Meeting Minutes

Institution:	The Research Institute of the McGill University Health Centre
Meeting Date:	September 08, 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
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Pressman, Cynthia	Yes	Core Member: Biosafety Expert/HGT Expert
Nair, Amogh	Yes	Local Unaffiliated Member
Kunin, Wendy	Yes	Local Unaffiliated Member
Vuong, Dac Hien	No	Biological Safety Officer

Invited Members Not in Attendance:	None
Guests:	Leroux, Dianna (left at 10:39 AM EST)
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 8-1-25 were approved by the IBC with no changes.

New Business:

PI:	Kassouf, Wassim
Sponsor:	CG Oncology
Protocol:	PIVOT-006 A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate-Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: PIVOT-006 is an open-label, randomized, Phase III clinical trial sponsored by CG Oncology designed to assess the safety and efficacy of cretostimogene grenadenorepvec ("cretostimogene"; previously known as CG0070) in adults with intermediate-risk non-muscle invasive bladder cancer (IR-NMIBC). Cretostimogene is a recombinant, conditionally replicating oncolytic adenovirus engineered to express human granulocyte-macrophage colony-stimulating factor (GM-CSF). The investigational product (IP) is administered by Intra-vesicular Instillation.

Biosafety Containment Level (BSL): The study agent cretostimogene is based on a recombinant Risk Group 2 virus containing more than two-thirds of the native genome, requiring the use of BSL-2/CL-2 containment 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, aerosols and 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 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: The Sponsor notes that individuals who are at a potentially higher risk from working with or handling the study agent, such as pregnant or breastfeeding women and severely immunosuppressed or immunocompromised individuals, should not prepare, administer, or otherwise handle the study agent or materials contaminated with the study agent or provide direct care for treated participants presenting with any symptoms of illness attributed to cretostimogene for at least 1 week after treatment or until complete resolution of symptoms.
- 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 the BSCs will be recertified this month. The Committee stipulated that the Site send Sabai the updated BSC Certification reports when they are available by 10/8/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Site confirmed that the biosafety training is renewed every 3 years and the shipping training is renewed every 2 years. The Site indicated that training requirements are outlined in applicable standard operating procedures and reminders are sent to employees for training renewals.
  - The Site confirmed that their Occupational Health team has a process for identifying personnel with medical conditions of concern that might prohibit them from working with the study agent or treated participants.
  - The Site confirmed that eyewash bottles are checked every 6 months and plumbed eyewashes are checked every 2 weeks.

Motion: A motion of Approval with Stipulations 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:
  - The Committee stipulated that the Site send Sabai the updated BSC Certification reports when they are available by 10/8/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

New Business:

PI:	Saleh, Ramy
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 the BSCs will be recertified this month. The Committee stipulated that the Site send Sabai the updated BSC Certification reports when they are available by 10/8/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Site confirmed that the biosafety training is renewed every 3 years and the shipping training is renewed every 2 years. The Site indicated that training requirements are outlined in applicable standard operating procedures and reminders are sent to employees for training renewals.
  - The Site confirmed that there is a biohazard sign on the anteroom door to the preparation area and the door to the biohazard waste storage room.

Motion: A motion of Approval with Stipulations for the study at CL-1 plus Routine Practices was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - The Committee stipulated that the Site send Sabai the updated BSC Certification reports when they are available by 10/8/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:52 AM

Post-Meeting Pre-Approval Note: None