Meeting Minutes

Meeting Date:	Wednesday, June 18, 2025 at 3:30 PM Eastern Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Members in Attendance:	Noriea, Nicholas Rastein, Daniel Reed, Craig Niemi, Christina Wooten, Ronald Dissanayake, Ravindika
Invited Members Not in Attendance:	Dudley, Richard Rohrs, Skylar
Guests:	Rachel Mcluckie, Chritina Sattler, Mahesh Pillai
Staff:	Casey Stark
Institution:	University of Toledo HGT

Call to Order: The meeting was called to order at 3:32 PM. 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:	Petros, Firas 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) in adults with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC). Cretostimogene is a recombinant, conditionally replicating oncolytic adenovirus engineered to express human granulocyte-macrophage colony-stimulating factor (GM-CSF). This trial has a maximum enrollment of up to 364 adults with pathologically confirmed IR-NMIBC who will be randomized into one of two arms to either receive standard-ofcare (SOC) transurethral resection of bladder tumor (TURBT) followed by adjuvant treatment with

cretostimogene (Arm A) or TURBT followed by surveillance (Arm B).

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 Committee noted that the representative IATA Shipping training certificate is coming due for renewal and reminded the Site to keep current on the required training and to send Sabai IBC Services an updated certificate once available.

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: 4:12 PM

Post-Meeting Pre-Approval Note: None