

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, December 29, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: AdventHealth Orlando, Orlando, FL
Principal Investigator: Philip Pancari, 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 1:05 pm 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 three 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.

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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. An Institutional Representative confirmed that the study agent infusion bag will be thawed in a waterbath on a countertop and then placed inside a Biological Safety Cabinet (BSC) where the study agent will be withdrawn into a syringe.
2. The Committee recommended that Biosafety SOP Section 3.3 be revised to indicate that the study agent infusion bag will be thawed in a waterbath on a countertop and then placed inside a Biological Safety Cabinet (BSC) where the study agent will be withdrawn into a syringe.
3. An Institutional Representative noted that staff members move their hands in and out of the BSC to dispose of items in a sharps container located next to the BSC. The Committee noted that moving hands in and out of the BSC to dispose of items disrupts the airflow (curtain), and that it is a safer practice if a sharps container is placed within the BSC.
4. The Committee recommended that a small sharps container be placed within the BSC during preparation of the study agent (and other biological agents), per best biosafety practices.
5. The Institutional Representative confirmed that the Biological Safety Cabinets (BSCs) used for study agent preparation were recently re-certified. The Committee recommended that the BSC certifications be provided to IBC Services when available.

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 1:19 pm Eastern Time.