Meeting Minutes

Institution:	Urology Center of Iowa Research
Meeting Date:	April 15, 2026
Meeting Time	2:00 PM Central 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 Campbell, Mark / Yes / Core Member: Biosafety Expert/HGT Expert Helgerson, Amy / Yes / Local Unaffiliated Member Matos, Bethzayda / Yes / Local Unaffiliated Member Hahn, Danielle / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 2:00 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 9/29/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Gallagher, Brian
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. This trial is designed to enroll up to 100 adult participants with qualifying disease. 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, or aerosols 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: Pregnant/breastfeeding women and immunosuppressed/immunocompromised individuals should not: prepare, administer, or otherwise handle the study agent or potentially contaminated materials; 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 participant will remain in the administration room for the duration of the study agent retention period. The Chair reminded the Site that the IBC will need to review and approve any new arrangements prior to their initiation. The Site had no concerns.
  - The Site confirmed the cardboard box shown in the photo has been removed and that they no longer use the cardboard waste containers.
  - The Committee recommended that the Site rotate the plumbed eyewash station fixture upward and place dust caps on the ends to prevent contamination. The Site had no questions.
  - The Site confirmed the arrangements, including that sharps containers are available in all rooms and that all furniture is easily cleanable. The Committee had no concerns.

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

- 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 2:26 PM.

Post-Meeting Pre-Approval Note: None