

Meeting Minutes



Institution:	St. David's South Austin Medical Center		
Meeting Date:	October 20, 2025		
Meeting Time	10:00 AM Central Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Holden, Leticia	Yes	Local Unaffiliated Member
	Levin, Patricia	Yes	Local Unaffiliated Member
	Runkle, Chelsea	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Goldin, Stephanie	No	Site Contact
	Longoria, Amy	No	Site Contact
Guests:	None		
Staff:	Hemmelgarn, Marian		

Call to Order: The IBC Chair called the meeting to order at 11:01 AM. 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.

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Review of Prior Business: None

Previous Meeting Minutes: Minutes from 9/4/25 were approved by the IBC with no changes.

New Business:

PI:	Rao, Uttam 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 the Second-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).

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- 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.
 - In response to a question from the Committee, the Site confirmed that preparation, administration and the biohazard waste storage locations are indicated in the St. David's Overall map. The Site maps will be administratively updated to more clearly depict the agent handling locations.
 - In response to a question from the Committee, the Site confirmed that the cart with the waterbath is used for agent thawing for both bedside thaw and Lab Flow Room thaw.
 - The Committee noted that the IATA training certificate provided by the Site only references air transport and reminded the Site to ensure that the training covered land transport as well. The Site confirmed they will verify staff has appropriate training.
 - The Committee discussed the biohazard waste containers in the Cancer Care Clinic treatment rooms. The Site confirmed that each room has a sharps and non-sharps biohazard waste container. The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste containers with the added biohazard stickers by 11/19/25.

Motion: A motion of Approval with Stipulations 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:
 - The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste

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containers with the added biohazard stickers by 11/19/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Ramakrishnan, Aravind MD
Sponsor:	Chimeric Therapeutics Ltd
Protocol:	CHM-1101-001 A Phase 1b Study to Evaluate CHM-1101, a Chimeric Antigen Receptor (CAR) T Cell Therapy with a Chlorotoxin Tumor-Targeting Domain for Patients with Matrix Metalloproteinase 2 Positive (MMP2+) Recurrent or Progressive Glioblastoma Multiforme (GBM)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CHM-1101-001 is a Phase 1b clinical trial sponsored by Chimeric Therapeutics Ltd and designed to determine the recommended Phase 2 Dose (RP2D), feasibility, and safety of CHM-1101, an autologous recombinant Chimeric Antigen Receptor (CAR) T cell product in participants with recurrent/progressive Glioblastoma Multiforme (GBM). CHM-1101 expresses a novel peptide-based CAR using the Chlorotoxin (CLTX) peptide as a targeting domain which specifically binds to glioma cells with minimal cross-reactivity to non-malignant cells. The investigational product (IP) is administered by intracavitary/intratumoral (ICT) and intraventricular (ICV) infusion.

Biosafety Containment Level (BSL): Because the study agent CHM-1101 consists of primary human cells engineered with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, 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.

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- 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 Site confirmed the accuracy of the Annual Review Report.
 - In response to a question from the Committee, the Chair confirmed that the Facility Details Form would be updated to list the Personal Protective Equipment (PPE) as described on the Biohazard Sign.
 - The Committee agreed that the Sponsor documents indicate all preparation is done inside the Biological Safety Cabinet (BSC). The Site agreed they will confirm all preparation is done in the BSC.
 - The Committee discussed the biohazard waste containers in the Cancer Care Clinic treatment rooms. The Site confirmed that each room has a sharps and non-sharps biohazard waste container. The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste containers with the added biohazard stickers by 11/19/25.

Motion: A motion of Approval with Stipulations 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:
 - The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste containers with the added biohazard stickers by 11/19/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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PI:	Ramakrishnan, Aravind MD
Sponsor:	Marker Therapeutics, Inc.
Protocol:	MRKR-22-601-01 A Phase 1 Study of Patient-Derived Multi-Tumor-Associated Antigen-Specific T Cells (MT-601) Administered to Patients with Relapsed or Refractory Non-Hodgkin and Hodgkin Lymphoma (APOLLO)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: MRKR-22-601-01 is a Phase I, multicenter, open-label study sponsored by Marker Therapeutics, Inc., to assess the safety, efficacy, and tolerability of the investigational T cell product MT-601 (neldaleucel) in subjects with relapsed or refractory non-Hodgkin and Hodgkin lymphoma. MT-601 is a non-genetically modified autologous T cell product designed to target multiple tumor antigens that are selectively overexpressed on malignant cells. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): MT-601 is a non-genetically modified human cell product derived from primary human cells with the potential for transmission of bloodborne pathogens requiring compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). Biosafety level 2 containment (BSL-2) is recommended for handling the MT-601 cellular product.

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 to the mucous membranes and percutaneous injury. 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

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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 Site confirmed the accuracy of the Annual Review Report.
 - The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste containers with the added biohazard stickers by 11/19/25.

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

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site ensure that biohazard waste containers in the Cancer Care Clinic Treatment Rooms have biohazard stickers affixed and either confirm the stickers have been added or provide updated photos showing the biohazard waste containers with the added biohazard stickers by 11/19/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:10AM

Post-Meeting Pre-Approval Note: None