

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, May 5, 2026
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Hoag Memorial Hospital Presbyterian, Newport Beach, CA
Principal Investigator: Raghuv eer Ranganathan MD
Protocol: Juno Therapeutics, Inc., a Bristol-Myers Squibb Company, CA0611011
NCT Number: NCT07015983
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEXT CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)

1. Call to order:

The Meeting was called to order at 8:02 am Pacific Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were the Principal Investigator, 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:

An Institutional Representative 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 CC-97540, 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 CC-97540 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: 4

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. An Institutional Representative confirmed dosing and biohazardous waste storage will occur on the 8th floor rather than the 2nd floor. The Committee noted that these dosing rooms have already been previously approved by the Committee for other similar studies. The Committee recommended that all site-specific documents be revised to reflect this information.
2. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to add that absorbent material will be placed inside of the Ziploc-style bag.
3. An Institutional Representative confirmed that PDI Sani-cloth Bleach Wipes or Peridox RTU will be used to decontaminate reusable face shields or eye goggles. The Committee recommended that Biosafety SOP Section 3.6 and Site Inspection Checklist #9 be revised to reflect this information.
4. The Committee discussed the aerosol settling time as noted in Section 5.1.1 of the Biosafety SOP. The Committee recommended that the Institution confirm that this information is consistent with their Institutional policy, and determined that an aerosol settling time should remain in this SOP.
5. An Institutional Representative confirmed that a plumbed eyewash station is available on the 8th Floor and that prefilled disposable eyewash bottles will be available within the dosing room. The Committee recommended that the Site Map be updated to indicate where the plumbed eyewash is located on the 8th Floor.
6. An Institutional Representative confirmed that the blue and black hazardous waste containers are used for chemo and non-chemo products, and that yellow and red biohazardous waste containers will be used to discard sharps/biohazardous waste generated in this study. The Committee recommended that the photos be updated to note the type of waste that is discarded in each of the different colored containers.
7. The Committee recommended that all biohazardous waste containers be labeled on all visible sides with the biohazard symbol per the State of California regulations.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:29 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 02, dated 11-13-2025

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, updated 01-23-2026

Site Map, Cancer Center, 2nd Floor, dated 04-16-2026

Site Inspection Checklist, expires 02-11-2028, updated 04-10-2026

Photos, dated 04-10-2026

Biohazard Sign, dated 04-15-2026

SOP, Biosafety for CC-97540, dated 04-15-2026

Training, Shipping Certifications, expire 04-2028

CV, Ranganathan. R, dated 11-10-2025