INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, December 29, 2025**
Time:	2:00 pm Arizona Time
Location:	Zoom Teleconference
Institution:	HonorHealth, Scottsdale, AZ
Principal Investigator:	**Abdullah Ladha, MD, MPH**
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 1:59 pm Arizona 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 three local members 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: 6 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

Point of Discussion:

1. An Institutional Representative confirmed that the Principal Investigator has prior clinical research experience and that an updated CV will be provided to IBC Services.

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 recommended that Biosafety SOP Section 3.4.1 be revised to indicate that absorbent material will be added to the Ziploc-style bag prior to transporting the study agent.
2. An Institutional Representative confirmed that PDI Sani-Cloth AF3 wipes and PDI Sani-Cloth Bleach wipes are available in clinic areas for decontamination of work surfaces. The Committee recommended that Biosafety SOP Section 3.6.1 be revised accordingly.
3. An Institutional Representative could not confirm whether the study agent would be thawed and prepared on a mobile cart in the [redacted] or in the nearby [redacted]. The Committee recommended that the Institution follow-up with IBC Services regarding this and revise site documents as needed.
4. An Institutional Representative could not confirm how other patients and staff would be isolated from [redacted] during study agent preparation and dosing and in the event of a spill. The Committee recommended that access to [redacted] be limited to study staff and the subject during preparation and dosing and that the Institution follow-up with IBC Services regarding how this will be implemented.
5. The Committee recommended that photos showing the [redacted] rooms and the [redacted] set-up for study agent thawing and preparation be provided to IBC Services.
6. The Committee recommended that photos of both soiled utility rooms used to store biohazardous waste be provided to IBC Services.
7. An Institutional Representative confirmed that red biohazardous waste containers are used for disposal of personal protective equipment and other non-sharps biohazardous waste. The Committee recommended that photos of the red biohazardous waste containers in the preparation and dosing rooms be provided to IBC Services.
8. The Committee recommended that an emergency eyewash sign be posted near the plumbed eyewash station in the [redacted] and that an updated photo be provided to IBC Services.
9. An Institutional Representative confirmed that the study agent is stored off-site by a 3rd party vendor.

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: 6 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:23 pm Arizona Time.