Meeting Minutes

Institution:	Banner Health
Meeting Date:	September 24, 2025
Meeting Time	10:00AM Pacific 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 Campbell, Mark / Yes / Core Member: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Stevenson, Karen / Yes / Local Unaffiliated Member Sefidvash-Hockley, Sepideh / Yes / Local Unaffiliated Member Reitz, Kathryn / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** None
Guests:	Ball, Alicja Sloan, Lisa Schohn, James (Joined at 10:08 am)
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 10:02 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

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Previous Meeting Minutes: Minutes from 8/25/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Mmeje, Chinedu MD, FACS
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:	Initial 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, splashes, aerosols and needlesticks of the IP during preparation and/or administration procedures. 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 PI's credentials 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 Committee discussed the Biological Safety Cabinet (BSC) certification reports and inquired about the specific location of the biosafety cabinets used for the study. The Committee further discussed the photo of the BSCs noting there is shelving in the way of one BSC and requested an updated photo with the shelves removed. The Committee stipulated that the Site provide updated photos of the Biosafety Cabinets (BSCs) used for the study with shelving removed, indicate the specific location of the BSCs used and indicate which BSC certification report corresponds to each BSC used by 10/23/25.
  - The Committee noted that the Facility Details Form indicates that the sink is in the Pharmacy however it is in the anteroom to the Pharmacy. The Facility Details Form will be administratively updated to reflect the correct location.
  - The Committee inquired about the process for disposal of sharps using the reusable sharps containers at the Site. The Site indicated that they would need to inquire about the internal process and would provide an update to the Committee. The Committee stipulated that the Site provide specifics on the process of disposal of sharps using the reusable sharps containers by 10/23/25.
  - 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 concerns.

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 provide updated photos of the Biosafety Cabinets (BSCs) used for the study with shelving removed, indicate the specific location of the BSCs used and indicate which BSC certification report corresponds to each BSC used by 10/23/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that the Site provide specifics on the process of disposal of sharps using the reusable sharps containers by 10/23/25. The Committee agreed that resolution of this stipulation can be approved following review by the Chair.

PI:	Kundranda, Madappa MD, PhD, FACP
Sponsor:	AstraZeneca Pharmaceuticals LP
Protocol:	NT-175-201 An Open-label, Phase 1, Multicenter Study to Evaluate the Safety and Preliminary Anti-tumor activity of NT-175 in Human Leukocyte Antigen -A*02:01-Positive Adult Subjects with Unresectable, Advanced and/or Metastatic Solid Tumors That Are Positive for the TP53 R175H Mutation
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: NT-175-201 (D8690C00001) is a Phase I, open-label dose-escalation study sponsored by AstraZeneca Pharmaceuticals LP (previously sponsored by Neogene Therapeutics, Inc.) and designed to evaluate the safety, maximum tolerated dose, recommended phase 2 dose, and preliminary efficacy of NT-175, a recombinant autologous TCR-T cell product expressing an HLA-A-*02:01 restricted T Cell Receptor (TCR) against p53 in participants with advanced and/or metastatic qualifying solid tumors positive for TP53 with the R175H mutation. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The NT-175 agent consists of primary human cells engineered with a CRISPR/Cas9 system and linear dsDNA, therefore BSL-2 is the recommended containment level under the NIH Guidelines II-A-3.

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, and needlesticks of the IP during preparation and/or administration procedures. The study agents are delivered in infusion bags that require

no formulation and are attached to a pre-placed catheter without the use of needles, therefore risks of spills, splashes, and needlesticks are minimal for the activities at the study site. 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: None
    - 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 the accuracy of the Annual Review Report.
    - The Committee discussed how carts are used for the study IP administration. The committee had no concerns.
    - In response to a question from the Committee, the Site confirmed that the dewar on the cart is used for transport of the agent from storage to administration. The committee had no concerns.
    - The Committee inquired about the frequency of eyewash station testing and where records are kept. The Site confirmed they are routinely tested but would need to inquire about where the records are stored. The Committee recommended the Site follow up and provide the information when available.

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.

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IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at Time 11:02 PM

Post-Meeting Pre-Approval Note: None