Meeting Minutes

Institution:	Accellacare of Duly
Meeting Date:	Tuesday, June 2, 2026
Meeting Time	9:00 AM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Bivona, John	Yes	Local Unaffiliated Member
Hughes, Emma	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert

Guests:	None
Staff:	Stark, Casey

Call to Order: The IBC Chair called the meeting to order at 9:00 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 7-21-25 were approved by the IBC with no changes. There

were no votes against and no abstentions.

New Business:

PI:	Miocinovic, Ranko MD
Sponsor:	CG Oncology, Inc
Protocol:	CORE-008 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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. 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 Chair noted that the representative bloodborne pathogens training certificate is due for renewal in the coming weeks and reminded the Site to keep current on certifications.
  - The Site confirmed that study agent is prepped on day of instillation so that it will not require temporary storage in a refrigerator. The Committee had no concerns.
  - The Site confirmed that the blue waste bags are used for biohazard waste and are picked up by a licensed medical waste vendor. The Committee had no concerns.
  - The Committee noted that in the recent biosafety cabinet (BSC) certification report the certifier did not indicate testing of the supply blower interlock and exhaust alarm, which are important to ensure safe operation of the BSC. The Site confirmed that the BSC will be recertified in July. The Committee stipulated that the Site has the biosafety cabinet certification vendor complete the required site installation assessment tests including testing the supply blower interlock and exhaust alarm at the upcoming certification.

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:
  - Site has the biosafety cabinet certification vendor complete the required site installation assessment tests including testing the supply blower interlock and exhaust alarm at the upcoming certification by 9/2/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Miocinovic, Ranko MD
Sponsor:	CG Oncology, Inc
Protocol:	PIVOT-006 A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: PIVOT-006 is an open-label, randomized, Phase III clinical trial sponsored by CG Oncology designed to assess the safety and efficacy of cretostimogene grenadenorepvec ("cretostimogene"; previously known as CG0070) in adults with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC). Cretostimogene is a recombinant, conditionally replicating oncolytic adenovirus engineered to express human granulocyte-macrophage colony-stimulating factor (GM-CSF). 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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during [preparation and/or administration. 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 severely 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 Chair noted that the representative bloodborne pathogens training certificate is due for renewal in the coming weeks and reminded the Site to keep current on certifications.
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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:
    - Site has the biosafety cabinet certification vendor complete the required site installation assessment tests including testing the supply blower interlock and exhaust alarm at the upcoming certification by 9/2/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 9:42 AM

Post-Meeting Pre-Approval Note: None