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| **Meeting Date:** | June 24, 2025 at 11:00 AM Pacific Time |
| **Meeting Place:** | Teleconference (Remote)  Meeting Open to Public |
| **Members in Attendance:** | |  | | --- | | Amshaqn, Ashraf, Biosafety Specialist | | Casebolt, Tamara, Biosafety Officer | | De Zoysa, Prashan, Local Non-Affiliated | | Hauke, Caitlyn A., Chair | | Rastein, Daniel, Non-Affiliated | | Tafoya, Christine, Local Non-Affiliated | |
| **Guests**: | Dekalb, Charlene |
| **Staff:** | Mahrt, Elena  Payne, Kaylie |
| **Institution:** | City of Hope-Lennar Center |

**Call to Order:** The meeting was called to order at 11 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:**

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| **PI:** | Janakiram, Murali MD |
| **Sponsor:** | Celgene Corporation |
| **Protocol:** | BB2121-EAP-001: Expanded Access Protocol (EAP) for Subjects Receiving Idecabtagene Vicleucel that is Nonconforming for Commercial Release |
| **Review Type:** | Initial Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** bb2121-EAP-001 is an expanded access clinical trial sponsored by Celgene Corporation and designed to provide access to a CAR-T cell-based agent when the manufacturing process is not able to produce the necessary number or characteristic of cells required for commercial release. The study agent bb2121 (idecabtagene vicleucel, ide-cel) consists of the patient’s own (autologous) T lymphocytes transduced with a recombinant, replication-defective lentiviral vector expressing an anti-BCMA chimeric antigen receptor (CAR).

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 Site noted that the Site Map & Photos document depicting 6 plumbed eyewashes per floor was inaccurate and should be updated. The Committee had no concerns with administrative revision of the site map and photos document.
  + The Committee stipulated that the Site provide photos of the internal transport container labeled with a biohazard sticker within 30 days. The Committee had no further concerns.

**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:
* The Committee stipulated that the Site provide photos of the internal transport container labeled with a biohazard sticker by 7/24/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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| **PI:** | Siddiqi, Tanya MD |
| **Sponsor:** | Juno Therapeutics, Inc. |
| **Protocol:** | JCAR017-EAP-001: Expanded Access Protocol (EAP) for Subjects Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release |
| **Review Type:** | Initial Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** JCAR017-EAP-001 is an expanded access clinical trial sponsored by Juno Therapeutics and designed to provide access to lisocabtagene maraleucel (liso-cel; Breyanzi®; formerly JCAR017), a CAR-T cell-based agent, when the manufacturing process is not able to produce the necessary number or characteristic of cells required for commercial release, and when remanufacturing is not feasible. Liso-cel consists of the patient’s own (autologous) T lymphocytes that have been transduced with a recombinant, replication-defective lentiviral vector to express a chimeric antigen receptor (CAR) targeting the tumor antigen CD19, along with a truncated form of the human protein Epidermal Growth Factor Receptor (EGFRt) as a reporter gene.

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 stipulated that the Site provide photos of the internal transport container labeled with a biohazard sticker within 30 days. The Committee had no further concerns.

**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:
  + The Committee stipulated that the Site provide photos of the internal transport container labeled with a biohazard sticker by 7/24/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

**Reminder of IBC Approval Requirements.**

**Adjournment:** 11:30 AM

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