Meeting Minutes

Institution:	The Sir Mortimer B. Davis Jewish General Hospital
Meeting Date:	October 14, 2025
Meeting Time	10:00 AM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Spinato, Joanna / 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:	Sullivan, Thomas
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 10:01 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

Previous Meeting Minutes: Minutes from 5/14/25 were approved by the IBC with no changes.

New Business:

PI:	Ferrario, Cristiano
Sponsor:	F. Hoffmann-La Roche Ltd
Protocol:	BO45230 A Randomized Phase II, Double-Blind, Multicenter Study Evaluating the Efficacy and Safety of Autogene Cevumeran plus Nivolumab Versus Nivolumab as Adjuvant Therapy in Patients with High-Risk Muscle-Invasive Urothelial Carcinoma
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: BO45230 is a randomized, double-blind, Phase II trial sponsored by F. Hoffmann-La Roche Ltd and designed to assess the safety and efficacy of autogene cevumeran (RO7198457) as an adjuvant combination treatment with nivolumab in adult participants with qualifying high-risk muscle-invasive urothelial carcinoma (MIUC). Autogene cevumeran is a therapeutic cancer vaccine consisting of a messenger RNA (mRNA) molecule expressing personalized tumor antigens and is formulated as an RNA-lipid nanoparticle. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent autogene cevumeran consists 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 Site confirmed that recertification of the BSC that is due for recertification by the end of November has been scheduled for early November and will provide Sabai with the updated certificate when it is available.
  - The Site confirmed that the door leading out of the BSC room opens in the direction of the eyewash.
  - The Committee noted the zoomed in photo of the -20° freezer does not match the zoomed-out photo. The Site will send an updated photo of the -20° freezer.
  - The Site confirmed that the sharps container placed in the BSC is the smaller container shown on the floor in the photo, not the sharps container on casters.
  - The Committee noted that some of the administration chairs look worn and may no longer be non-absorbent. The Site confirmed the chairs have been replaced and will send Sabai updated photos.
  - The Site confirmed that the biosafety training is refreshed every 3 years and the emergency SOPs are refreshed annually.
  - The Committee noted that not all the IATA training topics are checked in the certification and recommended that the Site ensure personnel are adequately trained. The site indicated they would ensure all topics are covered.
  - The Committee discussed the biosafety containment level for this study and agreed that CL-1 (plus Routine Practices) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at 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.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:37 AM

Post-Meeting Pre-Approval Note: None