Meeting Minutes

Institution:	University of California, Irvine HGT		
Meeting Date:	Wednesday, December 3, 2025		
Meeting Time	9:00 AM Pacific 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
	Makmura, Linna	Yes	Local Unaffiliated Member
	Zhou, Jennifer	Yes	Local Unaffiliated Member
	Tafoya, Christine	Yes	Biological Safety Officer
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Abegania, Judi	No	Biological Safety Officer
Guests:	None		
Staff:	Stark, Casey		

Call to Order: The IBC Chair called the meeting to order at 9:00 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.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 11-5-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	O'Brien, Susan MD
Sponsor:	Galapagos NV
Protocol:	CP0201-NHL A Phase I/II, multicenter study evaluating the feasibility, safety, and efficacy of point-of-care manufactured GLPG5101 (19CP02) in subjects with relapsed/refractory B-cell non-Hodgkin lymphoma (CP0201-NHL)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: CP0201-NHL is a single-arm, open-label Phase I/II trial sponsored by Galapagos NV and designed to assess the safety and efficacy of GLPG5101 in adult participants with relapsed/refractory B-cell non-Hodgkin lymphoma (r/r NHL). GLPG5101 consists of autologous T cells engineered with a 3rd generation lentiviral vector to express a chimeric antigen receptor (CAR) targeting CD19. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent GLPG5101 consists of primary human cells transduced with a recombinant, replication-defective lentivirus, therefore BSL-2 containment is the recommended containment 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.

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:	Ciurea, Stefan 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:	Annual Review and Change in Research
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 and needlesticks due to the use of needles during [preparation and/or administration. 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 Chair noted that the Site is proposing the addition of a new administration location which has not been previously reviewed by the Committee.
  - The Sabai Associate Partner confirmed that a wall mounted sharps container is present in the participant rooms. The Committee recommended the Site provide a picture of the sharps container if possible.
  - The Chair noted that the new administration location is expected to follow the Site's existing biohazard signage posting guidelines; however, the Site will inquire if biohazard signage can be posted during administration. The Committee had no concerns.
  - The Committee noted that the plumbed eyewash station was mounted on the incorrect side of the sink. The Site confirmed that the final safety walkthrough would be occurring in the upcoming weeks and would alert the appropriate personnel of the misconfiguration. 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 9:46 AM

Post-Meeting Pre-Approval Note: None