Meeting Minutes

Institution:	The Sir Mortimer B. Davis Jewish General Hospital
Meeting Date:	February 09, 2026
Meeting Time	2:30 PM Eastern 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
McGirr, Becky	Yes	Core Member: Biosafety Expert/HGT Expert
Venugopal, Devi	Yes	Local Unaffiliated Member
Nair, Amogh	Yes	Local Unaffiliated Member
Scarborough, Robert	Yes	Biological Safety Officer

Invited Members Not in Attendance:	None
Guests:	Cascini, Adele; Bartolucci, Rita; Sullivan, Thomas
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 2:32 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 10/14/25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Ma, Kim
Sponsor:	Genentech, Inc.
Protocol:	GO44479 A Phase II, Open-Label, Multicenter, Randomized Study Of The Efficacy And Safety Of Adjuvant Autogene Cevumeran Plus Atezolizumab And mFOLFIRINOX Versus mFOLFIRINOX Alone In Patients With Resected Pancreatic Ductal Adenocarcinoma
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: GO44479 is a randomized, open-label, Phase II trial sponsored by Genentech, Inc. and designed to assess the safety and efficacy of autogene cevumeran (RO7198457) plus atezolizumab and mFOLFIRINOX (leucovorin, 5-fluorouracil, irinotecan, and oxaliplatin) versus mFOLFIRINOX alone as an adjuvant therapy for adult participants with resected pancreatic ductal adenocarcinoma. Autogene cevumeran is an individualized neoantigen specific immunotherapy consisting of messenger RNAs (mRNA) expressing individualized tumor antigens and formulated in a lipid nanoparticle. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent autogene cevumeran consist of synthetic mRNA that is not infectious, does not encode any hazardous transgenes, and does not integrate, BSL1/CL1 containment is considered the minimum biocontainment level. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens (BBP) 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).

- 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 Committee confirmed the purpose of the training card is for proof of training and it should contain accurate info. The Committee agreed the printed CITI certificate would be adequate as confirmation.
    - The Site confirmed that a sharps container is placed in the BSC during preparation for sharps waste and that the whole sharps container is later placed in the larger red container, where non-sharps waste is also disposed of. The Committee had no concerns.
    - The Site confirmed that for administration, non-sharps waste is placed in the red bin, which is present in the room, and sharps waste is placed in the yellow sharps container.
    - The Site confirmed that no study related waste is placed in the non-hazardous black waste containers.
    - The Site confirmed the proximity of the plumbed eyewash to the dosing rooms.
    - The Committee discussed the biosafety containment level for this study and agreed that BSL-1/CL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2/CL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Full Approval for the study at CL-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.

Meeting Minutes

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:17 PM.

Post-Meeting Pre-Approval Note: None