

Meeting Minutes



Institution:	Oncology Hematology Care, Inc.		
Meeting Date:	October 05, 2026		
Meeting Time	2:30 PM Eastern 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
	Espinola, Marcia	Yes	Local Unaffiliated Member
	Nordling, Diana	Yes	Local Unaffiliated Member
	Hart, Douglas	No	Site Contact
Invited Members Not in Attendance:	None		
Guests:	None		
Staff:	Payne, Kaylie		

Call to Order: The IBC Chair called the meeting to order at 2:31 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.

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Review of Prior Business: None

Previous Meeting Minutes: Minutes from 7-15-26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Galal, Ahmed 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:	Annual 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 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).

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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 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 Admix room is used for transferring agent from bag to syringe.
 - The Site confirmed that the preference is to use the private room available in the dosing areas for this study. If the larger open bay areas are used, they do use a rolled partition device, or other patients or participants in the area will be specially segregated. The Site Maps & Photos will be administratively updated to note this preference.
 - The Site confirmed that sharps and non-sharps waste containers are segregated. The Site confirmed that similar containers are brought in for the non-sharps waste (similar to the container used in the preparation room). The Site Maps & Photos will be administratively updated.
 - The Site confirmed that the non-sharps biohazardous waste containers have a lid placed on them when not in use.
 - The Committee recommended that the Site encourages their study staff to use the plumbed eyewash in the hallway since the Lab plumbed eyewash station may be used as a mixed used sink. The Site had no concerns. The Site Map & Photos will be administratively updated.
 - The Committee discussed the minimum required PPE for handling the agent inside or outside of containment. The Committee agreed that the minimum requirements listed on the Biohazard Sign are sufficient. The Facility Details form will be administratively updated.

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

New Business:

PI:	Waterhouse, David MD
Sponsor:	Genprex, Inc.
Protocol:	ONC-005 A Phase 1/2 Clinical Trial of Quaratusugene Ozeplasmid and Atezolizumab Maintenance Therapy in Patients with Extensive Stage Small Cell Lung Cancer (ES-SCLC)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ONC-005 (Acclaim-3 Trial) is a Phase I/II open-label trial sponsored by Genprex Inc. designed to identify the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), safety profile, and progression-free survival (PFS) of quaratusugene ozeplasmid (REQORSA®) in combination with atezolizumab in adults with extensive stage-small cell lung cancer (ES-SCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the *TUSC2* tumor suppressor gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent quaratusugene ozeplasmid consists of a recombinant DNA plasmid incapable of replication and which encodes for a protein with no known toxic or tumorigenic properties, therefore, BSL-1 containment is the recommended biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

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

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- 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 Admix room is used for transferring agent from bag to syringe.
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 - The Site confirmed that the non-sharps biohazardous waste containers have a lid placed on them when not in use.
 - The Committee recommended that the Site encourages their study staff to use the plumbed eyewash in the hallway since the Lab plumbed eyewash station may be used as a mixed used sink. The Site had no concerns. The Site Map & Photos will be administratively updated.
 - The Committee discussed the minimum required PPE for handling the agent inside or outside of containment. The Committee agreed that the minimum requirements listed on the Biohazard Sign are sufficient. The Facility Details form will be administratively updated.
 - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

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.

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IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:24 PM

Post-Meeting Pre-Approval Note: None