Meeting Minutes

Institution:	UroPartners LLC
Meeting Date:	February 26, 2026
Meeting Time	1:30 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 Bivona, John / Yes / Local Unaffiliated Member Helm, Allen / Yes / Local Unaffiliated Member Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Wang, Anthony / Yes / Core Member: Biosafety Expert/HGT Expert Webb, Karolina / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type**
Guests:	None
Staff:	McFarland, Christine

Call to Order: The IBC Chair called the meeting to order at 1:31 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: Meeting minutes from 6/12/25 were approved by the IBC with no changes requested.

New Business:

PI:	Pearl, Jeffrey M.D.
Sponsor:	CG Oncology, Inc
Protocol:	CORE-008: A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CORE-008 is a multi-arm, open-label Phase II trial sponsored by CG Oncology, Inc. and designed to assess the safety and efficacy of cretostimogene grenadenorepvec in participants with high-risk non-muscle invasive bladder cancer. The study agent cretostimogene grenadenorepvec consists of a recombinant, conditionally replicating oncolytic adenovirus. The study agent is administered by intravesical instillation into the bladder.

Biosafety Containment Level (BSL): The study agent consists of a recombinant Risk-Group 2 adenovirus containing more than two-thirds of the native genome, requiring the use of BSL-2 containment per Section III-D of the NIH Guidelines. Administration of this study agent to humans constitutes human gene transfer and requires IBC approval prior to initiation under Section III-C of 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 the 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: 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 Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site confirmed the information submitted in the Annual Review Report remains accurate.
    - The Site verified that the Site arrangement information provided by the Chair was accurate and reaffirmed that study participants remain in the dosing rooms and are not moved to a waiting room during dwell time. The Committee had no further concerns.
    - The Site confirmed that urine drainage bags are disposed of as biohazardous wastes and that participants typically do not use the restroom at the Site. However, if restroom usage by a study participant were necessary, a restroom cleaning protocol is in place. The Committee had no additional concerns.
    - In response to a question from the Committee, the Site confirmed they have external transport protocols in place and that no issues or problems have been identified with external transport of the study agent to date. The Site stated that the study agent is placed inside their internal transport container which is then packaged into an external transport container with refrigerated packs. The Chair noted the Site Photos document will be administratively updated to reflect this practice. The Committee also recommended the Site ensure appropriate documentation is carried in the vehicle during transport.
    - In response to a question from the Committee, the Site stated that study agent vials are not removed from their secondary packaging and are placed directly into the freezer. The Site confirmed that a spill kit is available in the study agent storage room and clarified that any biohazardous wastes that might be generated in the storage room location will remain in the storage room until vendor pickup.
    - The Committee also discussed the biohazard waste storage room. The Site stated that biohazardous wastes are double-bagged before being placed inside the cardboard

boxes for vendor pickup The Committee recommended that the Site place a non-absorbent spill tray beneath the cardboard boxes to mitigate the risk of any potential leak and to replace the worn biohazard signage posted on the waste room door. The Committee reminded the Site that the sign must include the biohazard symbol and should have red or orange/red coloring. The Site confirmed that the cardboard boxes are kept closed when not in use. The Site Photos documentation will be administratively updated to reflect these practices.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were 0 votes against and 0 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 2:13 PM CST.

Post-Meeting Pre-Approval Note: None