

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, April 8, 2026
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Hackensack Meridian Health, Hackensack, NJ
Principal Investigator: Lori Ann Leslie, MD
Protocol: Kite Pharma, Inc., KT-US-484-0136
NCT Number: NCT05605899
Meeting Type: Continuing Review of Protocol and Site
Title: An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene CiloleuceL versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma (ZUMA-23)

1. Call to order:

The Meeting was called to order at 12:24 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution, and the Institution's Biosafety Officer. Also present was 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 Biosafety Officer 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: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 KTE-C19, since it consists of autologous T cells modified by a gammaretroviral 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 KTE-C19 locally**, provided all other criteria 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: 5 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

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

Point of Discussion:

1. The Committee noted that a staff member is due for IATA Shipping Training recertification in May 2026.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:29 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 3, dated 01-08-2024

Investigator's Brochure, Edition 16, dated 01-07-2026

Investigational Product Manual, Version 12, dated 11-26-2025

Research Modification Evaluation, Investigator's Brochure, Edition 16

Research Modification Evaluation, Investigational Product Manual, Version 11.0

Research Modification Evaluation, Investigational Product Manual, Version 12.0

Biological Risk Assessment and Summary, updated 02-09-2026

Site Maps, Genetically Modified Human Cells, updated 11-19-2025

Site Inspection Checklist, Genetically Modified Human Cells, expires 08-19-2026, updated 03-26-2026

Biohazard Sign, Leslie, dated 03-27-2026

Biosafety Guidelines for Genetically Modified Human Cells, dated 12-11-2025

Biosafety Guidelines, Addendum for Autologous Cells, dated 03-26-2026

Training, Shipping Certifications, expire 05-2026, 10-2026, 11-2026, 12-2026, 2027

CRRF, dated 01-20-2026

Prior Meeting Minutes, Continuing, dated 04-29-2025