Meeting Minutes

Meeting Date:	June 4, 2025 at 9:00 AM Pacific Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Institution:	University of California, Irvine - HGT

Call to Order: The meeting was called to order at 9:05 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:	Sy, Michael MD, PhD
Sponsor:	Juno Therapeutics
Protocol:	CA0611006 A Phase 1, Multicenter, Single-arm, Dose-escalation Study of CC-97540 (BMS-986353), CD19-Targeted NEX-T Chimeric Antigen Receptor (CAR) T Cells, Evaluating Safety and Tolerability in Participants with Relapsing Forms of Multiple Sclerosis (RMS) or Progressive Forms of Multiple Sclerosis (PMS)
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: CA0611006 is a multicenter, open-label, Phase I clinical trial sponsored by Juno Therapeutics, Inc. and designed to determine the recommended Phase II dose(s) (RP2D) and to evaluate the safety, pharmacokinetics, and efficacy of CC-97540, a CD19-targeting chimeric antigen receptor (CAR) T cell product, in participants with relapsing forms of multiple sclerosis (RMS), progressive forms of multiple sclerosis (PMS), or refractory myasthenia gravis (MG). The study agent CC-97540 (also known as BMS-986353) is a CD19-directed cellular immunotherapy that comprises patient-specific autologous CD4+ and CD8+ T-cell populations that have been transduced using a genetically engineered, replication-incompetent lentiviral vector encoding a CD19-specific CAR, along with a truncated form of the human protein Epidermal Growth Factor Receptor (EGFR) 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, Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
  - The Chair noted that the Site is requesting to add the Cell Therapy Lab (CTL) for storage and preparation of the study agent.
  - The Site verified that the information provided by the Chair was accurate.
  - The Chair highlighted that per pervious discussion, the Site is currently in the process of obtaining updated pictures of the biohazard labeled storage units in the CTL.
  - The Site confirmed that staff have current bloodborne pathogens (BBP) training and are in the process of sending updated training records to Sabai IBC Services. 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

PI:	Mozaffar, Tahseen MD
Sponsor:	Cabaletta Bio, Inc.
Protocol:	CAB-201-002 A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Idiopathic Inflammatory Myopathy or Active Juvenile Idiopathic Inflammatory Myopathy
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: CAB-201-002 is a Phase I/II open label trial sponsored by Cabaletta Bio, Inc. designed to assess the safety, tolerability, and efficacy of CABA-201, an autologous (participant-derived) T cell product engineered with a lentivirus vector to express a chimeric antigen receptor (CAR) targeting CD19, in adults with active idiopathic inflammatory myopathies (IIMs) and, as of Protocol Version 2.0, in juveniles 6 to 17 years of age with juvenile IIM (JIIM).

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 Chair noted that the Site is requesting to add the Cell Therapy Lab (CTL) for storage and preparation of the study agent.
    - The Site verified that the information provided by the Chair was accurate.
    - The Chair highlighted that per pervious discussion, the Site is currently in the process of obtaining updated pictures of the biohazard labeled storage units in the CTL.
    - The Site confirmed that staff have current bloodborne pathogens (BBP) training and are in the process of sending updated training records to Sabai IBC Services. The Committee had no concerns.
    - The Committee discussed that the study agent can be prepared at the participant's bedside. The AP confirmed that per Site practices, if infusion bag penetrations are needed, this would be performed inside the biological safety cabinet. The Site materials will be administratively updated to note this practice.

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

Meeting Minutes

Reminder of IBC Approval Requirements.

Adjournment: 9:46 AM

Post-Meeting Pre-Approval Note: None