Meeting Minutes

Meeting Date:	June 24, 2025, at 9:00 AM Central Time
Meeting Place:	Teleconference (Remote) Meeting open to the public
Members in Attendance:	Hauke, Caitlyn Naik, Veena Scott, Frederick Koetter, Danielle Rastein, Daniel Wang, Anthony
Members Not in Attendance:	None
Guests:	Rita Lopez
Staff:	Jennifer Smith, Melanie Gill
Institution:	Texas Oncology-Sammons CC (Txo-DS)

Call to Order: The meeting was called to order at 9:01 AM. 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:	Cowey, C. Lance, MD
Sponsor:	Replimune, Inc.
Protocol:	RP1-104 A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: RP1-104 is a Phase III, randomized, open-label study sponsored by Replimune, Inc. and designed to assess the efficacy of Vusolimogene Oderparepvec (VO; also known as RP1), a recombinant, selectively replicating oncolytic Type 1 Herpes Simplex Virus (HSV-1), in combination with nivolumab for the treatment of participants with qualifying advanced melanoma that has progressed on anti-PD-1 and anti-CTLA-4 treatment.

Biosafety Containment Level per Risk Assessment: BSL-2

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, 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 noted that the BBP Training on record expires soon and asked the Site to send an updated certificate when it is available.

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: 9:26 AM

Post-Meeting Pre-Approval Note: None