Meeting Minutes

Institution:	Texas Oncology-Austin (Txo-A)
Meeting Date:	January 15, 2026
Meeting Time	1:00 PM Central 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 Heaven, Marian / No / Site Contact - Rostered Helm, Allen / Yes / Core Member: Biosafety Expert/HGT Expert Holden, Letitia / Yes / Local Unaffiliated Member Levin, Patricia Levin / Yes / Local Unaffiliated Member Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert
Invited Members Not in Attendance:	None
Guests:	None
Staff:	Mahrt, Elena

Call to Order: The IBC Chair called the meeting to order at 1:00 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 9-4-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Cline, Vivian MD
Sponsor:	BioNTech SE
Protocol:	BNT122-01: A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BNT122-01 is a Phase II clinical trial sponsored by BioNTech SE designed to assess the safety and potential efficacy of a recombinant personalized cancer vaccine for the treatment of participants with advanced colorectal cancer following surgical resection. The study agent RO7198457 (autogene cevumeran) consists of messenger RNA (mRNA) expressing personalized tumor antigens formulated as a liposome complex for delivery by intravenous injections. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent RO7198457 (autogene cevumeran) consists of synthetic mRNA incapable of replication and does not encode for known hazardous transgenes (e.g., toxins or oncogenes), BSL1 containment is considered the minimum biocontainment level. The administration of this agent by intravenous infusion in a clinical setting requires compliance with the OSHA Bloodborne Pathogen Standard.

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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during [preparation and/or administration. 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 discussed the Biohazard Sign and noticed variability in the agent descriptions. The Biohazard Sign will be administratively revised to make the descriptions more consistent. The Committee had no concerns.
  - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

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:	Keyes, Kyle MD
Sponsor:	Merck Sharp & Dohme LLC
Protocol:	V940-011: A Phase 2 Open-label Randomized Study of V940 in Combination with BCG Versus BCG Monotherapy in Participants with High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: V940-011 is a Phase II randomized, active-controlled, open-label study sponsored by Merck Sharp & Dohme LLC designed to evaluate the efficacy and safety of the study agent V940 (also known as mRNA-4157) in combination with Bacillus Calmette Guerin (BCG) compared to BCG monotherapy in adult participants with high-risk non-muscle invasive bladder cancer (NIMBC) and have undergone transurethral resection of bladder tumor (TURBT). V940 is a novel mRNA-based individualized neoantigen therapy (INT) consisting of a single lipid encapsulated mRNA encoding up to 34 participant-specific neoantigens. The

investigational product (IP) is administered by intramuscular (IM) administration.

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. It 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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. 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 discussed the Biohazard Sign and noticed variability in the agent descriptions. The Biohazard Sign will be administratively revised to make the descriptions more consistent. The Committee had no concerns.
    - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the

Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

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

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 1:43 PM

Post-Meeting Pre-Approval Note: None