|  |  |
| --- | --- |
| **Institution:** | City of Hope HGT |
| **Meeting Date:** | July 15, 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 | Biological Safety Officer | | Hauke, Caitlyn A. | Yes | Chair: Biosafety Expert/HGT Expert | | Makmura, Linna | No | Site Contact | | Rastein, Daniel | Yes | Local Unaffiliated Member | | Tafoya, Christine | Yes | Local Unaffiliated Member | |
| **Guests**: | Gou, Dawei  Dekalb, Charlene |
| **Staff:** | Mahrt, Elena  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 6-17-25 were approved by the IBC with no changes.

**New Business:**

|  |  |
| --- | --- |
| **PI:** | Li, Daneng MD |
| **Sponsor:** | Imugene Ltd. |
| **Protocol:** | CF33-CD19-101: A Phase I, Dose Escalation and Dose Expansion, Safety and Tolerability Study of onCARlytics (CF33-CD19), Administered Intravenously or Intratumorally in Combination with Blinatumomab in Adults with Advanced or Metastatic Solid Tumors (OASIS) |
| **Review Type:** | Annual Review |
| **NIH Guidelines Section:** | III-C-1 |

**Trial Summary:** CF33-CD19-101 is an open-label, dose escalation and dose expansion, Phase I study sponsored by Imugene Ltd. to evaluate the safety and tolerability of CF33-CD19 (onCARlytics; HOV4) as a monotherapy and in combination with blinatumomab (a commercially available anti-CD19 targeting agent) with or without hydroxyurea in adult subjects with advanced or metastatic solid tumors. CF33-CD19 is a recombinant oncolytic novel chimeric orthopoxvirus (CF33) engineered to express a non-signaling, truncated CD19 antigen. The investigational product (IP) is administered by an intratumoral (IT) or intravenous (IV) administration.

**Biosafety Containment Level (BSL):** The study agent CF33-CD19 consists of a recombinant chimeric orthopoxvirus comprised mainly of vaccinia virus strains which is attenuated and classified as a Risk Group 2 agent associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available, therefore, BSL-2 containment is recommended.

**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 aerosols, spills, splashes and or needlesticks of the IP during preparation and 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 Committee discussed the BBP Training dates on file and reminded the Site that some will expire at the end of the month. The Site confirmed they could provide updated training dates.

**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:** | Aribi, Ahmed MD |
| **Sponsor:** | Kite Pharma, Inc. |
| **Protocol:** | KT-US-472-0141: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Brexucabtagene Autoleucel |
| **Review Type:** | Annual Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** KT-US-472-0141 is an Expanded Access Program (EAP) sponsored by Kite Pharma, Inc. and designed to provide patient access to a CAR-T cell product (brexucabtagene autoleucel; KTE-X19) which does not meet the pre-specified release criteria required by the US Food and Drug Administration (FDA) for commercial release. Brexucabtagene

autoleucel is an autologous T-cell product genetically engineered with a recombinant gammaretroviral vector expressing a chimeric antigen receptor (CAR) designed to target the tumor antigen CD19. This agent is very similar to the CAR-T cell agent axicabtagene ciloleucel (KTE-C19) that has been previously approved for the treatment of patients with the certain types of B cell cancers, but includes an additional step in the manufacturing process to assure the CAR-T cell product is free of residual cancer cells. The investigational product (IP) is administered by gravity feed or IV pump.

**Biosafety Containment Level (BSL):** Brexucabtagene autoleucel consists of primary human cells transduced with a recombinant, replication-defective derivative of a Risk Group 2 gammaretrovirus containing less than two-thirds of the native viral genome, thus Biosafety Level 2 (BSL-2) containment is considered the recommended containment level under the NIH Guidelines. This agent also includes primary human cells with the potential for transmission of bloodborne pathogens, further requiring 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 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 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 noted a clerical error in the Facility Details Form where the sinks should be described as being located in the hallway of an approved location. The form will be administratively revised. The Committee had no concerns.
  + The Site confirmed that vortexing of vials occurs inside of a Biosafety Cabinet. The Committee had no concerns.

**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 12:37 PM.

**Post-Meeting Pre-Approval Note:** None