Meeting Minutes

Meeting Date:	June 12, 2025 at 1:00 PM Central Time
Meeting Place:	Teleconference (Remote) Meeting is open to the public
Members in Attendance:	Reed, Craig Rastein, Daniel Helm, Allen Bivona, John Webb, Karolina
Members Not in Attendance:	None
Guests:	None
Staff:	Hemmelgarn, Marian; Bavaret, Tammy (Administrative Chair, non-voting); Noriea, Nicholas (non-voting)
Institution:	UroPartners LLC

Call to Order: The meeting was called to order at 12:59 PM CT. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Pearl, Jeffrey 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:	III-C

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.

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Pearl, Jeffrey MD
Sponsor:	CG Oncology, Inc
Protocol:	PIVOT-006 A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: PIVOT-006 is an open-label, randomized, Phase III clinical trial sponsored by CG Oncology designed to assess the safety and efficacy of cretostimogene grenadenorepvec ("cretostimogene"; previously known as CG0070), a recombinant, conditionally replicating oncolytic adenovirus, in adults with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC).

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.

- The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Adjournment: 1:29 PM

Post-Meeting Pre-Approval Note: None