Meeting Minutes

Institution:	Urology Nevada LTD		
Meeting Date:	Thursday, May 7, 2026		
Meeting Time	7:00 AM 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
	Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Hasenau, John	Yes	Local Unaffiliated Member
	Olsen-Wilson, Kimberly	No	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Dondanville, Michelle	Yes	Local Unaffiliated Member
Guests:	Vollmer, Angelique		
Staff:	Stark, Casey		

Call to Order: The IBC Chair called the meeting to order at 7:02 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

Previous Meeting Minutes: Minutes from 6-23-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Zlatev, Dimitar 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:	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 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: 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 Site confirmed that all personal protective equipment (PPE), except for goggles, are disposable. The Site additionally confirmed that goggles are disinfected with an appropriate disinfectant and rinsed with water after. The Committee had no concerns.
  - The Committee raised question as to what is done if a participant brings a service animal to the clinic. The Site confirmed that they currently do not have any participants that have service animals, but they will assess the risks if any participants with service animals are enrolled in the trial. The Committee recommended the Site consider restricting the animal during administration. The Site had no concerns with this recommendation.
  - The Site confirmed that sharps containers are routinely checked for level of fullness. The Site additionally confirmed that staff are trained to empty the sharps container once sharps containers reach two-thirds capacity. The Committee had no concerns.
  - The Site confirmed that the plumbed eyewash station is tested monthly to ensure that it is functioning properly. The Committee had no concerns.
  - The Site confirmed that more than one individual at the Site is certified in IATA shipping training. 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.

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IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 7:43 AM

Post-Meeting Pre-Approval Note: None