Meeting Minutes

Institution:	Case Western Reserve University		
Meeting Date:	January 22, 2026		
Meeting Time	10:00 AM Eastern 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
	Wilson, LaKetta (joined at 10:15 am EST)	Yes	Local Unaffiliated Member
	Yun, Yang H. (joined at 10:05 AM EST)	Yes	Local Unaffiliated Member
	Karlo, Colleen	Yes	Site Contact
	Young, Andrew	Yes	Biological Safety Officer
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Tepfenhart, Benjamin	Yes	Site Contact
Guests:	Tokach, Nicholas		
Staff:	Smith, Jennifer		

Call to Order: The IBC Chair called the meeting to order at 10:02 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 12/2/2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Sindel, Ariel
Sponsor:	Miltenyi Biomedicine
Protocol:	M-2024-423 A Phase 1 Multicohort Trial of Zamtocabtagene autoleucel (zamto-cel) in Subjects with Severe Refractory Autoimmune Diseases
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: M-2024-423 is a Phase 1, multicenter study sponsored by Miltenyi Biomedicine, GmbH. The study is designed to evaluate the safety, tolerability, and efficacy of the study agent, zamtocabtagene autoleucel (zamto-cel) also referred to as MB-CART2019.1, in adult participants with progressed and/or refractory autoimmune disease after receiving standard therapy. MB-CART2019.1 consists of autologous CD4/CD8-enriched T cells genetically engineered with a lentiviral vector (LV) to express chimeric antigen receptors (CARs) targeting the CD19 and CD20 antigens. The primary aim of this study is to determine a safe and tolerable dose based on DLTs and determine the recommended Phase 2 dose (RP2D). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent MB-CAR2019.1 consists of primary human cells transduced with a recombinant, replication-defective lentiviral vector, therefore BSL-2 containment is the recommended minimum containment 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 or splashes 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 Site confirmed that personnel contacted by the spill response line are highly trained in all types of spills that may occur and would know how to respond appropriately in the event of a biohazardous spill.
  - The Committee discussed the PPE for administration and previous discussions about the use of only gloves and face masks in this area. The Committee reiterated their previous recommendation that the Site wear eye protection.
  - The Committee confirmed the BBP training completion date is present on page two of the document and the training is up-to-date.

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:	Deng, Changchun
Sponsor:	Janssen Research and Development, LLC
Protocol:	90014496LYM1001 A Phase 1b Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants with B-cell Non-Hodgkin Lymphoma
Review Type:	Annual Review

NIH Guidelines Section:	III-C-1

Trial Summary: 90014496LYM1001 (formerly CCAR039L1101) is a Phase 1b/2 multicenter, open-label study sponsored by Janssen Research and Development, LLC and designed to assess the safety and tolerability of JNJ-90014496, an autologous bi-specific chimeric antigen receptor (CAR) T cell product targeting CD19 and CD20 in adult participants with relapsed/refractory or frontline high-risk B-cell non-Hodgkin lymphoma (B-NHL). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent JNJ-90014496 consists of primary human cells transduced with a recombinant, replication-defective form of a Risk Group 3 lentivirus, therefore BSL-2 containment is minimum 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 or splashes 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 Site confirmed that personnel contacted by the spill response line are highly trained in all types of spills that may occur and would know how to respond appropriately in the event of a biohazardous spill.
- The Committee discussed the PPE for administration and previous discussions about the use of only gloves and face masks in this area. The Committee reiterated their previous recommendation that the Site wear eye protection.
- The Committee confirmed the BBP training completion date is present on page two of the document and the training is up-to-date.

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 10:37 AM

Post-Meeting Pre-Approval Note: None