INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 20, 2025**
Time:	9:00 am Central Time
Location:	Zoom Teleconference
Institution:	Northwestern University, Chicago, IL
Principal Investigator:	**Reem Karmali, MD, MS**
Protocol:	Miltenyi Biomedicine, GmbH, **M-2018-344**
NCT Number:	NCT04792489
Meeting Type:	Continuing Review of Protocol and Site
Title:	A multi-center single arm Phase II study to evaluate the safety and efficacy of genetically engineered autologous cells expressing anti-CD20 and anti-CD19 specific chimeric antigen receptor in subjects with relapsed and/or refractory diffuse large B cell lymphoma

1. Call to order:

The Meeting was called to order at 8:59 am Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. Also present was one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 6 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for MBCART2019.1, since it consists of primary human cells modified with a recombinant lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of MB-CART2019.1 locally,** provided all other biosafety criteria required for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6 NO: 0 ABSTAIN: 0

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee noted that IATA/DOT Shipping Training Certification will expire in June 2025 and recommended that the training be renewed prior to the expiration date and an updated certificate be provided to IBC Services.
2. The Committee noted that although the Biological Safety Cabinet (BSC) certification reports were available for review, the BSCs are not used for study agent preparation since the product arrives on-site as a fresh, non-cryopreserved product ready for infusion.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:08 am Central Time.