

Meeting Minutes



Institution:	Medstar Washington Hospital Center		
Meeting Date:	March 11, 2026		
Meeting Time	3:00 PM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
	Browne, Angella	Yes	Local Unaffiliated Member
	Singh, Christopher	Yes	Local Unaffiliated Member
	Guebre-Xabiher, Hiwot	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	None		
Guests:	Clark, Brandon; Cavanaugh, Carlette		
Staff:	Sreedharan, Aswathy		

Call to Order: The IBC Chair called the meeting to order at 3:01 PM Eastern Time. 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

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Previous Meeting Minutes: Minutes from 12-16-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Stamatakis, Lambros MD
Sponsor:	CG Oncology, Inc
Protocol:	CRETO-EAP An Expanded Access Program of Cretostimogene Grenadenorepvec in Participants with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CRETO-EAP is an open-label, expanded access trial (EAP) sponsored by CG Oncology, Inc. and designed to provide access to cretostimogene grenadenorepvec, a recombinant, conditionally replicating oncolytic adenovirus, in patients with non-muscle invasive bladder cancer (NMIBC) unresponsive to BCG. 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.

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- 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: 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 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 subjects will remain in the administration room after dosing, and the waiting area will not be utilized.
 - In response to a question from the Committee, the Site confirmed that the preparation area is access controlled, and a biohazard sign is placed on the door leading to the anteroom when the study agent is handled. Additionally, the dosing areas are also access controlled and affixed with a biohazard sign with emergency contact information.
 - The Site confirmed that biohazardous waste is picked up is from the respective rooms and not stored in a common area.
 - In response to a question from the Committee, the Site confirmed that a water bath is not used for thawing.
 - The Committee stipulated that the Site affix biohazard stickers on the Biosafety Cabinets and provide an updated photo to Sabai by 4-11-26.

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 affix biohazard stickers on the Biosafety Cabinets and provide an updated photo to Sabai by 4-11-26. The Committee agreed that resolution of this stipulation can be approved following review by the AP

Review of Incidents: Nothing to report.

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IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:38 PM Eastern Time

Post-Meeting Pre-Approval Note: None