INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

| | |
|---|---|
| **Meeting Date:** | **Wednesday, September 10, 2025** |
| **Time:** | 11 am Eastern Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Michigan Institute of Urology, PC, Troy, MI |
| **Principal Investigator:** | **Jason Hafron, MD** |
| **Protocol:** | CG Oncology, Inc., **CRETO-EAP** |
| **NCT Number:** | NCT06443944 |
| **Meeting Type:** | Initial Review of Protocol and Site |
| **Title:** | An Expanded Access Program of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG) |

**1. Call to order:**

The Meeting was called to order at 11:02 am Eastern 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 two local members 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 cretostimogene grenadenorepvec**,** since it consists of a replication-competent oncolytic adenovirus administered in a clinical setting.

The Committee determined that IBC oversight will continue for **6 months after the last subject's last dose of cretostimogene grenadenorepvec 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. An Institutional Representative confirmed that the Biological Safety Cabinet (BSC) is scheduled for recertification on 09-17-2025.
2. The Committee recommended that the Institution submit the new BSC Certification document to IBC Services when it becomes available from the certifying company.
3. The Committee recommended that the Biohazard Sign be updated to note the full name of the study agent which is “cretostimogene grenadenorepvec”.
4. The Committee noted that staff members who are breast feeding should not handle the study agent and recommended that Biosafety SOP Section 1 be revised to add this information to the second paragraph.
5. An Institutional Representative confirmed that a solidifier is not added to the biohazardous waste container. Instead, a urine bag used to collect the post-dosing bladder contents via a catheter. The urine bag is then placed in a biohazard-labeled sealable bag, which then disposed of into a hard-sided biohazardous waste container. The Committee recommended that Biosafety SOP Dosing section E.b be revised accordingly.

**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 11:19 am Eastern Time.