|  |  |
| --- | --- |
| **Meeting Date:** | June 3, 2025 at 12 PM Pacific Time |
| **Meeting Place:** | Teleconference (Remote)Meeting Open to Public |
| **Members in Attendance:** |

|  |
| --- |
| Amshaqn, Ashraf, Biosafety Specialist |
| Campbell, Mark, Non-Affiliated |
| Casebolt, Tamara, Biosafety Officer |
| Hauke, Caitlyn A., Chair |
| Enriquez, Rowelle, Non-Voting Contact |
| Rastein, Daniel, Local Non-Affiliated |
| Tafoya, Christine, Local Non-Affiliated |

 |
| **Guests**: | Charlene Dekalb, Jennifer Kim, Dawei Gou, Suwannee Srisatidnarakul |
| **Staff:** | Elena Mahrt, Casey Stark |
| **Institution:** | City of Hope |

**Call to Order:** The meeting was called to order at 12:02 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:**

|  |  |
| --- | --- |
| **PI:** | Li, Daneng MD  |
| **Sponsor:** | Eureka Therapeutics  |
| **Protocol:** | ETUS20GPC3AR124: An Open-Label, Dose Escalation, Multi-Center Phase I/II Clinical Trial of ECT204 T-Cell Therapy in Adults with Advanced Hepatocellular Carcinoma (HCC)  |
| Li, Daneng MD  |
| **Review Type:** | Annual Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** ETUS20GPC3AR124 is an open-label, dose escalation, Phase I/II clinical trial sponsored by Eureka Therapeutics to assess the safety, tolerability and recommended Phase 2 dose (RP2D) of ECT204, an autologous T-cell therapy whereby a subject’s own T cells are transduced with a lentiviral vector expressing an antibody-T cell receptor and a co-stimulatory molecule that binds Glypican 3 (GPC3), a membrane proteoglycan highly expressed on hepatocellular carcinoma (HCC) tumor cells.

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 BBP Training certificates and noted that some individuals’ training has expired. The Committee confirmed that they would not require updated training dates until the training dates had expired for all individuals listed. The Site confirmed that refresher training had been issued to all staff, and they can provide an updated list of training dates at the end of the month. The Committee had no further concerns.
	+ The Site considered combining location “private infusion bays/chairs” with “private rooms” as administration location for all relevant studies. The Committee noted the concern that some study agents require greater containment with closable doors and the separate locations would need to be specified for those studies. The Committee did not propose any changes for this study and suggested the Site discuss how they would like to move forward and report back to their Sabai Associate Partner.

**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

**New Business:**

|  |  |
| --- | --- |
| **PI:** | Yip, Wesley MD  |
| **Sponsor:** | Merck Sharp & Dohme Corp  |
| **Protocol:** | V940-004: A Phase 2, Randomized, Double-blind, Clinical Study of V940 (mRNA-4157) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab in the Adjuvant Treatment of Participants with Renal Cell Carcinoma (INTerpath-004)  |
| Yip, Wesley MD  |
| **Review Type:** | Annual Review |
| **NIH Guidelines:** | III-C |

**Trial Summary:** V940-004 is a Phase II, randomized, double-blind study sponsored by Merck Sharp & Dohme LLC and designed to evaluate the efficacy and safety of V940, an mRNA encoding multiple patient-specific neoantigens and complexed in a liposome, as a combination adjuvant therapy with pembrolizumab in participants with renal cell carcinoma.

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 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 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:** 12:39 PM

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