Meeting Minutes

Meeting Date:	July 16, 2025 at 2:30 PM Central Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Members in Attendance:	Bellan, Phillip Ellis, Robert Fish, Abigail Noriea, Nicholas PhD, MCS, RBP Rastein, Daniel MD, MPH Olivier, Simone
Members Not in Attendance:	none
Guests:	Garrett, Brooke Sandoz, Alaina
Staff:	Spruill, Chad
Institution:	Southern Urology

Call to Order: The meeting was called to order at 2:34 PM CT. 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:	Fontenot, Christopher
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)
	Initial Review (Protocol and Site)
Review Type:	Fontenot, Christopher
NIH Guidelines:	III-C

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.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

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 reviewed the Site's facility details, study-specific procedures and practices, training records, 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 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.
    - The Site confirmed they would like the IBC to consider allowance of the preparation and dosing rooms reviewed for this study to also apply to all other approved studies at the institution. The Chair shared the previously approved preparation and dosing rooms, noting the facilities and features are consistent with the locations reviewed for this study. The Committee had no concerns with the administrative addition of the preparation and dosing rooms reviewed at this meeting to be included as approved preparation and dosing locations for active studies at the institution. The Chair further noted two of the three active studies have annual reviews coming up where the new locations will be listed. The Committee had no questions.

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: 3:12 PM CT

Post-Meeting Pre-Approval Note: None