

Meeting Minutes



Institution:	St. David's South Austin Medical Center		
Meeting Date:	February 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
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Levin, Patricia	Yes	Local Unaffiliated Member
	Holden, Letitia	Yes	Local Unaffiliated Member
	Goldin, Stephanie	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 10:02 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 12/12/25 were approved by the IBC with no changes.

New Business:

PI:	Ramakrishnan, Aravind MD
Sponsor:	AstraZeneca Pharmaceuticals LP
Protocol:	D8310C00001 (GC012F-CD19/BCMA-001) A Phase Ib/II Study of AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR T) Therapy Directed Against CD19 and B-cell Maturation Antigen (BCMA) in Participants with Relapsed/Refractory Multiple Myeloma (DURGA-1)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: D8310C00001 (GC012F-CD19/BCMA-001) is an open-label single-arm Phase Ib/II clinical trial sponsored by AstraZeneca Pharmaceuticals LP and designed to evaluate the safety, tolerability, and efficacy of AZD0120 (previously GC012F) in adult participants with relapsed/refractory multiple myeloma after receiving at least three prior treatment lines of therapy. AZD0120 is composed of autologous T cells genetically engineered with a replication-deficient recombinant lentiviral vector to express dual-targeting chimeric antigen receptors (CARs) against CD19 and B-cell maturation antigen (BCMA). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent AZD0120 (GC012F) consists of primary human cells transduced with a recombinant Risk Group 3 lentiviral vector, BSL2 containment is considered the default biocontainment level under the NIH Guidelines. This agent also includes primary human cells with the potential for transmission of bloodborne pathogens, further requiring 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, splashes, and/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).

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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 accuracy of the Annual Review Report.
 - The Committee discussed access control to the CTL temporary biohazard waste storage area. The Committee stipulated that the Site provide confirmation that the area is access controlled by 3/2/26.
 - The Committee discussed access control to the outside biohazard waste storage containers. The Committee stipulated that the Site provide confirmation that the containers are access controlled by 3/2/26.

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 provide confirmation that the CTL temporary biohazard waste storage area is access controlled by 3/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
 - The Committee stipulated that the Site provide confirmation that the outside biohazard waste storage containers are access controlled by 3/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Ramakrishnan, Aravind MD
Sponsor:	Collectis S.A.
Protocol:	UCART22_01

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	Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: UCART22_01 is a Phase I/II open-label, dose-escalation, sub-study, and expansion study sponsored by Cellectis S.A. and designed to assess the safety, tolerability, and maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of UCART22, a genetically engineered allogeneic T cell product expressing a Chimeric Antigen Receptor (CAR) against tumor antigen CD22 in participants with relapsed/refractory CD22+ B-cell Acute Lymphoblastic Leukemia (r/r B-ALL). The UCART22 cells are engineered using a recombinant lentiviral vector to insert an anti-CD22 CAR as well as a RQR8 depletion ligand as a “safety switch” to enable clearance of the UCART22 cells by administering rituximab. Additionally, the UCART22 cells have been engineered with a TALEN-based nuclease to knock out expression of the native T cell receptor (TCR) to prevent graft rejection and the native CD52 gene to allow use of alemtuzumab (CLLS52) in the lymphodepletion regimen. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent UCART22 consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, BSL2 containment is the recommended containment level under the NIH Guidelines. This agent also includes primary human cells with the potential for transmission of bloodborne pathogens, further requiring compliance with OSHA Bloodborne Pathogens Standard Precautions.

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, and/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).

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Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

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Adjournment: The IBC Chair adjourned the meeting at 10:45 AM

Post-Meeting Pre-Approval Note: None