Meeting Minutes

Meeting Date:	Wednesday, August 6, 2025 at 9:00 AM Pacific Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Members in Attendance:	Hauke, Caitlyn Campbell, Mark Rastein, Daniel Makmura, Linna Tafoya, Christine Rebujio Abegania, Judi (non-voting)
Invited Members Not in Attendance:	Zhou, Jennifer
Guests:	Azadbadi, Zahra (left at10:09 AM)
Staff:	Stark, Casey
Institution:	University of California, Irvine HGT

Call to Order: The meeting was called to order at 9:01 AM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Uchio, Edward MD, FACS, CPI
Sponsor:	CG Oncology, Inc.
Protocol:	CORE-008 A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: CORE-008 is a multi-arm, open-label Phase II trial sponsored by CG Oncology, Inc. and designed to assess the safety and efficacy of cretostimogene grenadenorepvec in participants with high-risk non-muscle invasive bladder cancer. The study agent cretostimogene grenadenorepvec consists of a recombinant, conditionally replicating oncolytic adenovirus.

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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 explained that biohazard signage is not posted in patient areas per Institutional Policy. The Site Checklist will be administratively updated to note this practice.
    - The Committee discussed that the Facility Details report noted special precaution practices for individuals who are at a potentially higher risk from working or handling the study agent. The Site confirmed that staff instructions on risks would be provided to the staff separately in lieu of biohazard signage in patient areas. The Facility Details report will be administratively updated to reflect this practice.
    - The Committee noted that the representative Site Map for the Center for Urological Care appears to show the plumbed eyewash behind walls. The Site confirmed that the depicted walls in the map are not present. The Site Map will be administratively updated to remove the non-existent walls. The Committee requested a note be added to the Facility Details report that the plumbed eyewash is located in an exam room.
    - The Site noted that to their knowledge, Chao Pharmacy does not have an ultra-low freezer and explained that typically study agents requiring the ultra-low freezer would be stored in the IDS Pharmacy. The Committee stipulated that the Site confirm the location of study agent storage. If study agent will be stored in the Chao Pharmacy, the Committee stipulated that a picture of the ultra-low freezer be provided. If the study agent is stored in the IDS Pharmacy, the Committee agreed that the Facility Details report and related study attachments can be administratively updated.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - Confirm the location of study agent storage. If study agent will be stored in the Chao Pharmacy, submit a picture of the ultra-low freezer by 9/6/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Tran, Thuy MD
Sponsor:	Replimune, Inc.
Protocol:	RP1-104 A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: RP1-104 is a Phase III, randomized, open-label study sponsored by Replimune, Inc. and designed to assess the efficacy of Vusolimogene Oderparepvec (VO; also known as RP1), a recombinant, selectively replicating oncolytic Type 1 Herpes Simplex Virus (HSV-1), in combination with nivolumab for the treatment of participants with qualifying advanced melanoma that has progressed on anti-PD-1 and anti-CTLA-4 treatment.

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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 noted that the Risk Assessment describes priming the study agent at the bedside and questioned if the study team would be following this practice or priming the study agent elsewhere. The Site representative was unsure on the priming practices. The Committee stipulated that the Site confirm where the study agent will be primed and how priming occurs, either in the cap or under sterile gauze. If study agent will be primed at the bedside, a note will be administratively added to the Facility Details report regarding this practice.
    - The Facility Details report will be administratively updated to indicate that catheters are not used for this study.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - Confirm where the study agent will be primed and how priming occurs by 9/6/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Kuppermann, Baruch MD, PhD
Sponsor:	Ray Therapeutics, Inc.
Protocol:	RTx-015-CP-101
	Phase 1, Open-Label, Dose-Escalation Study to Evaluate Safety of a Single Intravitreal Injection of RTx-015 in Patients with Retinitis Pigmentosa
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: RTx-015-CP-101 is an open-label Phase I clinical trial sponsored by Ray Therapeutics designed to assess the safety and preliminary efficacy of RTx-015, a recombinant adeno-associated virus (rAAV) vector expressing the channelrhodopsin protein, ChRown, in participants with retinitis pigmentosa (RP).

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, 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 explained that the GMP Facility was shut down for the month of July and the biosafety cabinet has not yet been recertified because the blower motor on the cabinet is currently not functioning properly. The Site is actively working to schedule repair and

recertification of the biosafety cabinet. The Committee stipulated the Site provide the updated biosafety cabinet recertification report once available.
    - The Facility Details report will be administratively updated to indicate that catheters are not used for this study.
    - 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 Approval with Stipulations for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - Provide the updated biosafety cabinet recertification report for the GMP Facility once available by 9/6/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Reminder of IBC Approval Requirements.

Adjournment: 10:12 AM

Post-Meeting Pre-Approval Note: None