INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, June 18, 2025**
Time:	8:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Swedish Health Services, Seattle, WA
Principal Investigator:	**Philip Mease, MD, MACR**
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:

Five voting members were present, including two local members unaffiliated with the institution. Also present were eleven 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: 5 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.

Points of Discussion:

1. The Committee discussed specific information for preventing leakage during preparation that is provided in the Global Product Administration Manual, Version 1.0. The Committee recommended that Biosafety SOP Section 3.2.5 be revised to include the following language since the study agent is prepared on a countertop: “Once the specified volume has been drawn into the syringe(s) and verified, shift the vial and syringe to a horizontal position and remove the syringe with needle still attached from the vial. Place the used vial in the vial carton to avoid leakage from the punctured port.”
2. An Institutional Representative could not confirm whether the scissors used to cut the seal on study agent vials are reusable or disposable. The Committee recommended that the Institution follow-up with IBC Services and revise site documents to note whether they are reusable or disposable and if reusable, to include how the scissors are decontaminated after use.
3. The Committee noted that as previously discussed for other studies at the Institution, the [redacted] biohazardous waste storage room photo shows numerous items stored around the sink and on top of the sharps container. An Institutional Representative confirmed that these items have been removed, and an updated photo was provided to IBC Services just prior to the meeting.
4. An Institutional Representative confirmed that study staff receive annual bloodborne pathogens and biosafety SOP training.
5. The Committee discussed that the locations listed on page 3 of the Site Inspection Checklist are reflective of multiple protocols and that the corresponding Biosafety SOPs define the specific locations where research activities occur for that protocol.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:16 am Pacific Time.