Institutional Biosafety Committee

Biological Full Committee

Minutes

Monday, March 30, 2026

Present:	Henrique Borges da Silva, John Copland, Marion Curtis, Marina Hanson, John Jasker, Richard Kennedy, Daniel Montonye, Suzannah Schmidt-Malan, Melanie Swift
Absent:	Richard Chichester, Hind Fadel, Madiha Fida, Kathleen McNaughton, Russel Sinor, Elitza Theel
Mayo Guests:	
Guests:	
Duration:	9:30 AM - 10:00 AM

Quorum was present during all committee decisions.

Discussion Items

Note Items

Approvals

Protocols Reviewed

- **Hassan Alkhateeb** A Single-Arm, Open-Label, Multi-Center, Phase 1b/ 2 Study to Evaluate the Safety, Efficacy, and Cellular PK Profile of CTD402 in Participants With Relapsed/Refractory T-ALL and T-LBL (TENACITY-01)

  The Biological Hazard Application, Bios00002172, for "A Single-Arm, Open-Label, Multi-Center, Phase 1b/ 2 Study to Evaluate the Safety, Efficacy, and Cellular PK Profile of CTD402 in Participants With Relapsed/Refractory T-ALL and T-LBL (TENACITY-01)" (IRB 26-001096) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of CTD402, a universal CAR T product targeting CD7+ T cell malignancies, that is transduced by the BHV015E retroviral vector (RVV) to introduce an anti-CD7 CAR, PD-L1 and NK inhibitory (NKi) molecule, in a clinical trial.

  This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

  This trial is approved for administration at the Mayo Clinic Rochester location only. If the enrollment of patients at either Mayo Clinic Jacksonville or Mayo Clinic Scottsdale is desired, the laboratory is directed to inform the IBC of the expansion.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Yi Lin** A Phase 1 Dose-escalation and Expansion Study to Evaluate Safety, Pharmacodynamics and Preliminary Efficacy of VV169 in Patients with Relapsed or Refractory Multiple Myeloma

  The Biological Hazard Application, Bios00002177, for "A Phase 1 Dose-escalation and Expansion Study to Evaluate Safety, Pharmacodynamics and Preliminary Efficacy of VV169 in Patients with Relapsed or Refractory Multiple Myeloma" (IRB 26-002090) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of VV169, a lentiviral vector carrying a BCMA-CAR that is capable of seeking out T cells in the body, and delivering this BCMA-CAR to the T cells, thereby giving rise to BCMA_CAR T cells in the body, in a clinical trial

  This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

  This trial is approved for administration at the Mayo Clinic Rochester, Scottsdale, and Jacksonville locations.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.