Meeting Minutes

Institution:	City of Hope HGT		
Meeting Date:	August 19, 2025		
Meeting Time	12:00 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
	Casebolt, Tamara	Yes	Biosafety Officer
	Hauke, Caitlyn A.	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Tafoya, Christine	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Makmura, Linna	No	Site Contact
	Amshaqn, Ashraf	Yes	Biological Safety Officer
	Enriquez, Rowelle	No	Site Contact
Guests:	Betram, Rickey Dekalb, Charlene Srisatidnarakul, Suwannee		
Staff:	Stark, Casey		

Call to Order: The IBC Chair called the meeting to order at 12:02 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 7-15-25 were approved by the IBC with no changes.

New Business:

PI:	Maghami, Ellie MD, FACS
Sponsor:	MeiraGTx, LLC
Protocol:	MGT-AQP1-201: A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: MGT-AQP1-201 is a double-blinded, placebo-controlled Phase II clinical trial sponsored by MeiraGTx, Ltd., and designed to assess the efficacy and safety of AAV2-hAQP1, a recombinant, replication-defective serotype 2 adeno-associated virus (AAV2) for the treatment of late xerostomia (dry mouth) caused by radiotherapy for cancers of the upper aerodigestive tract. AAV2-hAQP1 is designed to introduce functional hAQP1, a water channel protein, to the salivary gland to restore saliva flow. The investigational product (IP) is administered by intraoral, retroductal cannulation administration.

Biosafety Containment Level (BSL): The study agent AAV2-hAQP1 is based on a recombinant AAV (rAAV) that does not contain a potentially hazardous transgene and is produced in the absence of a helper virus, and therefore is classified as a Risk Group 1 (RG1) agent under the NIH Guidelines. As such, biosafety level-1 (BSL-1) may be considered as the minimum containment level for handling the study agent. The administration of this agent in a clinical setting further requires compliance with the OSHA Bloodborne Pathogen 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).

- 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 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. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

PI:	Rugo, Hope MD
Sponsor:	Quantum Leap Healthcare Collaborative
Protocol:	I-SPY 2 TRIAL: I-SPY 2 TRIAL– Investigation of Serial Studies to Predict your Therapeutic Response with Imaging and Molecular Analysis 2
Review Type:	Change in Research Review (Change in PI)
NIH Guidelines Section:	III-C-1

Trial Summary: I-SPY 2 TRIAL is sponsored by Quantum Leap Healthcare Collaborative and designed to evaluate and develop biomarkers of early response to therapeutic regimens, and to develop a strategy to improve outcomes of adults with locally advanced Stage II or III breast cancer with high risk for early recurrence. This platform trial will continue until agents or agent

combinations are discovered that achieve the endpoint of over 90% pathologic complete response rates in all high-risk breast cancer subtypes. The investigational product (IP) is administered by intratumoral injection.

Biosafety Containment Level (BSL): The study agent VSV-IFNβ-NIS (VV1) is based on a recombinant Risk Group 2 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 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).
    - 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: Clinical staff who are immunocompromised or pregnant should not prepare or administer the study agent VSV-IFNβ-NIS and, along with close contacts of the study participant, should not come into direct contact with the injection sites, dressings, or body fluids of treated participants.
    - 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 Chair noted that this Change in Research is for a Principal Investigator change to Dr. Hope Rugo. The Committee had no concerns with this change.

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 12:36 PM

Post-Meeting Pre-Approval Note: None