Meeting Minutes

Institution:	UroPartners, Chicago Ridge		
Meeting Date:	November 24, 2025		
Meeting Time	1:00 PM CST		
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
	Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
	Helm, Allen	Yes	Local Unaffiliated Member
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Canning, Daniel	No	Site Contact
Guests:	Webb, Karolina		
Staff:	McFarland, Christine		

Call to Order: The IBC Chair called the meeting to order at 1:00 PM CST. 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 5/9/25 were approved by the IBC with no changes requested.

New Business:

PI:	Berger, Aaron
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 investigational product (IP) is administered via slow push 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. Therefore, Biosafety Level 2 containment is recommended under 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) 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.
    - 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 immunocompromised/ immunosuppressed individuals should not:

prepare, administer, or otherwise handle study agent or potentially contaminated items or provide direct care for treated subjects presenting with any symptoms attributed to cretostimogene until complete resolution of any symptoms thought possibly related to cretostimogene.
    - 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 in the Annual Review report was still accurate.
    - The Site confirmed that the Site's activities with study agent and arrangements, as summarized by the Chair, were accurately described. The Site noted that additional dosing rooms are being renovated for future use. The Site confirmed they intend to follow the same arrangements as they are currently doing in these new rooms, i.e., participants will remain in the dosing room throughout agent administration and dwell time. The Site confirmed understanding of the process for obtaining IBC approval for the use of these new rooms once renovations are complete. The Committee had no further concerns.

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 1:27 PM CST.

Post-Meeting Pre-Approval Note: None