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| **Meeting Date:** | June 17, 2025 at 12:00 PM Pacific Time |
| **Meeting Place:** | Teleconference (Remote)  Meeting Open to the Public |
| **Members in Attendance:** | |  | | --- | | Amshaqn, Ashraf, Biosafety Specialist | | Campbell, Mark, Non-Affiliated | | Casebolt, Tamara, Biosafety Officer | | Hauke, Caitlyn A., Chair | | Rastein, Daniel, Local Non-Affiliated | | Tafoya, Christine, Local Non-Affiliated | |
| **Guests**: | Jennifer Kim, Allen Lin, Charlene Dekalb |
| **Staff:** | Elena Mahrt, Casey Stark |
| **Institution:** | City of Hope HGT |

**Call to Order:** The meeting was called to order at 12 PM. 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:**

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| **PI:** | Goldsmith, Scott MD |
| **Sponsor:** | AstraZeneca Pharmaceuticals LP |
| **Protocol:** | D831EC00001 (GC012F-CD19/BCMA-003): A Phase 1 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Early-Line Treatment in Subjects with Multiple Myeloma |
| **Review Type:** | Initial Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** KT-US-471-0140 is an Expanded Access Program (EAP) sponsored by Kite Pharma, Inc. and designed to provide patient access to a CAR-T cell product (axicabtagene ciloleucel; KTE-C19) which does not meet the pre-specified release criteria required for commercial release. Axicabtagene ciloleucel is an autologous T-cell product genetically engineered with a recombinant gammaretroviral vector expressing a chimeric antigen receptor (CAR) designed to target the B-cell-specific cell surface marker CD19.

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, the PI’s credentials 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 location of sinks in administration areas. Most locations have sinks but in the small percentage that don’t, hand sanitizer will be used prior to exiting the rooms and then staff will wash their hands in the sinks immediately outside the rooms. The Facility Details Form (FDF) will be administratively revised to clarify this distinction between locations. The Committee had no further concerns.
  + The site confirmed that updated BBP training certificate dates will be provided soon. The Committee noted that within date certificates for some individuals were still on file.
  + The BSC certificate attached to the FDF is outdated and will be administratively replaced with the correct updated version that was available to the Committee via the event attachments page. The Committee had no concerns.
  + The Committee discussed that the Preparation Practices of the FDF should be administratively corrected to indicate that the study agent is transferred from an infusion bag to a syringe for administration. The Committee had no concerns.
  + The Committee noted that the Study Specific Special Practices for preparation of the study erroneously indicated that a dosing needle is added as part of the preparation process. The FDF will be administratively revised to remove this incorrect statement. The Committee had no concerns.

**Motion:** A motion of Full Approval 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: None

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| **PI:** | Baird, John MD |
| **Sponsor:** | Kite Pharma, Inc. |
| **Protocol:** | KT-US-471-0140: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Axicabtagene Ciloleucel |
| **Review Type:** | Annual Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** D831EC00001 (GC012F-CD19/BCMA-003) is an open-label, nonrandomized Phase I trial sponsored by AstraZeneca Pharmaceuticals LP and designed to assess the safety, tolerability, and recommended Phase 2 Dose (RP2D) of GC012F (AZD0120) as an early-line treatment in adult participants with multiple myeloma. GC012F (AZD0120) is an autologous T cell product engineered to express a dual Chimeric Antigen Receptor (CAR) targeting both CD19 and BCMA.

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 discussed the location of sinks in administration areas. Most locations have sinks but in the small percentage that don’t, hand sanitizer will be used prior to exiting the rooms and then staff will wash their hands in the sinks immediately outside the rooms. The Facility Details Form (FDF) will be administratively revised to clarify this distinction between locations. The Committee had no further concerns.
  + The site confirmed that updated BBP training certificate dates will be provided soon. The Committee noted that within date certificates for some individuals were still on file.

**Motion:** A motion of Full Approval 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: None

**Reminder of IBC Approval Requirements.**

**Adjournment:** 12:36 PM

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