

Meeting Minutes

Institution:	Houston Metro Urology		
Meeting Date:	October 09, 2025		
Meeting Time	9:00 AM Central Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Ellis, Lena	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	LeBlanc, Chavaun	Yes	Local Unaffiliated Member
	Kotkar, Shalaka	Yes	Local Unaffiliated Member
Guests:	Jack, Monica		
Staff:	Parrish, Wendy		

Call to Order: The IBC Chair called the meeting to order at 9:01 AM. The Chair noted that there was quorum with the current attendance, as defined in the Sabai IBC Charter, and that the review could proceed without local members present. The Chair also noted that the NIH Office of Science Policy considers local member attendance to be a strong recommendation and best practice, but not a requirement. The Committee and Site had no concerns about proceeding with the review.

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.

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Review of Prior Business: None

Previous Meeting Minutes: Minutes from 8-21-25 were approved by the IBC with no changes.

New Business:

PI:	Schiffman, Zvi 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 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 aerosols, 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).

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- 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.
 - In response to a question from the Committee, the Site confirmed that the majority of participants have completed dosing, and one participant is still undergoing active treatment.
 - In response to a question from the Committee, the Site confirmed that the Laboratory and Research Pharmacy are located on the same floor, approximately 25 feet apart. The Committee had no concerns.
 - The Committee discussed the photo of the Research Pharmacy, noting the location of the portable bottle station on the wall. The Committee reminded the Site of the importance of maintaining a clear pathway to the eyewash bottles.
 - In response to a question from the Committee, the Site confirmed that the participant will remain in the administration room for the duration of the study agent retention period. The Chair reminded the Site that if the participant needs to be moved to a waiting room or other area during the retention period, the IBC will need to review and approve any new arrangements prior to their initiation. The Site had no concern.

Motion: A motion of Full Approval 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: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 9:29 AM.

Post-Meeting Pre-Approval Note: None