

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, September 30, 2021
Time: 2:00 pm Eastern Time
Web Participants: <https://wgcclinical.webex.com/wgcclinical/j.php?MTID=ma0c8c9689c3b494488625ff6b9e4ccc5>
Telephone Only Participants: 1-888-788-0099 Access Code: 2316 091 1506
Institution: Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator: Muna Qayed, MD, MsCR
Protocol: Novartis Pharmaceuticals, CCTL019G2201J
Meeting Type: Continuing Review of Protocol and Site
Title: A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation

1. Call to order:

The Meeting was called to order at 2:01 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three voting members were present, including one local member unaffiliated with the institution. Also present were two non-voting Institutional Representatives, two non-member 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:

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. Approval of previous meeting minutes:

Minutes Approved - YES: 3 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the dosing status.

The Chair provided an overview of the protocol.

The Chair provided an overview of changes since the last review.

Point of Discussion:

1. An Institutional Representative confirmed that a research-related incident was reported to IBC Services. The incident pertained to dosing rooms used prior to IBC approval. These dosing rooms are now listed on the site documents and will be reviewed during today's meeting.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices are required for CTL019**, since it consists of autologous T cells modified by a lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of CTL019 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

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9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 3 NO: 0 ABSTAIN: 0

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 that training on the study agent-specific Biosafety SOP is up to date for all study staff. The Committee recommended that site documents be updated to reflect training on SOPs per protocol.
2. An Institutional Representative confirmed that a sharps container is within arm's reach of the Biosafety Cabinet used for study agent preparation.

11. Site requirements:

The Chair reviewed 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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:12 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 02-11-2020

Investigator's Brochure, Edition 10, dated 03-17-2021

Product Handling Manual, Version 2, dated June 2019

Research Modification Evaluation, Investigator's Brochure, Edition 10

Biological Risk Assessment and Summary, updated 07-23-2021

Research Modification Evaluation, Site Change, Addition of Dosing Rooms, dated 09-13-2021

Site Map, Egelston Hospital, updated 06-22-2021

Site Map, BMT Outpatient, dated 08-05-2021

Site Visit Checklist, dated 07-20-2021

Biohazard Sign, dated 07-02-2021

Photos, dated 09-09-2021

Biological Safety Cabinet Certification, Cellular Lab, dated 08-16-2021

SOP, Biosafety for CTL019, dated 09-09-2021

Training, Shipping Certification, expires 06-24-2022

Continuing Review Report Form, dated 07-20-2021

Prior Meeting Minutes, Continuing, dated 09-30-2020