

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, March 3, 2026
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Corewell Health, Grand Rapids, MI
Principal Investigator: Sami Brake, MD
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 9:59 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. 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. 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: 4

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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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 the Shipping Training Certifications will expire in March and May of this year and recommended that newer Certifications be submitted to IBC Services upon completion of retraining.
2. The Committee recommended that a representative photo of the biohazardous waste container that is brought to the dosing room for disposal of used PPE and non-sharps waste be provided to IBC services.
3. The Institutional Representative confirmed that the plumbed eyewash is flushed weekly. The Committee recommended that a blank plumbed eyewash flush form be submitted to IBC Services and that the Photos document be updated with this form (to be used as an example that the Institution flushes plumbed eyewashes on a regular basis).

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the 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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:10 am Eastern 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 Maps, Butterworth Hospital, 5th Floor, dated 02-17-2026

Site Inspection Checklist, expires 01-09-2027, updated 02-17-2026

Photos, BW Hospital, Dosing Area, dated 02-18-2026

Biohazard Sign, LYL314, dated 02-17-2026

SOP, Biosafety for LYL314, dated 02-17-2026

Training Shipping Certifications, expire 2026

CV, Brake, S., signed 04-14-2025