**Montefiore Medical Center**
**BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES**
**Tuesday, November 18, 2025[1]**

*[1]The materials for this agenda were made available electronically to all appropriate parties.*

**MMC IBC Members Present**
1. Brian Currie, MD (IBC Chair)
2. Alan Yood (Member)
3. Izzy Fujiwara (Non-Affiliated Member)

**Guests Present:**
1. Vanessa Rodriguez, CIP, IRB/IBC Supervisor
2. Kyla Sumter, Junior Associate IRB/IBC Coordinator

**This meeting was called to order at 2:58 PM with a quorum[2] present.**

*[2]Note: According to the roster registered with NIH on 3/06/25, the MMC BRANY IBC membership totals 5, making the members required for quorum 3 or greater.*

**Announcements:**

I. IBC members were reminded to disclose any potential conflicts of interests prior to reviewing items on this agenda by recusing yourself. Contact BRANY IBC staff in advance of the meeting if this is the case.

II. IBC members were reminded to state their names when joining or leaving the call ensures that all of the meeting proceedings occur with quorum present.

**Minutes:**

- 11/6/2024
- 10/7/2025
- 10/24/2025

IBC Action and Vote: Having no comments or concerns, the committee voted to accept the minutes as submitted

Total: 3 For: 3 Against: 0 Abstentions: 0

**I. Initial Review – Response to Deferral**

**Protocol Title:** A Single-Arm, Open-Label, Multi-Center, Phase 1b/ 2 Study to Evaluate the Safety, Efficacy, and Cellular Pharmacokinetic Profile of CTD402 in Participants with Relapsed/Refractory T-cell Acute Lymphoblastic Leukemia (T-ALL) and Lymphoblastic Lymphoma (TLBL) (TENACITY-01)

Principal Investigator: Roberto Alejandro Sica, MD
BRANY File # IBC25-008-01 (Montefiore Medical Center)

**Materials Provided for Review:**
1. Sponsor IBC Query Responses (11/3/2025)
2. Sites application (9/24/2025)

a. CV and Training: Roberto Alejandro Sica, MD, Monika Paroder, MD, PhD, Calogero Palesi
3. Consent form
4. Protocol, VERSION: 1.2, 4/25/2024
   a. Clarification Memos: 8/19/2025
5. Drug Brochure, Edition Number: 1.4, 2/27/2025

Discussion: At the meeting on 10/7/25 the IBC deferred this study requesting the following clarification:

- Identification of the retrovirus.
- Details on how it is rendered non-virulent.
- Engineering methods to prevent recombination events

Discussion: The chair presented the sponsor response to these inquiries to the committee and provided a summary of the purpose of the study and nature of the study drug previously reviewed by the committee at the last meeting.

Project overview: CTD402 is an allogeneic anti-CD7 CAR T-cell therapy designed to target malignant T-cells in T-cell Acute Lymphoblastic Leukemia (T-ALL) and Lymphoblastic Lymphoma (T-LBL). The therapy utilizes donor-derived T-cells that are genetically engineered using CRISPR/Cas9 technology to knock out endogenous T-cell receptor (TCR) and CD7 expression, thereby reducing the risk of graft-versus-host disease and fratricide among therapeutic T-cells. The CAR construct is introduced via a retroviral vector (BHV-015E), which encodes a chimeric antigen receptor specific to CD7, a surface protein highly expressed on malignant T-cells. BHV-015E y-retroviral vector is a murine stem cell virus-based vector pseudo-typed with the feline endogenous retrovirus RD114 envelope. The required gene for viral packaging in transfer plasmid sare eliminated  resulting in viruses produced that are replication incompetent.

The committee noted the study agent is a risk group 2 agent and noted the site correctly identified the use of biosafety level 2 precautions and containment, due to the use of a retrovirus vector and human donor cells. The site has a biosafety liaison, which the committee agreed to be adequate. The staff and facility are adequately trained/equipped to handle the study agent. The committee noted it falls under sections III-C-1 and III-D-1 of the NIH guidelines.

IBC Action and Vote: Having no further comments or concerns, the committee voted unanimously to approve for an initial period of 12 months.

Total: 3 For: 3 Against: 0 Abstentions: 0

## II. Continuing Review

**Protocol Title:** A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen

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Principal Investigator: Yvonne Saenger, MD
BRANY File # IBC24-013-01 (Montefiore Medical Center)

**Materials Provided for Review:**

1. Continuing Review Application (11/13/2025)
    a. License: Yvonne Saenger, MD
    b. DSMB (3/6/2025)
2. Consent forms
3. Protocol, VERSION: 2.0 (5/3/2024)
    a. Protocol Clarification Letter #2 (2/5/2025)
4. Drug Brochure, Edition Number: 10.0 (2/19/2025)
5. Acknowledgement letters (3/14/2025 & 4/23/2025)

Discussion: The IBC discussed the continuation of this study, noting that there have been no material changes to the study protocol or study agent affecting the biosafety considerations for this research. The committee noted the study continues to fall under sections III-C-1 and III-D-1 of the NIH Guidelines.

The site reported that there have not been any emergencies, potential biohazard problems, spills, significant safety issues, or contamination since the last IBC review.

This site is open to subject accrual. To date a total of 2 subjects have been enrolled and are currently in follow-up. The study drug has been administered 6 times to each subject since the last review with no subjects reporting benefits or complaints. No SAE's or unanticipated problems have been reported since the last review. 49 sites study wide have enrolled 45 participants with no significant issues reported.

The DSMB met on March 6, 2025, and recommended continuing the study.

The informed consent form remains adequate.

The designated Biosafety Officer (BSO) for this project has not changed since the last IBC review. There have been no changes to the staff or to the facility used for this research and it continues to be adequate.

The risks assessment has not changed since the prior review of this project. There were no concerns that would necessitate termination of the protocol. The biosafety level remains unchanged (BL 2).

IBC Action and Vote: Having no further comments or concerns, the committee voted unanimously to continue its approval for this project for a period of 12 months.

Total: 3 For: 3 Against: 0 Abstentions: 0

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***This meeting adjourned at 3:12 PM (EST).***

Respectfully submitted,

Vanessa Rodriguez, CIP IRB/IBC Coordinator

Brian Currie, MD, IBC Chairman