

Meeting Minutes



Institution:	St. David's South Austin Medical Center		
Meeting Date:	December 12, 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
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Holden, Leticia	Yes	Local Unaffiliated Member
	Levin, Patricia	Yes	Local Unaffiliated Member
	Longoria, Amy	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Runkle, Chelsea	No	Site Contact
	Goldin, Stephanie	No	Site Contact
Guests:	Chavez, Melanie		
Staff:	Hemmelgarn, Marian		

Call to Order: The IBC Chair called the meeting to order at 10:00 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

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Previous Meeting Minutes: Minutes from 10/20/25 were approved by the IBC with no changes.

New Business:

PI:	Ramakrishnan, Aravind MD
Sponsor:	Kite Pharma, Inc.
Protocol:	KT-US-499-0150 A Phase 1/2 Open-label, Multicenter Study Evaluating the Safety and Efficacy of KITE-363 or KITE-753, Autologous Anti-CD19/CD20 CAR T-cell Therapies, in Subjects With Relapsed and/or Refractory B-cell Lymphoma
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: KT-US-499-0150 is an open-label, multicenter Phase 1/2 trial sponsored by Kite Pharma, Inc. and designed to evaluate the safety and efficacy of KITE-363 or KITE-753 in adult participants with relapsed/refractory (r/r) B-cell lymphoma. KITE-363 and KITE-753 are autologous anti-CD19/CD20 chimeric antigen receptor (CAR) T-cell products genetically modified using a replication-deficient lentiviral vector to introduce the anti-CD19 CAR and anti-CD20 CAR transgenes. KITE-753 is a rapidly manufactured version of KITE-363. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agents KITE-363 and KITE-753 consist of primary human cells transduced with a recombinant, replication-defective form of a Risk Group 3 lentivirus, therefore BSL-2 containment is the minimum 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 needlesticks, 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 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 combine similar agents under the same description.
 - The Committee stipulated that the Site add a biohazard label to the waterbath and provide an updated photo by 1/11/26.
 - In response to a question from the Committee, the Site confirmed bedside thawing of the study agent occurs within the administration room.
 - The Committee discussed PPE, noting that eye protection is used during preparation in the BSC. The Site confirmed this is accurate. The Facility Details form will be administratively updated to add eye protection when using the BSC.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site add a biohazard label to the waterbath and provide an updated photo by 1/11/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Ramakrishnan, Aravind MD
Sponsor:	Poseida Therapeutics, Inc.
Protocol:	P-BCMA-ALLO1-001 Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-BCMA-ALLO1 in Subjects with Relapsed / Refractory Multiple Myeloma (MM)
Review Type:	Annual Review

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NIH Guidelines Section:	III-C-1
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Trial Summary: P-BCMA-ALLO1-001 (XO44788) is a Phase 1 open-label, dose escalation study sponsored by Poseida Therapeutics, Inc. to assess the safety, maximum tolerated dose (MTD), and tolerability of P-BCMA-ALLO1 in participants with B-cell maturation antigen (BCMA)-positive relapsed/refractory multiple myeloma. The study agent P-BCMA-ALLO1 consists of allogeneic T lymphocytes gene edited with a DNA transposon/Cas-CLOVER system to express the following transgenes: an anti-BCMA variable human heavy-chain domain (VH)-based Chimeric antigen receptor (vCAR), a dihydrofolate reductase (DHFR) selection gene, and an inducible caspase 9 (iCasp9)-based safety switch gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent P-BCMA-ALLO1 consists of primary human cells engineered with a DNA transposon and Cas-Clover gene editing system. BSL-2 containment is the recommended containment level for handling body fluids and tissues from all humans under NIH Guidelines Section 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 needlesticks, 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.

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- 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 add a biohazard label to the waterbath and provide an updated photo by 1/11/26.
 - In response to a question from the Committee, the Site confirmed bedside thawing of the study agent occurs within the administration room.
 - The Committee discussed PPE, noting that eye protection is used during preparation in the BSC. The Site confirmed this is accurate. The Facility Details form will be administratively updated to add eye protection when using the BSC.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site add a biohazard label to the waterbath and provide an updated photo by 1/11/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Rao, Uttam MD
Sponsor:	Tscan Therapeutics, Inc.
Protocol:	TSCAN-001 A Controlled Multi-Arm Phase 1 Umbrella Study Evaluating the Safety and Feasibility of T-Cell Receptor Engineered Donor T-Cells Targeting HA-1 (TSC-100) or HA-2 (TSC-101) in HLA-A*02:01 Positive Patients Undergoing Haploidentical Allogeneic Peripheral Blood Stem Cell Transplantation
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: TSCAN-001 is a non-randomized, open-label Phase 1 study sponsored by TScan Therapeutics, Inc. and designed to evaluate the feasibility, safety, and preliminary efficacy of TSC-100 and TSC-101 combined with standard of care in adult participants with acute myeloid leukemia, myelodysplastic syndromes, or acute lymphoblastic leukemia who have received hematopoietic stem cell transplantation (HCT). TSC-100 and TSC-101 are recombinant allogeneic T Cell Receptor (TCR) T cells (TCR-T) intended to augment the graft-vs.-leukemia (GvL) response following HCT and express TCRs against minor histocompatibility antigen HA-1+ (TSC-100) or HA-2+ (TSC-101)

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when presented on Human Leukocyte Antigen A*02:01 (HLA-A*02:01). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The TSC-100 and TSC-101 study agents each consist of primary human cells engineered with a transposon plasmid system derived from *S. frugiperda* and does not encode any known toxins or oncogenes, therefore BSL-2 is the recommended containment 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 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 add a biohazard label to the waterbath and provide an updated photo by 1/11/26.
 - In response to a question from the Committee, the Site confirmed bedside thawing of the study agent occurs within the administration room.

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- The Committee discussed PPE, noting that eye protection is used during preparation in the BSC. The Site confirmed this is accurate. The Facility Details form will be administratively updated to add eye protection when using the BSC.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee:
 - The Committee stipulated that the Site add a biohazard label to the waterbath and provide an updated photo by 1/11/26. 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 10:50 AM

Post-Meeting Pre-Approval Note: None