

Meeting Minutes



Institution:	St. David's South Austin Medical Center		
Meeting Date:	March 03, 2026		
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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
	Levin, Patricia	Yes	Local Unaffiliated Member
	Holden, Letitia	Yes	Local Unaffiliated Member
	Goldin, Stephanie (arrived at 10:09 AM)	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Runkle, Chelsey	No	Site Contact
	Longoria, Amy	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.

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Review of Prior Business: None

Previous Meeting Minutes: Minutes from 2/3/26 were approved by the IBC with no changes.

New Business:

PI:	Ramakrishnan, Aravind MD
Sponsor:	AstraZeneca AB
Protocol:	D8311C00001 A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CART) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma.
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: D8311C00001 is a randomized, open-label, multicenter Phase III clinical trial sponsored by AstraZeneca designed to evaluate the safety and efficacy of AZD0120 (a dual-targeting autologous CAR-T therapy) in adult participants with relapsed or refractory multiple myeloma (RRMM). The investigational product, AZD0120, consists of autologous T cells transduced with a lentiviral vector encoding a dual anti-CD19 and anti-BCMA chimeric antigen receptor (CAR). The investigational product (IP) is administered by intravenous (IV) infusion.

Biosafety Containment Level (BSL): The study agent AZD0120 consists of primary human cells transduced with a recombinant Risk Group 3 lentiviral vector; therefore, BSL2 containment is considered the minimum biocontainment level under the NIH Guidelines. Since this agent consists of primary human cells with the potential for transmission of bloodborne pathogens, compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) is also required.

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, splashes or needlesticks 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

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- 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 Site confirmed that all the treatment rooms at the Cancer Care Clinic have sharps containers. The Chair noted that a photo had been previously provided and will be added to the corresponding slide in the Site photos file.

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

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

PI:	Ramakrishnan, Aravind MD
Sponsor:	Autolus Inc.
Protocol:	AUTO1-OS1 Expanded Access Program (EAP) for Obecabtagene-Autoleucel (obecel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: AUTO1-OS1 is a single-arm, open-label, expanded access program (EAP) sponsored by Autolus Inc. to provide access to an out-of-specification (OOS) product,

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obecabtagene autoleucel (obe-cel), to adult patients with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (ALL). Obe-cel is a recombinant autologous T cell agent expressing a chimeric antigen receptor (CAR) targeting tumor antigen CD19. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent obe-cel consists of primary human cells transduced with a recombinant, replication-defective Risk-Group 3 lentiviral vector, BSL2 containment is considered 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, splashes or needlestick exposures 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 Site confirmed that all the treatment rooms at the Cancer Care Clinic have sharps containers. The Chair noted that a photo had been previously provided and will be added to the corresponding slide in the Site photos file.

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

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

PI:	Ramakrishnan, Aravind MD
Sponsor:	Juno Therapeutics, Inc.
Protocol:	CAR017-EAP-001 Expanded Access Protocol (EAP) for Subjects Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: JCAR017-EAP-001 is an expanded access clinical trial sponsored by Juno Therapeutics and designed to provide access to lisocabtagene maraleucel (liso-cel; Breyanzi®; formerly JCAR017), a CAR-T cell-based agent, when the manufacturing process is not able to produce the necessary number or characteristic of cells required for commercial release, and when remanufacturing is not feasible. Liso-cel consists of the patient's own (autologous) T lymphocytes that have been transduced with a recombinant, replication-defective lentiviral vector to express a chimeric antigen receptor (CAR) targeting the tumor antigen CD19, along with a truncated form of the human protein Epidermal Growth Factor Receptor (EGFRt) as a reporter gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the liso-cel product consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus prepared with packaging genes, BSL2 containment is considered the default biocontainment level under the NIH Guidelines. This agent also includes primary human cells with the potential for bloodborne pathogens, further requiring compliance with the OSHA Bloodborne Pathogen 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, splashes or needlesticks of the IP during preparation and/or administration procedures. These potential risks are mitigated through a combination of

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

- 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: 49 AM

Post-Meeting Pre-Approval Note: None