

Meeting Minutes



Institution:	City of Hope Lennar Center		
Meeting Date:	July 07, 2026		
Meeting Time	1:00 PM Pacific Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	De Zoysa, Prashan	Yes	Local Unaffiliated Member
	Hauke, Caitlyn A.	Yes	Chair: Biosafety Expert/HGT Expert
	Makmura, Linna	No	Site Contact - Rostered
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Tafoya, Christine	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	Member	Voting	Member Type
	Enriquez, Rowelle	No	Site Contact - Rostered
	Kim, Jennifer	No	Site Contact - Rostered
Guests:	Gou, Dawei Amshaqn, Ash		
Staff:	Mahrt, Elena		

Call to Order: The IBC Chair called the meeting to order at 12:44 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.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 06/26/2026 were approved by the IBC with no changes. There were no votes against and no abstentions.

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New Business:

PI:	Lee, Lisa X MD
Sponsor:	AstraZeneca AB
Protocol:	D7540C00001: A Modular, Phase I/II, Open-label, Multicentre Study to Evaluate the Safety, Tolerability, Cellular Kinetics, and Efficacy of AZD4045, an Allogeneic Chimeric Antigen Receptor-T cell (CAR-T) Therapy Targeting B Cell Maturation Antigen (BCMA) in Participants with Relapsed or Refractory Multiple Myeloma
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: D7540C00001 is a modular, single-arm, open-label multicenter Phase I/II clinical trial sponsored by AstraZeneca AB and designed to assess the safety, tolerability, cellular kinetics, and preliminary efficacy of the study agent AZD4045 as a potential anticancer therapy in adult participants with relapsed or refractory multiple myeloma (RRMM) who have received at least 3 prior lines of therapy, including a proteasome inhibitor, immunomodulatory drug, and anti-CD38 antibody. AZD4045 is an allogeneic, off-the-shelf, B cell maturation antigen (BCMA)-targeted chimeric antigen receptor (CAR) T-cell product derived from healthy donor T cells and genetically modified for broad patient applicability. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent AZD4045 consists of CRISPR/Cas9-edited human cells, Biosafety Level 2 (BSL-2) containment is considered appropriate for handling under the NIH Guidelines, consistent with work involving human-derived materials and gene-modified cells. This agent also includes viable 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 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 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 Committee reminded the Site that the BBP training records on file are approaching expiry. The Site confirmed that BBP training refresher courses have been completed by at least one staff member and an updated training record will be provided. The Committee had no concerns.
 - The Site noted that the Sponsor allows for preparation of the study agent at the bedside. The Committee had no concerns with administratively revising the Biohazard Sign and Facility Details Form to reflect the additional bedside preparation locations.

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.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 12:51 PM

Post-Meeting Pre-Approval Note: None