

## Meeting Minutes

<b>Institution:</b>	Morristown Medical Center		
<b>Meeting Date:</b>	February 27, 2026		
<b>Meeting Time</b>	2:00 PM Eastern Time		
<b>Meeting Type:</b>	Virtual Platform Teleconference (Remote) Open to the Public		
<b>Members in Attendance:</b>	<b>Member</b>	<b>Voting</b>	<b>Member Type</b>
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Fitzgerald, Sean	Yes	Local Unaffiliated Member
	McNab, Gaitree	Yes	Local Unaffiliated Member
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
<b>Invited Members Not in Attendance:</b>	<b>Member</b>	<b>Voting</b>	<b>Member Type</b>
	Richards, Anita	No	Site Contact - Rostered
<b>Guests:</b>	Zitelli, Leah		
<b>Staff:</b>	Mahrt, Elena		

**Call to Order:** The IBC Chair called the meeting to order at 2 PM. 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 03-03-25 were approved by the IBC with no changes.

**New Business:**

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<b>PI:</b>	Prasad, Sandip MD, MPHIL
<b>Sponsor:</b>	CG Oncology, Inc
<b>Protocol:</b>	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)
<b>Review Type:</b>	Annual Review
<b>NIH Guidelines Section:</b>	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 (IVE) instillation into the bladder.

**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

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- 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 Site confirmed that the study agent is prepared immediately prior to administration to the participant and is not stored temporarily in the refrigerator. The Committee had no concerns.
    - The Site confirmed that there is a door separating the storage and preparation rooms. The Committee had no concerns.
    - The Site confirmed that soft biohazardous waste contaminated with cretostimogene are disposed of in yellow trace chemo or red biohazardous waste bins and expired or unused vials of study agent will be disposed of in black RCRA waste containers. The Committee confirmed that black RCRA containers containing biohazardous waste must be labeled with a biohazard symbol. The Site confirmed this practice would be followed. The Site Map + Photos document will be administratively revised to describe this practice.
    - The Site confirmed that the windows in dosing rooms do not open. The Site Map + Photos document will be administratively revised to describe this. The Committee had no further concerns.
    - The Committee noted that the BBP and IATA training certificates on file were expired. The Site confirmed that updated certificates can be provided. The Committee stipulated that updated BBP and IATA training certificates be provided.

**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

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- Stipulations stated by the Committee:
  - The Committee stipulated that updated BBP and IATA training certificates be provided by 3/27/2026. 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 2:44 PM

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