## Meeting Minutes

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| **Institution:** | Charleston Area Medical Center (CAMC), Clinical Trials Center |
| **Meeting Date:** | November 18, 2025 |
| **Meeting Time** | 9:30 AM Eastern Time |
| **Meeting Type:** | Virtual Platform Teleconference (Remote)<br>Open to the Public |
| **Members in Attendance:** | **Member** / **Voting** / **Member Type**<br>Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert<br>Wang, Anthony / Yes / Core Member: Biosafety Expert/HGT Expert<br>Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert<br>Moran, Janine / Yes / Local Unaffiliated Member<br>Day, Bruce / Yes / Local Unaffiliated Member |
| **Invited Members Not in Attendance:** | **Member** / **Voting** / **Member Type**<br>Sutphin, Kristi / No / Site Contact |
| **Guests**: | Campanelli, Jordan (Representing Site) |
| **Staff:** | Hemmelgarn, Marian |

**Call to Order:** The IBC Chair called the meeting to order at 9:30 AM. A quorum was present as defined in the Sabai IBC Charter.

**Conflicts of Interest:** The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

**Public Comments:** No public comments were made prior to or at the meeting.

**Review of Prior Business:** None

**Previous Meeting Minutes**: Minutes from 4/23/25 were approved by the IBC with no changes**.**

**New Business:**

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| **PI:** | Stencel, Michael DO |
| **Sponsor:** | CG Oncology, Inc |
| **Protocol:** | CORE-008<br>A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) |
| **Review Type:** | Annual Review |
| **NIH Guidelines Section:** | III-C-1 |

**Trial Summary:** CORE-008 is a multi-arm, open-label Phase II trial sponsored by CG Oncology, Inc. and designed to assess the safety and efficacy of cretostimogene grenadenorepvec in participants with high-risk non-muscle invasive bladder cancer. The study agent cretostimogene grenadenorepvec consists of a recombinant, conditionally replicating oncolytic adenovirus. The investigational product (IP) is administered by intravesical instillation.

**Biosafety Containment Level (BSL):** The study agent cretostimogene is based on a recombinant Risk Group 2 virus containing more than two-thirds of the native genome, requiring the use of BSL-2 containment under the NIH Guidelines.

**Risk Assessment and Discussion:**

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills, splashes, and needlesticks of the IP during preparation and/or administration procedures**.** During administration, failure or leaks of the catheter, instillation lines, or drainage bag could result in spill of the agent, or urine contaminated with the agent. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).
    - The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
    - The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
    - The Site confirmed that staff members receive Bloodborne Pathogens training.

- Occupational Health Recommendations: The Sponsor notes that individuals who are at a potentially higher risk from working with or handling the study agent, such as pregnant or breastfeeding women and immunosuppressed or immunocompromised individuals, should not prepare, administer, or otherwise handle the study agent or materials contaminated with the study agent or provide direct care for treated participants presenting with any symptoms of illness attributed to cretostimogene for at least 1 week after treatment or until complete resolution of symptoms.
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Site confirmed the accuracy of the Annual Review Report.
    - In response to a question from the Committee, the Site confirmed that the bloodborne pathogens (BBP) training is completed annually, and the Site has an updated certificate which they can provide. The Committee stipulated that the Site provide an updated BBP training certificate by 12/17/25.
    - The Committee discussed the previous stipulation requesting that a biohazard sign be added to the door of the biohazard waste storage room in the Pharmacy area. The Committee discussed the OSHA requirement for biohazard signage noting that the Site, at minimum, should add a biohazard sign on the wall inside the room in the area where the biohazard waste is stored. The Committee stipulated that the Site provide a photo of the biohazard sign on the wall near the biohazard waste inside the Pharmacy biohazard waste storage room by 12/17/25.

**Motion:** A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous] vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee stipulated that the Site provide an updated bloodborne pathogens (BBP) training certificate by 12/17/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that the Site provide a photo of the biohazard sign on the wall near the biohazard waste inside the Pharmacy biohazard waste storage room by 12/17/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

**Review of Incidents:**

- NIH Incident Report.
    - The Chair reviewed the incident report previously submitted to the NIH pertaining to the PIVOT-006 study. The NIH acknowledged receipt and had no further questions or concerns.

**IBC Training:** Nothing to report.

**Reminder of IBC Approval Requirements.**

**Adjournment:** The IBC Chair adjourned the meeting at 10:09 AM

**Post-Meeting Pre-Approval Note:** None