Meeting Minutes

Institution:	Virginia Oncology Associates (VOA)
Meeting Date:	October 23, 2025
Meeting Time	9:30 AM Eastern 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 Marz, Aylin / Yes / Local Unaffiliated Member Welch, Nancy (left at 10:16am) / Yes / Local Unaffiliated Member Gobhardt, Wendi / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** None
Guests:	Morris, Chris
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 9:31 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 9/15/25 were approved by the IBC with no changes.

New Business:

PI:	Simmons, Gary DO
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 Biohazard Sign will be administratively updated to indicate T cells are transduced with a replication defective lentiviral vector.
    - In response to a question from the Committee, the Site confirmed the study agent is sent to the Site as a just-in-time delivery and is kept in the dewar until use. .
    - The Committee recommended the shredder seen in the Nurse's area photo be moved away from the preparation area and that the waste containers be placed directly under the preparation area instead.
    - The Committee noted a food item on the Nurse's station in one of the photo slides. The Committee reminded the Site that food should be kept away from the preparation area. The Committee stipulated that the Site remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25.
    - In response to a question from the Committee, the Site clarified that IV bags and chemotherapy waste go in yellow biohazard waste containers and red biohazard waste containers are used for sharps. The Committee noted there are non-sharps seen in the photo of the red sharps container and reminded the Site to keep sharps and non-sharps waste separated. The Site indicated they would remind staff of this practice.

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 remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Simmons, Gary DO
Sponsor:	Juno Therapeutics, Inc.
Protocol:	CA0881000 A Phase 2, Open-Label, Multicenter Study of BMS-986393, a GPRC5D-directed CAR T Cell Therapy in Adult Participants with Relapsed or Refractory Multiple Myeloma (QUINTESSENTIAL)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CA0881000 is an open-label Phase II trial sponsored by Juno Therapeutics, Inc., a Bristol-Myers Squibb Company, and designed to assess the efficacy and safety of BMS-986393 (arlocabtagene autoleucel), an autologous cellular product expressing a Chimeric Antigen Receptor (CAR) targeting GPRC5D, for the treatment of adult participants with relapsed and/or refractory multiple myeloma who have received at least 3 prior lines of therapy. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent BMS-986393 consists of primary human cells transduced with a recombinant, replication-defective lentiviral vector derived from a Risk-Group 3 lentivirus, BSL2 containment is the recommended biocontainment level under the NIH Guidelines II-A-3. This study also requires compliance with the OSHA Bloodborne Pathogens Standard.

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 when handling the catheter needle. 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 Site confirmed the accuracy of the Annual Review Report.
  - The Committee recommended the shredder seen in the Nurse's area photo be moved away from the preparation area and that the waste containers be placed directly under the preparation area instead.
  - In response to a question from the Committee, the Site clarified that IV bags and chemotherapy waste go in yellow biohazard waste containers and the red biohazard waste containers are used for sharps. The Committee noted there are non-sharps seen in the photo of the red sharps container and reminded the Site to keep sharps and non-sharps waste separated. The Site indicated they would remind staff of this practice.
  - The Committee noted a food item on the Nurse's station in one of the photo slides. The Committee reminded the Site that food should be kept away from the preparation area. The Committee stipulated that the Site remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25.

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 remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Simmons, Gary DO
Sponsor:	Caribou Biosciences, Inc.
Protocol:	CB10A 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)

Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: CB10A is a Phase I CAR-T cell study sponsored by Caribou Biosciences, Inc. and designed to assess the safety, tolerability, and efficacy of CB-010, an allogeneic T cell product genome edited to express a chimeric antigen receptor (CAR) targeting the tumor antigen CD19 in patients with relapsed or refractory B-cell non-Hodgkin lymphoma. The study agent CB-010 has been genetically engineered to disrupt the genes encoding the native T cell receptor alpha chain (TRAC) and checkpoint inhibitor protein programmed cell death-1 (PDCD1), and to insert an anti-CD19 CAR expression cassette into the disrupted TRAC locus. The genomic disruptions are created by electroporation with CRISPR/Cas9 ribonucleoprotein complexes, 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 CB-010 consists of primary human cells engineered with a recombinant Risk Group 1 AAV vector, therefore BSL-2 is the recommended containment level under section II-A-3 of 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 needlestick, 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 Site confirmed the accuracy of the Annual Review Report.
    - The Committee recommended the shredder seen in the Nurse's area photo be moved away from the preparation area and that the waste containers be placed directly under the preparation area instead.
    - In response to a question from the Committee, the Site clarified that IV bags and chemotherapy waste go in yellow biohazard waste containers and the red biohazard waste containers are used for sharps. The Committee noted there are non-sharps seen in the photo of the red sharps container and reminded the Site to keep sharps and non-sharps waste separated. The Site indicated they would remind staff of this practice.
    - The Committee noted a food item on the Nurse's station in one of the photo slides. The Committee reminded the Site that food should be kept away from the preparation area. The Committee stipulated that the Site remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25.

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 remind staff to keep food and drinks out of the study agent preparation area and provide an updated photo of the Nurse's station with the food removed by 11/22/25. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Kok, Boon MD
Sponsor:	Genprex, Inc.
Protocol:	ONC-003 A Phase 1/2 Open-Label, Dose-Escalation and Clinical Response Study of Quaratusugene Ozeplasmid in Combination with Osimertinib in Patients with Advanced, EGFR-Mutant, Metastatic Non-Small Cell Lung Cancer who have Progressed after Treatment with Osimertinib
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial

Summary: ONC-003 (Acclaim-1 Trial) is a Phase 1/2 open-label trial sponsored by Genprex Inc.

designed to identify the maximum tolerated dose (MTD) and progression-free survival of quaratusugene ozeplasmid (Reqorsa® ; formerly known as GPX-001), in combination with osimertinib (Tagrisso®) for treatment of participants with advanced metastatic non-small cell lung cancer (NSCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the TUSC2 tumor suppressor gene and complexed in a cholesterol nanoparticle. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because 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 carcinogenic properties, BSL1 containment can be considered as the minimum biocontainment level. The administration of this agent by intravenous injection in a clinical setting requires compliance with the Bloodborne Pathogens Standard.

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 needlesticks, spills, and 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 Site confirmed the accuracy of the Annual Review Report.

- The Committee reminded the Site that the Biosafety Cabinet (BSC) will be due for recertification next month and to provide the BSC recertification report once available.
- In response to a question from the Committee, the Site confirmed that agent preparation takes place before participants are brought into the room for administration. The Facility Details form will be updated to note this practice.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions 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 10:31 AM.

Post-Meeting Pre-Approval Note: The Site provided the requested updated photo of the Nurse's Station without food soon after the end of the meeting, fulfilling the discussed stipulation. Full Approval was granted for the applicable studies.