INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, June 18, 2026**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Shanmuganathan Chandrakasan, 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 3:08 pm Eastern 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 two local members unaffiliated with the institution. Also present was one Institutional Representative 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 stated that notice of the meeting was not publicly posted per institutional policy.

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.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices. The Committee had no questions or concerns regarding these.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	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 3:11 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 03, dated 03-27-2026
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 05-08-2026
Site Maps, dated 06-04-2026
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 05-28-2026
Photos, dated 06-03-2026
Biohazard Sign, genetically modified human cells, dated 05-27-2026
Biological Safety Cabinet Certifications, Cell Therapy Lab, expires 09-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 05-08-2026
SOP Addendum, Genetically Modified Human Cells, dated 05-08-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, Chandrakasan, S., signed 10-09-2025