Meeting Minutes

Institution:	Texas Oncology-Sammons CC (Txo-DS)
Meeting Date:	December 11, 2025
Meeting Time	10:00 AM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Hauke, Caitlyn / Yes / Chair: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Campbell, Mark / Yes / Core Member: Biosafety Expert/HGT Expert Naik, Veena / Yes / Local Unaffiliated Member Scott, Frederick / Yes / Local Unaffiliated Member Koetter, Danielle / No / Site Contact
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 10:01 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 10-30-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Konduri, Kartik
Sponsor:	Genprex Inc.
Protocol:	ONC-005 A Phase 1/2 Clinical Trial of Quaratusugene Ozeplasmid and Atezolizumab Maintenance Therapy in Patients with Extensive Stage Small Cell Lung Cancer (ES-SCLC)
Review Type:	Change in Research Review (Addition of Preparation Room)
NIH Guidelines Section:	III-C-1

Trial Summary: ONC-005 (Acclaim-3 Trial) is a Phase I/II open-label trial sponsored by Genprex Inc. designed to identify the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), safety profile, and progression-free survival (PFS) of quaratusugene ozeplasmid (REQORSA®) in combination with atezolizumab in adults with extensive stage-small cell lung cancer (ES-SCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the TUSC2 tumor suppressor gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent quaratusugene ozeplasmid consists of a recombinant DNA plasmid incapable of replication and which encodes for a protein with no known toxic or tumorigenic properties, therefore, BSL-1 containment is the recommended biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

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 and splashes 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: None
- 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 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 there will be 13, not 12, potential administration rooms. The Site Map will be administratively updated to clarify this.
    - The Site confirmed that the sink is located in the anteroom of the Research Pharmacy BSC Room and the door is self-opening. The Committee recommended that the Site send Sabai a photo of the handwashing sink in the anteroom.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions 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.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:23 AM

Post-Meeting Pre-Approval Note: None