INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

| | |
|---|---|
| **Meeting Date:** | **Monday, July 7, 2025** |
| **Time:** | 1:00 pm Eastern Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Sarasota Memorial Health Care System, Sarasota, FL |
| **Principal Investigator:** | **Robert Carey, 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 1:26 pm Eastern 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 four 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: 5 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. An Institutional Representative confirmed that the study agent storage unit has not yet arrived. The Committee recommended that the storage unit be labelled with a biohazard symbol once received and that a photo be provided to IBC Services.
2. The Committee recommended that non-sharps and sharps biohazardous waste be disposed of into separate containers. The Committee recommended that both non-sharps and sharps biohazardous containers be made available in the preparation and dosing rooms and that photos of these containers be provided to IBC Services.
3. The Committee discussed options for disposal of non-sharps biohazardous and noted that these can include a red, biohazard bag in a frame, with a lid, or a regular garbage can, lined with a red biohazard bag, labelled with a biohazard symbol on the lid.
4. The Committee recommended that the institution follow up with IBC Services on whether or not Clorox HP Wipes are effective against non-enveloped viruses (such as the study agent) and noted that if not, Peridox RTU is effective. The Committee recommended that site documents be revised as necessary upon receipt of the follow-up information.
5. The Committee recommended that a small sharps container be placed inside the Biological Safety Cabinet (BSC) during study agent preparation per best biosafety practices and that a photo be provided to IBC Services.
6. An Institutional Representative confirmed that subjects remain in the dosing room for the dwell time after administration and that only study staff are present.
7. The Committee recommended that the study agent specific biohazard sign be posted at the entrance to the areas where the study agent is handled and that photos of the posted signage be provided to IBC Services.
8. An Institutional Representative confirmed that biohazard signage is posted on the door/entrance to the biohazardous waste storage areas. The Committee recommended that photos of the posted signage be provided to IBC Services.
9. An Institutional Representative confirmed that a plumbed eyewash station is located about two steps away from the dosing rooms. The Committee found this to be acceptable and recommended that the site map be revised to indicate the location of the eyewash.

**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 1:29 pm Eastern Time.