Montefiore Medical Center
BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) Minutes
Wednesday, July 9, 2025 Via Telephone Conference [1]

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

MMC IBC Members Present:

1. Brian Currie, MD (Chair)
2. James Wetmur, PhD (Member)
3. Alan Yood (Member)
4. Izzy Fujiwara (Non Affiliated Local community member)

Guests Present:

1.

1. Vanessa Rodriguez, CIP, IRB/IBC Supervisor
2. Kyla Sumter, Junior Associate IRB/IBC Coordinator
1. Man Yu Chen (Einstein IBC)

This meeting was called to order at 10:05 AM with a quorum[2] present.

[2]*Note: According to the roster registered with NIH on 03/06/2025, 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.

A. Minutes:

- **January 07, 2025 IBC minutes**

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

Total: 4 For: 4 Against: 0 Abstentions: 0

B. Initial Reviews

1. **Protocol Title:** A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NM/BC)

Principal Investigator: Alexander Sankin, MD
BRANY File # IBC25-005-01 (Montefiore Medical Center)
CG Oncology, Inc Protocol # CORE-008

Materials Provided for Review:

1. Sites application (Signature 6/3/2025)

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a. CV and Training: Alexander Sankin, Ahmed Aboumohamed, Asencio Andrea, Jerel Johnson, Odume Josephine, & Pragna Patel,

2. Consent forms
3. Protocol, VERSION: 1.0
4. Drug Brochure, Edition Number: 7.0

Discussion: The chair presented this study to the committee describing the purpose of the study and nature of the study drug.

Project overview: The protocol involves the use of cretostimogene, a conditionally replicating oncolytic serotype 5 adenovirus designed to preferentially replicate and kill Rb pathway-defective cancer cells. Human E2F-I promoter is cloned in place of the endogenous E1A promoter in the human Ad5 backbone. Polyadenylation signal is used to protect from transcriptional read-through activating E1A expression. Cretostimogene includes the entire wild type E3 region except for the 19kD encoding region, this is replaced with cDNA from human GM-CSF under the control E3 promoter.

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. Protocol provides detailed necessary precaution requirements for staff while inpatient as well as for family and care givers while the participant is at home. The site has identified Dr. Goldstein as the 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: 4 For: 4 Against: 0 Abstentions: 0

C. Change in PI

2. **Protocol Title:** A Phase 1 Study of FT819 in Participants With Moderate to Severe Active Systemic Lupus Erythematosus

Principal Investigator: Wang, Shudan, MD
BRANY File # IBC24-014-01 (Montefiore Medical Center)
Fate Therapeutics, Inc. Protocol # FT819-102

Materials Provided for Review:

5. Sites application (Signature date)
   a. CV and Training: April Fu, Carmen Rodriguez, Dennis Cooper, Monica Paroder, Shudan Wang, Yitzchak Goldstein
6. Consent forms
7. Protocol, VERSION: 5.0
8. Drug Brochure, Edition Number: 7.0
9. Sites procedures on Spills and emergencies

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

Discussion: The chair presented this study to the committee describing the purpose of the study and nature of the study drug. The study was previously reviewed by this IBC on 1/7/25, subsequently the PI has left the institution, the site is requesting the PI be changed to Shudan Wang. The committee noted there have been no changes to the facility, staff, or study drug since this review, given the study was placed on hold prior to official approval there has been no activity conducted since the last review.

Project overview: The protocol involves the use of allogenic T cells derived from a cloned T cell receptor knockout, human induced pluripotent stem cell line that expresses a CD19-targeted chimeric antigen receptor regulated by the T-cell receptor and constant TRAC locus. The genetic engineering of the stem cells involves the knock-in of an anti-CD19 CAR into the TRAC locus with simultaneous knock out of the endogenous TCR resulting in CAR expression controlled by the endogenous TCR alpha promoter. CRISPR was used to create a double strand break at the TRAC locus facilitating a biallelic targeted insertion of the transgene provided via a donor plasmid. The clonal MCB is free of integrated recombinant DNA, infectious viruses and microbial contamination. It was noted that exposure to mouse cells occurs during production, although unlikely there is a potential risk of animal cell infections that theoretically could be transmitted to others and/or result in tumors. Participants will receive 1 dose of the study drug via IV infusion followed by 3 days of inpatient observation. After 24 months participants will be enrolled into a long-term follow-up study.

Risk Assessment and Biosafety Level Assignment: The committee noted the study agent is a risk group 2 agent due to the potential for administration of xenotransplantation material and noted the site correctly identified the use of biosafety level 2 precautions and containment. The site has identified Dr. Goldstein as the 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 section III-C-1 of the NIH guidelines.

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

Total: 4 For: 4 Against: 0 Abstentions: 0

This meeting adjourned at 10:24 AM (EST).

Respectfully submitted,

Vanessa Rodriguez

Digitally signed by Vanessa Rodriguez
Date: 2025.07.15 09:33:05 -04'00'

Vanessa Rodriguez, CIP IRB/IBC Coordinator

Brian Currie MD

Brian Curie, MD, IBC Chairman