committee recommended that Site Inspection Checklist (#7) be revised to reflect this.

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 10:25 am Mountain Time.