Meeting Minutes

Meeting Date:	June 23, 2025 at 10:00 AM Pacific Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Members in Attendance:	Dondanville, Michele Hansenau, John Noriea, Nicholas Rastein, Daniel Wang, Anthony
Members Not in Attendance:	Becker, Jennifer
Guests:	Peres, Sabrina Valdovinos, Christian Vollmer, Angelique
Staff:	Parrish, Wendy
Institution:	Urology Nevada LTD

Call to Order: The meeting was called to order at 10:02 AM. 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:	Zlatev, Dimitar, 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).

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 reminded the Site they must also report any accidental spills/exposures to the IBC in addition to the procedures described in the Sponsor's Accidental Exposure and Toxicity Manual.

- 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 discussed the Annual Review Report. The Site confirmed that the study is open to enrollment, and dosing is ongoing. The Annual Review Report xForm will be updated to reflect this information.
    - The Site confirmed study agent is transported between rooms using the removable hard-sided specimen box shown in the Site Photos document. The Committee had no concerns.
    - The Committee reminded the Site that Bloodborne Pathogen training was recently due. The Site confirmed all clinical staff complete Bloodborne Pathogen Training on an annual basis, and confirmed they are awaiting an updated certificate. The Committee recommended the Site provide the updated Certificate to Sabai once available.
    - The Committee discussed the Site's IATA Training. The Site confirmed one person at the Site is certified. The Committee recommended an additional person at the Site complete the training. The Site had no concerns.
    - The Site confirmed participants will remain in the dosing room with the catheter in place for the dwell period. Participant will then void into a urine drainage bag, and the bag is then sealed and disposed of as biohazardous waste.
    - The Site confirmed they have a procedure for disinfecting the restroom and toilet water if needed.
    - The photo of the PreAmp room shows a clean bench. The Site confirmed the clean bench is not used for study agent preparation, and all work will be done within the biosafety cabinet. The Committee had no concerns.
    - The Site confirmed the biosafety cabinet is scheduled to be recertified prior to the date listed on the Biosafety Cabinet Certification Report.
    - The Site confirmed that the cloth chair shown in the photo of the PreAmp Room is used for computer work, and is removed from the room before any work with the study agent occurs. The Committee recommended the Site provide an updated photo showing the

vinyl stool used when preparing study agent.

- The Committee discussed the Site Map. The Site confirmed that plumbed eyewash is located in the Sterilization Room, which is separate from the Biohazardous Waste Closet. The Site further confirmed that there is a clear path to the eyewash station. The Site documents will be administratively revised to label the room with the plumbed eyewash for easy reference.
- The Chair noted the new Clinical Biosafety Manual. Per a discussion as a previous meeting, the Site noted they will continue to follow up to ensure their Exposure Control Plan is reviewed on an annual basis.
- The Committee noted a comment about references to pneumatic tubes in the Site's Exposure Control Plan. The Committee noted this may be template language and non-applicable. The Site confirmed they do not use pneumatic tubes at the Institution. The Committee had no concerns.

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: 11:03 AM

Post-Meeting Pre-Approval Note: None