

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, February 10, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Reem Karmali, MD, MS
Protocol: Lyell Immunopharma, Inc., LYL314-102
NCT Number: NCT05421663
Meeting Type: Initial Review of Protocol and Site
Title: A phase 3 randomized controlled trial of Rondecabtagene Autoleucel, a dual-targeting CD19/CD20 CAR T-Cell product candidate, versus investigator's choice of CD19 CAR T-Cell therapy in patients with relapsed or refractory large B-Cell Lymphoma in the second-line setting (PiNACLE-H2H)

1. Call to order:

The Meeting was called to order at 9:09 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 were four Institutional Representatives 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:

An 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for LYL314 since it consists of autologous T cells modified by a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of LYL314 locally**, provided all other criteria for study closure are met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 the biological safety cabinets (BSCs) are due to be re-certified in March 2026.

11. Site requirements:

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

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 9:14 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 07-24-2025

Investigator's Brochure, Edition 7, dated 03-14-2025

Drug Administration Manual, Revision 2, dated 11-03-2025

Biological Risk Assessment and Summary, updated 12-04-2025

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 01-30-2026

Photos, Prentice Hospital, dated 04-25-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Feinberg and Olson Loading Dock, dated 03-05-2025

Biohazard Sign, Prentice and Olson, dated 01-29-2026

Biohazard Sign, Olson MCCT, dated 01-29-2026

Biological Safety Cabinet Certifications, Olson MCCT, expire 03-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 03-17-2025

SOP Addendum, Biosafety for Autologous Cells, dated 01-30-2026

Training, Shipping Certification, expires 06-05-2027

CV, Karmali, R., signed 03-22-2024