INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, November 21, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Northside Hospital, Atlanta, GA
Principal Investigator:	**Melhem Solh, 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 10:00 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 were two 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: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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 had no questions or concerns about the facilities and practices.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with 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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:08 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 1, dated 03-24-2025
Biological Risk Assessment and Summary, dated 10-09-2025
Site Map, BMT Unit, 4th Floor, dated 01-29-2024
Site Map, HSC Laboratory, dated 01-29-2024
Site Inspection Checklist, GMHC, expires 02-10-2027, updated 11-11-2025
Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025
Photos, HSC Lab, BMT Unit, dated 07-03-2025
Biohazard Sign, Genetically Modified Human Cells, dated 11-11-2025
Biological Safety Cabinet Certifications, HSC Lab, expire 12-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 11-11-2025
SOP Addendum, Biosafety for Autologous Cells, dated 11-11-2025
Training, Shipping Certifications, expire 03-10-2026, 04-30-2026
CV, Solh, M., signed 06-02-2025