INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, January 6, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Corewell Health, Grand Rapids, MI
Principal Investigator:	**Sami Brake, MD**
Protocol:	Janssen Research and Development, **68284528MMY4006**
NCT Number:	NCT05346835
Meeting Type:	Initial Review of Protocol and Site
Title:	Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucel (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma.

1. Call to order:

The Meeting was called to order at 10:59 am Eastern 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 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:

The 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 JNJ- 68284528, since it consists of genetically modified primary human cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of JNJ-68284528 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 recommended that the Site Inspection Checklist, Site Map, and Biosafety SOP be revised to indicate that the preparation of the study agent which includes thawing a frozen infusion bag in a waterbath will occur in the dosing rooms.
2. The Committee recommended that waterbath used to thaw study agent infusion bags be labeled with a biohazard symbol/sign (could be magnetic and removable).
3. The Committee recommended that the front of the internal transport container be labeled with a biohazard symbol/sign and that an updated photo showing the side and top of this container be submitted to IBC Services.
4. The Institutional Representative confirmed that eye protection is used for study agent handling. The Committee recommended that the Biohazard Sign be revised to replace “goggles” with “eye protection”.
5. The Institutional Representative confirmed that red biohazardous waste bags removed from containers for transportation the biohazardous waste storage area are placed inside a closable container on a cart. The Committee recommended that Site Inspection Checklist item 15 be revised to reflect this information.
6. The Institutional Representative confirmed that the Principal Investigator’ main phone number and Secondary Contact’s alternate phone number are available “24/7”. The Committee recommended that the Biohazard Sign be updated accordingly.
7. The Committee noted that the biohazard symbol sticker on a biohazardous waste container in BW Room 5462 appears to be peeling off. The Committee recommended that this sticker be replaced if it is peeling and that a new photo of this container be submitted to IBC Services.
8. The Committee recommended that the Institution confirm if any of the areas outlined in blue in the upper right of the A-level Site Map are used for study agent-related activities.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:18 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 09-30-2024
Investigator's Brochure, Edition 10, dated 04-15-2025
Carvykti Prescribing Information, dated 10-2025
Biological Risk Assessment and Summary, updated 11-12-2025
Site Map, Butterworth Hospital, 5th Floor, dated 12-23-2025
Site Inspection Checklist, expires 01-09-2027, updated 12-11-2025
Photos, BW Hospital, Dosing Area, dated 12-23-2025
Biohazard Sign, dated 12-18-2025
SOP, Biosafety for JNJ-68284528, dated 12-22-2025

Training, Shipping Certification, expires 03-18-2026
CV, Brake, S., signed 04-14-2025