Meeting Minutes

Meeting Date:	June 18, 2025 at 11:00 AM Pacific Time Meeting Open to Public
Meeting Place:	Teleconference (Remote)
Members in Attendance:	De Zoysa, Prashan Ellis, Robert Hauke, Caitlyn Lally, Rebecca Rastein, Daniel
Members Not in Attendance:	Andres, Leila
Guests:	Chin, Christina Pasalkar, Neeraja Fuller, AJ Blancas, Rosie Jones, Patrice Nguyen, Chi Alshamali, Meera
Staff:	Parrish, Wendy
Institution:	Hoag Memorial Hospital Presbyterian

Call to Order: The meeting was called to order at 11:02 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:	Becerra, Carlos, MD
Sponsor:	AstraZeneca Pharmaceuticals LP
Protocol:	NT-175-201 An Open-label, Phase 1, Multicenter Study to Evaluate the Safety and Preliminary Anti-tumor activity of NT-175 in Human Leukocyte Antigen -A*02:01-Positive Adult Subjects with Unresectable, Advanced and/or Metastatic Solid Tumors That Are Positive for the TP53 R175H Mutation
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: NT-175-201 (D8690C00001) is a Phase I, open-label dose-escalation study sponsored by AstraZeneca Pharmaceuticals LP (previously sponsored by Neogene Therapeutics,

Inc.) and designed to evaluate the safety, maximum tolerated dose, recommended phase 2 dose, and preliminary efficacy of NT-175, a recombinant autologous TCR-T cell product expressing an HLA-A-*02:01 restricted T Cell Receptor (TCR) against p53 in participants with advanced and/or metastatic qualifying solid tumors positive for TP53 with the R175H mutation. NT-175 is engineered using a CRISPR/Cas9 system to express an HLA-restricted TCR targeting p53 encoded by TP53 with the R175H mutation and to knock out native TRAC, TRBC, and TFGFBR2 genes to prevent endogenous TCR expression and reduce T-cell inhibition in the tumor microenvironment.

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 Facility Details xForm, Special Practices section will be administratively revised to include catheter-related information.

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: 11:25 AM

Post-Meeting Pre-Approval Note: None