

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, February 5, 2026
Time: 9:00 am Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Yazan Samhour, 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 9:14 am Arizona Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were seven 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: 5

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.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:19 am Arizona 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, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor, dated 08-28-2023

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, T Cell Studies, expires 01-19-2028

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 07-30-2025

Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-13-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025

SOP Addendum, Biosafety for Autologous Cells, dated 01-13-2026

Training, Shipping Certification, expires 06-2027

CV, Samhuri, Y., signed 07-28-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, February 5, 2026
Time: 9:00 am Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Matthew Ulrickson, MD
Protocol: Caribou Biosciences, Inc., CB10A
NCT Number: NCT04637763
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1, Multicenter, Open-Label Study of CB-010, a CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ANTLER)

1. Call to order:

The Meeting was called to order at 9:20 am Arizona Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were seven 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for CB-010 since it consists of primary human cells modified using an adeno-associated viral (AAV) vector and chRDNA-Cas9 complex. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of CB-010 locally**, provided that all biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 Addendum for Allogeneic Cells Section 3.4.2 be revised to include CB-010.
2. The Committee recommended that the comment in Site Inspection Checklist, Item #13 be updated to replace Dr. Nath with Dr. Ulrickson due to a recent Change in Principal Investigator (PI).
3. An Institutional Representative confirmed that the biohazardous waste containers in BMDACC Room 300244 and BGMC 2nd and 5th Floor rooms have not yet been labeled with biohazard symbols per Banner's biohazardous waste policy.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:26 am Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 7.0, dated 05-21-2024

Investigator's Brochure, Version 6.0, dated 11-11-2025

Pharmacy Manual, Version 4.0, dated 10-04-2023

Research Modification Evaluation, Investigator's Brochure, Version 6.0

Biological Risk Assessment and Summary, updated 12-17-2025

Research Modification Evaluation, PI Change, CB10A, dated 06-12-2025

Site Map, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor, dated 08-28-2023

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, T Cell Studies, expires 01-19-2028

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 07-30-2025

Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-13-2026

Biological Safety Cabinet Certifications, Cell Therapy Lab, expire 06-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025

SOP Addendum, Biosafety for Allogeneic Cells, dated 01-20-2026

Training, Shipping Certification, expires 06-2027

CRRF, dated 10-20-2025

Prior Meeting Minutes, Continuing, 01-15-2025

CV, Ulrickson, M., dated 03-25-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, February 5, 2026
Time: 9:00 am Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Joseph W. Mashni, Jr., MD
Protocol: ImmunityBio, Inc., ResQ132EX-NMIBC
NCT Number: NCT06810141
Meeting Type: Initial Review of Protocol and Site
Title: Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Non-muscle Invasive Bladder Cancer

1. Call to order:

The Meeting was called to order at 9:00 am Arizona Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were seven 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 rMBCG since it consists of an attenuated mycobacterium administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of rMBCG locally**, provided that other biosafety criteria for study closure are also 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: 5

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.

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. The Committee recommended that Biosafety SOP Section 3.5.1 be revised to add that subjects are advised to disinfect voided bladder contents with an equal volume of bleach for 15 minutes prior to flushing for 6 hours after dosing.
3. An Institutional Representative confirmed that subjects will void into a toilet after dosing and there is no other liquid waste to be disposed of. The Committee recommended that Biosafety SOP Sections 3.6.4 and 4.2 be removed.
4. The Committee recommended that emergency eyewash signage be posted above the plumbed eyewash stations in the BMDACC 3rd floor dosing areas.
5. The Committee recommended that the study agent storage refrigerator be labeled with a biohazard symbol when the study agent is being stored onsite.
6. The Committee recommended that all site maps be updated to identify the locations of toilets that will be used by subjects for voiding their bladder after dosing.

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:13 am Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 3.0, dated 02-12-2025

Investigator's Brochure, Version 1.0, dated 02-19-2025

Pharmacy Manual, Version 1, dated 02-11-2025

TICE BCG Package Insert, dated 08-2022

Biological Risk Assessment and Summary, dated 07-21-2025

Site Map, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor Imaging, dated 10-11-2022

Site Map, BMDACC 2nd Floor, dated 10-11-2022

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, Non-T Cell Studies, expires 01-15-2028

Photos, Non-T Cell Studies, BGMC Dosing Rooms, dated 02-12-2025

Photos, Non-T Cell Studies, BMDACC, Dosing Rooms, dated 01-14-2026

Photos, Non-T Cell Studies, Storage and Preparation, dated 02-03-2026

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

Biohazard Sign, rMBCG, dated 12-15-2025

Biological Safety Cabinet Certifications, BMDACC Pharmacy, expire 05-2026

SOP, Biosafety for rMBCG, dated 12-15-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Training, Shipping Certification, expires 06-2027
CV, Mashni, J., signed 03-13-2024