**Minutes
Institutional Review Board - Institutional Biosafety Committee for Human Subjects Meeting - IBC
June 6, 2025**

**Location:** Virtual

**Total Voting Members 10; Quorum 6**

**Members Present:** Ana Nobis, MD, MPH (PS), Antonios Hatzopoulos, PhD (OS), Bipin Savani, M.D. (PS), Donna Torr, PharmD (OS), Douglas Johnson, M.D., MSCI (PS), Kimberly Towers, BS (NS), Richard DiTullio, PhD (OS)

**Members Absent:** Allison Wheeler, M.D., MSCI (PS), Cary Fu, M.D. (PS), Rolinda Bailey, BSMT(ASCP) (NS)

**Ex-Officio Members Present:** None

**Administrative Staff Present:** James Arrington, BA, CIP, Tiffany Alexander, MPH, BSN, RN, CIP

**Guests:** None

**Meeting Called to Order:** 2:02PM

**Meeting Adjourned:** 2:22PM

**Announcements and Education**

THANK YOU ALL for being flexible this month and reviewing early. I appreciate it! We will NOT meet 6/20.

**Reveal Possible Conflicts of Interest**

250731: Douglas Johnson

**Review and Approval of the Previous Minutes and Review of Approvals by the Chair**

The Chair polled the committee for corrections to the minutes for the meeting dated 5/16/2025. No changes were provided. The minutes were approved as written.

**Subcommittee**

**IRB#: 250731**

**VICCDTCTT 23027P (D8310C00001) A Phase 2 Study of GC012F, a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects with Relapsed/ Refractory Multiple Myeloma**

**PI: Muhamed Baljevic, MD**

**Sponsor:** AstraZeneca

**Comments:**

The Reviewers presented a summary and comments followed by discussion. A Reviewer stated this is a Phase 2 study of GC012F, a Chimeric Antigen Receptor T-cell (CAR T) therapy targeting CD19 and B-cell maturation antigen (BCMA) in subjects with relapsed/refractory multiple myeloma. The Sponsor: for the study is AstraZeneca AB, Sweden. The Principal Investigator at Vanderbilt University Medical center is Dr. Muhamed Baljevic, MD, Division of Hematology/Oncology. All current key study personnel have the appropriate human subjects training to conduct the study.

The Reviewer noted this is a Phase 1b/2 study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) therapy targeting CD19 and B-cell Maturation Antigen (BCMA) in subjects with relapsed/refractory multiple myeloma. GC012F, is an autologous T cells transduced with a lentiviral vector The first-in-human (FIH) studies of GC012F (NCT04236011 and NCT04182581) in subjects with relapsed/refractory BCMA+ multiple myeloma (MM) are ongoing. Follow-up through 24 weeks is completed. Safety data available and acceptable (most CRS grade I and no ICANS observed) and high efficacy observed. For the second part (Phase 2 portion) of the study, approximately 50 subjects will be enrolled at the dose level determined to have acceptable safety and tolerability in Phase 1b. All subjects will be followed for safety and efficacy up to two years after GC012F infusion, or until the occurrence of disease progression, death, or withdrawal of consent. All subjects who complete the study or discontinue from the study (for reasons other than death) after receiving GC012F will be followed yearly for up to 15 years after infusion for the risks of replication-competent lentivirus and lentivirus insertion sites. The Reviewer noted no specific biosafety concerns.

There were no comments for discussion from the Pharmacy Reviewer, Occupational Health Reviewer or Community. The Biosafety Representative noted BSL-2 conditions would be appropriate for this study. The Committee agreed there were no biosafety concerns of note for this study and recommended approval.

**Motion:** The Committee found that the description of the agent, use, precautions, and risks are appropriately described in the submitted documents including the consent document(s). The Committee found that the requirements for protocol submission, review, and reporting per Section III-C and section III-C-1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules have been met. Approval was recommended.

**Total votes for Approve: 6** (Total Members Voting: 6)

**For: 6 Against: 0 Abstained: 0**

**Abstained:**

**Quorum Notes**

Dr. Johnson was not present for the discussion or vote as a conflict of interest was noted. Quorum was maintained.

**IRB#: 250673**

**A Phase 1 Study to Evaluate the Safety and Immunogenicity of Two Doses of a Novel H5 Antigenically Central (AC)-Anhui mRNA-LNP Vaccine in Healthy Adults**

**PI: Clarence Creech, M.D.**

**Sponsor:** National Institute of Allergy and Infectious Diseases

**Summary:**

**Subcommittee:**

**Comments:**

The Reviewers presented a summary and comments followed by discussion. A Reviewer stated this is a Phase 1 study to evaluate the safety and immunogenicity of two doses of a novel H5 antigenically central (AC)-Anhui mRNA-LNP vaccine in healthy adults. This study is federally funded by the National Institute of Allergy and Infectious Diseases. The IRB review is under the purview of the Advarra IRB. The Principal Investigator at Vanderbilt University Medical Center is Buddy Creech, MD, Division of Infectious Diseases. All current key study personnel have the appropriate human subjects training to conduct this study.

Highly pathogenic avian influenza A/H5 viruses pose a panzootic/pandemic threat among avian and mammalian populations. An urgent need exists for avian-influenza vaccines that can protect against a broader range of strains and be produced quickly in response to emerging threats. The H5 Astrakhan antigen is representative of the HA antigen found in split inactivated H5N8 vaccines in the US National Pre-pandemic Influenza Vaccine Stockpile (NPIVS). Side effects to the investigational products are considered non-differential; there are no anticipated differences in risk based on the specific strain-type that the vaccine construct towards which the vaccine is aimed. A summary of safety data provided by sponsor and reviewed. The Reviewer noted no specific biosafety issues or concerns.

Another Reviewer noted that Stage 1 will have 30 participants open label with 12.5, 25, and 50mcg dose of Anhui vaccine, stage 2 randomization to two different RNA vaccines (Anhui and Astrakhan, 25 each). The study population will be in healthy adults, ages 18-49. Dosed Day One and 29. The vaccine products being evaluated in this study are (mRNA) Primary endpoints are safety. Risks, including myocarditis, appropriately outlined. The Reviewer noted no specific biosafety concerns or issues.

There were no comments for discussion from the Pharmacy Reviewer, Occupational Health Reviewer or Community. The Biosafety Representative noted BSL-1 conditions for this study would be appropriate. The Committee agreed there were no biosafety concerns and recommended approval.

**Motion:** The Committee found that the description of the agent, use, precautions, and risks are appropriately described in the submitted documents including the consent document(s). The Committee found that the requirements for protocol submission, review, and reporting per Section III-C and section III-C-1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules have been met. Approval was recommended.

**Total votes for Approve: 7** (Total Members Voting: 7)

**For: 7 Against: 0 Abstained: 0**

**Abstained:**

**Quorum Notes**