INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, October 31, 2025**
Time:	10:30 am Eastern Time
Location:	Zoom Teleconference
Institution:	Orlando Health Cancer Institute, Orlando, FL
Principal Investigator:	**Julio Gonzalez Paoli, MD**
Protocol:	Novartis Research and Development, **CYTB323K12201**
NCT Number:	NCT06655896
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis

1. Call to order:

The Meeting was called to order at 11:29 am 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 one local member unaffiliated with the institution. Also present were five 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 YTB323, 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 YTB323 locally**, provided all other criteria for study closure are 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.

Points of Discussion:

1. The Committee recommended that the reference to infusion bags and intravenous (IV) gravity flow be removed from Biosafety SOP Section 3.5 since dosing will only occur using a syringe via IV push infusion.
2. The Committee recommended that Biosafety SOP Section 5.1.4c be revised to be consistent with other BSOPs that describe waterbath decontamination procedures in the event of a spill (e.g., replace 70% alcohol with bleach).
3. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to remove “If the study agent is removed from its original sponsor packaging,”.
4. An Institutional Representative confirmed that the study agent-specific biohazard sign is posted at the entrance to the areas where the study agent is handled, including the storage, preparation, dosing rooms. The Committee recommended that the Photos document be updated with photos depicting doors and rooms properly labeled with biohazard signage.
5. An Institutional Representative confirmed that storage units used to store other genetically modified study agents are labeled with biohazard signage. The Committee recommended that updated photos be submitted to IBC Services.
6. The Committee recommended that a biohazard symbol be posted on the waterbath used to prepare study agents and that a photo be submitted to IBC Services.
7. The Committee recommended that a larger biohazard symbol be placed on the internal transport container and that a new photo of this container be submitted to IBC Services.
8. An Institutional Representative confirmed that pillows in the dosing area are made of a plastic (impervious) material, and that the covers are washable. The Committee recommended that Biosafety SOP Section 5 be revised to add a description of how bed linens would be handled in the event there was a leak of the study agent on bed linen.
9. The Committee recommended that Photos Slide 44 (Logs) be removed since this information is captured in other site-specific documentation.
10. The Committee recommended that the Institution confirm if study agent-specific biohazard signs are posted on the outside of biohazardous waste storage rooms when waste generated in this study is stored in the rooms.
11. The Committee discussed labeling biological safety cabinets (BSCs) with a biohazard sticker and noted that since this may not be required per state law, the biohazard signage on the door to the entrance of the preparation room is adequate.
12. An Institutional Representative confirmed that the yellow chemo hazardous containers arrive labelled with a biohazard symbol and that these containers are ultimately incinerated by the commercial biohazardous waste hauler. The Committee noted that these containers are acceptable for discarding biohazardous waste.
13. The Committee recommended that if the black hard-sided waste containers are used to dispose of biohazardous waste that these containers be appropriately labeled with a biohazard symbol.
14. An Instiutional Representative confirmed that that storage room photos depict liquid nitrogen supply dewers and that nothing is stored in these dewers.
15. An Institutional Representative confirmed that in [redacted], subjects may or may not be dosed with the study agent in bed. Some subjects may be sitting in a chair during dosing.
16. An Institutional Representative confirmed that biohazard waste containers will be available in all dosing rooms during dosing of the study agent.
17. An Institutional Representative confirmed that the [redacted] is no longer used. The Committee recommended that this location be removed from the Site Inspection Checklist.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:33 am Eastern Time.