Meeting Minutes

Institution:	VA Cancer Specialists HGT
Meeting Date:	January 12, 2026
Meeting Time	10:30 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
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Hawley, Robert	Yes	Local Unaffiliated Member
Cochrane, Monica	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Browne, Angella	Yes	Local Unaffiliated Member

Guests:	Han, Sarah Sullivan, Marcy Hooley, Morgan
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 10:31 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 9/22/25 were approved by the IBC with no changes.

New Business:

PI:	Spira, Alexander MD
Sponsor:	AMAL Therapeutics S.A.
Protocol:	KISIMA-02 A Phase 1b Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of a Heterologous Prime Boost Vaccination (ATP150/ATP152/ATP162, VSV-GP154) and Ezabenlimab (BI 754091) in Patients with Pancreatic Ductal Adenocarcinoma
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: KISIMA-02 is an open-label Phase 1b clinical trial sponsored by AMAL Therapeutics S.A. and designed to assess the safety, tolerability, maximum tolerated dose (MTD) and/or recommended phase 2 dose (RP2D), preliminary efficacy, and immunogenicity of a heterologous prime boost vaccine (protein and viral vector) regimen with the PD-1 inhibitor Ezabenlimab for the treatment of participants with pancreatic ductal adenocarcinoma (PDAC). The viral vector vaccine study agent VSV-GP154 is a recombinant, conditionally replication-competent vesicular stomatitis virus (VSV) engineered to express a multiple antigenic domain (Mad) composed of tumor-specific antigens to allow the induction of a Mad-specific cellular immune response: CEACAM5, KRAS-G12D, KRAS-G12V, KRAS-uORF1, TPX2-uORF1, AURKA-uORF, and DUOXA2. The protein vaccine study agents ATP150 and ATP152 are immunogenic recombinant proteins each consisting of three functional domains including six of the tumor-specific antigens that comprise the Mad found in VSV-GP154. ATP162 refers to a 1:1 equimolar mixture of ATP150 and ATP152. The investigational product (IP) is administered by intravenous (IV) injection.

Biosafety Containment Level (BSL): The study agent VSV-GP154 is based on a recombinant Risk Group 2 vesicular stomatitis virus containing more than two thirds of the native viral genome, requiring the use of BSL-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 needlesticks, spills or splashes 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: Based on information from the Sponsor, pregnant or immunosuppressed study personnel should not prepare or administer the study agent VSV-GP154 and should not come into direct contact with the injection sites, dressings, or body fluids of treated participants that may contain spread virus.
- 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 the Biosafety Cabinet report noting that the BSC's in the photos are ducted with a canopy connection, but the reports do not indicate the BSC's are ducted. The Committee suggested this may be a nuance from the certifier and informed the Site for awareness.
  - The Committee noted that plumbed eyewash stations are flushed weekly and recommended using plumbed eyewashes over eyewash bottles.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Spira, Alexander MD
Sponsor:	Genprex, Inc.
Protocol:	ONC-005 A Phase 1/2 Clinical Trial of Quaratusugene Ozeplasmid and Atezolizumab Maintenance Therapy in Patients with Extensive Stage Small Cell Lung Cancer (ES-SCLC)
Review Type:	Annual Review

NIH Guidelines Section:	III-C-1

Trial Summary: ONC-005 (Acclaim-3 Trial) is a Phase I/II open-label trial sponsored by Genprex Inc. designed to identify the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D), safety profile, and progression-free survival (PFS) of quaratusugene ozeplasmid (REQORSA®) in combination with atezolizumab in adults with extensive stage-small cell lung cancer (ES-SCLC). Quaratusugene ozeplasmid is a recombinant DNA plasmid expressing the TUSC2 tumor suppressor gene. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent quaratusugene ozeplasmid consists of a recombinant DNA plasmid incapable of replication and which encodes for a protein with no known toxic or tumorigenic properties, therefore, BSL-1 containment is the recommended biocontainment level. The administration of this agent in a clinical setting requires 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 needlesticks, spills or splashes 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 the accuracy of the Annual Review Report.
- The Committee discussed the Biosafety Cabinet report noting that the BSC's in the photos are ducted with a canopy connection, but the reports do not indicate the BSC's are ducted. The Committee suggested this may be a nuance from the certifier and informed the Site for awareness.
- The Committee noted that plumbed eyewash stations are flushed weekly and recommended using plumbed eyewashes over eyewash bottles.
- The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-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 BSL-2 was passed by unanimous vote.

- 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 11:13 AM

Post-Meeting Pre-Approval Note: None