Meeting Minutes

Institution:	Lakeland Regional Health Systems, Inc
Meeting Date:	September 16, 2025
Meeting Time	2:00 PM Eastern 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 Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Reed, Craig / Yes / Core Member: Biosafety Expert/HGT Expert Moulvi, Farah / Yes / Local Unaffiliated Member Schoenfield, Elizabeth / Yes / Local Unaffiliated Member Crowder, Dana / No / Site Contact
Invited Members Not in Attendance:	**None**
Guests:	Jaimes, Jeniffer Collins, Brittany Kratz, Maria (joined at 2:07pm)
Staff:	Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 2:00 PM. 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 8-26-25 were approved by the IBC with no changes. There

were no votes against and no abstentions.

New Business:

PI:	Hinds, Peter
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 Section:	III-C-1

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). The investigational product (IP) is administered by 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, 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, splashes, aerosols and needlesticks of the IP during preparation and/or administration procedures. 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 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.
  - In response to a question from the Committee, the Site confirmed that the BSC has been certified and passed testing. The report will be sent to the site in October from the vendor and the site will forward to Sabai. The committee had no concerns.
  - In response to a question from the Committee, the Site confirmed that the eyewash station is located right outside of the BSC door. It was noted that the site map did not accurately show the location and layout of the pharmacy area including the correct locations of the sinks and eyewash. The Site Map will be updated to accurately reflect the Pharmacy area.

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:
  - The Site to provide the updated BSC report once it has been received from the vendor by 10/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Site Map to be updated to reflect the correct location and layout of the Pharmacy including correct sink and eyewash locations by 10/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the Chair.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:32 PM

Post-Meeting Pre-Approval Note: None