Meeting Minutes

Institution:	Texas Oncology-Sammons CC (Txo-DS)
Meeting Date:	February 19, 2026
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
Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
Scott, Frederick	Yes	Local Unaffiliated Member
Koetter, Danielle	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Naik, Veena	Yes	Local Unaffiliated Member

Guests:	None
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 10:00 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 12/11/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Konduri, Kartik
Sponsor:	Krystal Biotech, Inc.
Protocol:	KB707-02 KB707-02: A Phase 1 Study of Inhaled KB707 in Patients with Advanced Solid Tumor Malignancies Affecting the Lungs
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: KB707-02 is a Phase I, open-label, dose escalation and expansion clinical trial sponsored by Krystal Biotech, Inc., and designed to assess the safety, tolerability, and preliminary efficacy of KB707, a recombinant, fully replication-defective, non-integrating Type 1 Herpes Simplex Virus (HSV-1) vector designed to express human immunostimulatory cytokines IL-2 and IL-12, in adult participants with advanced solid tumors affecting the lungs. The investigational product (IP) is administered by inhalation via nebulization.

Biosafety Containment Level (BSL): Because the study agent KB707 is a recombinant derivative of a Risk-Group 2 herpesvirus and contains more than two-thirds of the native genome, BSL-2 containment is considered the recommended biocontainment level 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/or needlestick exposures 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, 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.
  - The Committee reminded the Site to keep training up-to-date and send Sabai updated certificates when they are available.
  - The Site confirmed the BSCs are scheduled to be recertified this month and the Committee reminded the Site to send Sabai the updated certification reports when they are available.
  - The Committee recommended that the Site require participants to wear nose clips during administration. The Site had no concerns.
  - The Committee discussed the use of respiratory protection, due to the aerosolized nature of administration. The Committee recommended that the Site wear N95s during administration. The Site had no concerns. The Facility Details form and Biohazard Sign will be administratively updated to reflect the additional PPE during administration.
  - The Committee discussed the potential of shedding and the replication defective nature of the study agent. The Committee suggested the Site consider contacting Infection Prevention for additional information if there are concerns regarding shedding from the face after administration, though the Committee concluded that the risk is likely low. The Committee also suggested the Site ask the Sponsor for patient and caregiver instructions, in the event the Sponsor has specific recommendations.
  - The Site confirmed that dosing rooms have doors, which will be closed during administration. The Site also confirmed that a limited number of staff will be present during administration and a delegated research nurse will be performing administration.
  - The Committee discussed the risk of the study agent recombining with wildtype HSV-1 in participants with underlying HSV-1 infection. The Committee further noted that subjects are likely tested for HSV-1 as part of the screening criteria.

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: None

PI:	Konduri, Kartik

Sponsor:	Merck Sharp & Dohme LLC
Protocol:	V940-009 A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab with or Without V940 in Participants with Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab with Platinum-based Doublet Chemotherapy (INTerpath-009).
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: V940-009 is a Phase III randomized, placebo-controlled study sponsored by Merck Sharp & Dohme LLC designed to evaluate the safety and efficacy of V940 in combination with pembrolizumab in adult participants with non-small cell lung cancer (NSCLC). V940 (also known as mRNA-4157) is a novel mRNA-based individualized neoantigen therapy (INT) consisting of a lipid encapsulated mRNA that encodes up to 34 participant-specific neoantigens. The investigational product (IP) is administered by intramuscular (IM) injection.

Biosafety Containment Level (BSL): The study agent V940 (mRNA-4157) is a non-infectious synthetic mRNA that is not associated with disease in healthy adults. The mRNA is incapable of replication and does not express known hazardous transgenes. Therefore, BSL-1 containment may be considered as the minimum biocontainment level when handling the study agent. 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, splashes, and/or needlestick exposures 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, 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.
  - The Committee reminded the Site to keep training up-to-date and send Sabai updated certificates when they are available.
  - The Site confirmed the BSCs are scheduled to be recertified this month and the Committee reminded the Site to send Sabai the updated certification reports when they are available.

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 10:51 AM

Post-Meeting Pre-Approval Note: The Chair confirmed that participants are tested for HSV-1 antibodies as part of the screening process.