

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, June 29, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: George Georges, MD
Protocol: Juno Therapeutics, Inc., a Bristol-Myers Squibb Company, CA0611005
NCT Number: NCT07335562
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc)

1. Call to order:

The Meeting was called to order at 9:00 am Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. Also present were four Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Biosafety Officer confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for BMS-986353, since it consists of autologous T cells modified by a lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of BMS-986353 locally**, provided that other biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Biosafety Officer confirmed that the information in the Site Inspection Checklist is still accurate. The Committee recommended that this be noted in the table on the first page.
2. The Committee noted that the Biological Safety Cabinet (BSC) Certifications were certified on March 27, 2026, with an annual certification schedule. The Biosafety Officer noted that these BSCs are typically certified every six months and that they will follow up with staff members to ensure they are aware that the BSC certifying company indicated these are due annually.
3. The Committee recommended that the expiration date of the BSC Certifications be revised to “expires 03-2027” to reflect the due date noted in the document.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

ETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:12 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, dated 11-25-2025

Investigator's Brochure, Version 07, dated 10-28-2025

Global Product Administration Manual, Version 1.0, dated 10-31-2025

Biological Risk Assessment and Summary, dated 02-04-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 06-12-2026

Photos, Prentice Hospital, dated 04-25-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Dosing Areas, dated 06-12-2026

Biohazard Sign, Olson MCCT, dated 06-15-2026

Biological Safety Cabinet Certifications, Olson MCCT, expires 09-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Autologous Cells, dated 06-15-2026

Training, Shipping Certification, expires 06-05-2027

CV, Georges, G., signed 01-14-2026