IBC Meeting Minutes

Meeting Minutes
10/9/2025

Voting Members Present
Biana Godin, PhD Chair
Daniel Kiss, PhD
Sasha Azar, PhD Vice Chair
Chas Gray, RPh
Jillian Chahal
Nagendran Tharmalingam, PhD
Vicente Zuno, BSO
Wenhao Chen, PhD
Tamara Steele
Anjana Tiwari, PhD
Joan Nichols, PhD
Jiangyong Shao
Tanya Herzog, PhD
Edward Graviss, PhD

Other Non-Voting Attendees:
Malissa Mayer-Diaz
Prince Agyapong
Shane Wilson
Perla J. Rodriguez

Voting Members Absent:
Sachin Thakkar, PhD
Dimitrios L. Wagner, MD, PhD
Francesca Taraballi, PhD

Non-Voting Members Present:
None

Call to Order:

The Institutional Biosafety Committee convened an ad hoc virtual meeting via Microsoft Teams on October 9, 2025. The meeting was called to order at 10:32 a.m. with 14 members in attendance, exceeding the quorum requirement of 9 members.

Reports: Reports were not discussed during this meeting

Conflict of Interest:

Committee members were reminded by the IBC Chair to recuse themselves in the event

of any conflicts of interest.

Old Business: None discussed

New Business: None discussed

Minutes Review: Meeting minutes were not reviewed during this meeting.

AGENDA ITEMS

IBC NEW APPLICATIONS

IBC00002380
Title: Phase 2 study evaluating rapcabtagene autoleucel in participants with severe active Granulomatosis with Polyangiitis or Microscopic Polyangiitis
Principal Investigator: Sarah Kazzaz

Study Overview: CTL019 (murine) HIV-1 vector: The CTL019 lentiviral vector used for the transduction of the patient's T cells is a replication-defective, recombinant third-generation Self-Inactivating (SIN) lentiviral vector derived from the Human Immunodeficiency 1 Virus (HIV-1) lentiviral genome. The majority (approximately 85%) of the native HIV-1 sequence has been removed to produce a replication-defective minimal lentiviral vector system.

Rapcabtagene autoleucel, also known as YTB323, is a novel, investigational, autologous, CD19-directed CAR-T cell therapy manufactured through an innovative process. The manufacturing process preserves naive and stem cell memory T cell subpopulations compared to traditional CAR-T cell manufacturing. These T cell subpopulations are associated with greater proliferative potential, long-term product persistence and improved antitumor activity compared to CAR-T cell products manufactured via conventional manufacturing methods. Rapcabtagene autoleucel, utilizes the FMC63 single chain antibody variable fragment domain for CD19 recognition and the same lentiviral vector as tisagenlecleucel, but is manufactured with a different process, known as T-Charge.

The T-charge process reduces turnaround times compared to traditional manufacturing (TM) processes. The main difference in manufacturing of rapcabtagene autoleucel is that T-Charge does not have the in vitro expansion phase and allows formulation after minimal time in culture

Dose range: Total viable total nucleated cells (TNC) is recommended to not exceed 20.0 x 10^9 TNC for a range between 1.0 - 3.0 x 10^9 CD3+ cells. These cells will be shipped to Novartis for IP production. The finished product bags/cryobags range in volume from 10 to 30 mL depending on the target dose and transduction efficiency of

the T cells. The administration dose is a single infusion of rapcabtagene autoleucel (YTB323) at a target dose of 12.5×10^6 CAR-positive viable T cells.

- **Training**: All staff members have completed and are current with their required training.
- **Applicable NIH Guidelines**: Section III-C-1
- **Containment Conditions to be implemented**: BSL2
- **Risk assessment and Discussion**: The clinical site will not directly handle the CTL019 (murine) HIV-1 lentiviral vector, which is used in the transduction of T cells during the manufacturing of YTB323. All vector-related activities are conducted off-site at the Novartis manufacturing facility. At the administration site, YTB323 is thawed and administered to patients via intravenous infusion following specific protocols. While no intentional environmental release is anticipated, there is a theoretical risk of exposure to healthcare personnel in the event of a leak or spill during handling. In such cases, standard decontamination procedures—consistent with institutional biosafety protocols for human blood and potentially infectious materials—will be followed. No additional product-specific containment measures are required, as the modified T cells do not survive outside the human body. YTB323 is not considered an infectious agent, and its viability in the environment is minimal. Therefore, no immediate or long-term risks are expected for individuals handling the product or those in proximity to the administration site.
- **Comments sent to the PI for clarification**:
    - **Sponsor Information**: The sponsor contact information must be provided. Having this information will help employee health if an accidental exposure occurs.

Motion: Approve by Administrative Review

- Yes Votes: 14
- No Votes: 0
- Abstained: 0

Adjournment:

- The meeting adjourned at 10:46 am.
