Meeting Minutes

Meeting Date:	June 05, 2025 at 9:30 AM Eastern Time
Meeting Place:	Teleconference (Remote) Meeting is open to the public
Members in Attendance:	Wang, Anthony Rastein, Daniel Marz, Aylin Gobhardt, Wendi
Members Not in Attendance:	Welch, Nancy
Guests:	Morris, Chris
Staff:	Hemmelgarn, Marian; Bavaret, Tammy (Administrative Chair, non-voting); Hauke, Caitlyn (non-voting)
Institution:	Virginia Oncology Associates (VOA)

Call to Order: The meeting was called to order at 9:32 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:	Simmons, Gary DO
Sponsor:	Allogene Therapeutics, Inc.
Protocol:	ALLO-501A-202 A Randomized, Open-Label Study Evaluating the Efficacy and Safety of Cemacabtagene Ansegedleucel in Participants with Minimal Residual Disease After Response to First Line Therapy for Large B-Cell Lymphoma
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: ALLO-501A-202 (ALPHA3 Study) is a Phase II randomized, open-label study sponsored by Allogene Therapeutics, Inc. designed to assess the safety and efficacy of cemacabtagene ansegedleucel (cema-cel; formerly known as ALLO-501A) for the treatment of large B-cell lymphoma (LBCL) in adult subjects with minimal residual disease (MRD) after completion of first line (1L) therapy. Cema-cel consists of allogeneic T lymphocytes isolated from a pool of peripheral blood mononuclear cells collected from multiple healthy volunteer donors. These

cells are then transduced with a recombinant lentiviral vector designed to express a CAR targeting the tumor antigen CD19.

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 noted that a participant had been enrolled since the completion of the Annual Review Report which indicated dosing was on hold or had not yet started. The Annual Review Report will be administratively updated to reflect this information.
    - The Site verified that the remaining information provided by the Chair was accurate.
    - The Site clarified that a Biological Safety Cabinet (BSC) is available at the Site but is not used for this study due to its distance from the storage, preparation, and administration areas.

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: 9:56 AM

Post-Meeting Pre-Approval Note: None