Meeting Minutes

Institution:	Methodist Healthcare system of San Antonio, LTD, dba Methodist Hospital HGT
Meeting Date:	Wednesday, October 22, 2025
Meeting Time	2:00 PM Central Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Moroney, Brian	Yes	Local Unaffiliated Member
Herrera, Christian	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Shade, Sherri	No	Site Contact
Barrera, Jessika	No	Site Contact
Wang, Anthony	Yes	Local Unaffiliated Member

Guests:	None
Staff:	Stark, Casey Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 2:01 PM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 8-27-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Fenske, Timothy MD
Sponsor:	Lyell Immunopharma, Inc.
Protocol:	LYL314-102 A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Therapy Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in theSecond-Line Setting (PiNACLE-H2H)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: LYL314-102 is a randomized Phase III study sponsored by Lyell Immunopharma, Inc. and designed to evaluate the efficacy and safety of rondecabtagene autoleucel (ronde-cel; LYL314) as a second line therapy in adult participants with relapsed or refractory Large B-Cell Lymphoma (LBCL). Rondecabtagene autoleucel is an autologous T cell product engineered to express a dual-targeting chimeric antigen receptor (CAR) targeting cluster of differentiation (CD)19 and CD20. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent rondecabtagene autoleucel (LYL314) consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, BSL-2 containment is the recommended biocontainment level under the *NIH Guidelines* II-A-3.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration

procedures. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package)

  - The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
  - The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
  - The Site confirmed that staff members receive Bloodborne Pathogens training.
  - Occupational Health Recommendations: None
  - The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the biohazard sign lists personal protective equipment (PPE) for preparation inside the biosafety cabinet (BSC) and outside the BSC; however, the Facility Details form notes full PPE for preparation. The Facility Details form will be administratively updated to note that difference in PPE when being prepared within the BSC.
  - The Site confirmed that there is a sink in the same room where study agent will be prepared. The Committee had no concerns.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Fenske, Timothy MD
Sponsor:	Lyell Immunopharma, Inc.
Protocol:	LYL314-101 A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, a CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T Cell Therapy in Participants with Aggressive B-Cell Non-Hodgkin Lymphoma
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: LYL314-101 (formerly MPCT-012L) is a Phase I/II multi-center, open-label study sponsored by Lyell Immunopharma, Inc. and designed to evaluate the safety, efficacy, and recommended Phase 2 dose (RP2D) of LYL314 (formerly IMPT-314) in adult participants with aggressive B-cell Non-Hodgkin Lymphoma (NHL). LYL314 is an autologous T cell product engineered to express a dual-targeting chimeric antigen receptor (CAR) targeting cluster of differentiation (CD)19 and CD20. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent LYL314 consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, BSL-2 containment is the recommended biocontainment level under the *NIH Guidelines* II-A-3.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package)
    - The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.

- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the biohazard sign lists personal protective equipment (PPE) for preparation inside the biosafety cabinet (BSC) and outside the BSC; however, the Facility Details form notes full PPE for preparation. The Facility Details form will be administratively updated to note that difference in PPE when being prepared within the BSC.
  - The Site confirmed that there is a sink in the same room where study agent will be prepared. The Committee had no concerns.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Farhadfar, Nosha MD
Sponsor:	Calibr-Skaggs Institute for Innovative Medicines
Protocol:	CBR-sCAR19-3003 A Phase 1b Open-Label Study Evaluating the Safety and Efficacy of the Combination of CLBR001, an Engineered Autologous T Cell Product, and SWI019, a CD19-directed Antibody-based Biologic with or without Lymphodepletion in Subjects with Autoimmune Disorders Including Systemic Lupus Erythematosus, Systemic Sclerosis, Idiopathic Inflammatory Myositis, or Rheumatoid Arthritis.
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: CBR-sCAR19-3003 is a multicenter, open-label, Phase IB basket trial sponsored by Calibr-Skaggs Institute for Innovative Medicines and designed to assess the safety and tolerability of the combination of CLBR001 and SWI019 in adult subjects with autoimmune disease. The recombinant study agent CLBR001 consists of the subject's own (autologous) T lymphocytes transduced with a lentiviral vector expressing a chimeric antigen receptor (CAR) targeting a novel neoantigen tag added to an engineered antibody. This engineered antibody, SWI019, is designed to target the antigen CD19 and to serve as a bridge for recruiting the CLBR001 CAR-T cells. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent CLBR001 consists of primary human cells transduced with a recombinant Risk Group 3 lentiviral vector; therefore, BSL2 containment is the recommended biocontainment level under the *NIH Guidelines*.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package)

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the biohazard sign lists personal protective equipment (PPE) for preparation inside the biosafety cabinet (BSC) and outside the BSC; however, the Facility Details form notes full PPE for preparation. The Facility Details form will be administratively updated to note that difference in PPE when being prepared within the BSC.
  - The Site confirmed that there is a sink in the same room where study agent will be prepared. The Committee had no concerns.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Shaughnessy, Paul MD
Sponsor:	CRISPR Therapeutics
Protocol:	CRSP-ONC-006 A Phase 1/2, Open-Label, Multicenter, Dose Escalation and Cohort Expansion Study of the Safety and Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Subjects with Relapsed or Refractory B Cell Malignancies
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CRSP-ONC-006 is a first-in-human Phase I/II clinical trial sponsored by CRISPR Therapeutics AG, designed to assess the safety and efficacy of an allogeneic T cell product (CTX112) engineered by genome editing to disrupt four genes of interest and to express a chimeric antigen receptor (CAR) targeting the tumor antigen CD19 in adult subjects with qualifying B cell malignancies. The gene editing disruptions are created ex vivo by CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats/CRISPR-associated protein 9) gene editing, while the CAR donor sequences are introduced by transient transfection with a replication-defective adeno-associated virus (AAV) vector. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent CTX112 was generated from primary human cells electroporated with CRISPR/Cas9 complexes and transduced with a recombinant AAV vector. Such primary human cells carry the potential for transmission of bloodborne pathogens, requiring compliance with the OSHA Bloodborne Pathogen Standard. BSL-2 containment is recommended for handling of such cellular products.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package)

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the biohazard sign lists personal protective equipment (PPE) for preparation inside the biosafety cabinet (BSC) and outside the BSC; however, the Facility Details form notes full PPE for preparation. The Facility Details form will be administratively updated to note that difference in PPE when being prepared within the BSC.
  - The Site confirmed that there is a sink in the same room where study agent will be prepared. The Committee had no concerns.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:55 PM

Post-Meeting Pre-Approval Note: None