

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, September 7, 2023  
**Time:** 3:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**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 3:01 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 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. Approval of previous meeting minutes:

Minutes Approved - YES: 4                      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. The Institutional Representative confirmed that enrollment is still paused pending an update to the Protocol.

### 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.

### 9. 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

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### **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 Institutional Representative was unable to confirm that the Biological Safety Cabinet (BSC) was recertified and agreed to look into this and submit the newer Certification to IBC Services if it is available.
2. The Committee recommended that the Institution submit an updated/newer BSC Certification to IBC Services. The Chair noted that IBC Services will evaluate the BSC Certification to confirm that it passed all test and the Committee agreed to this arrangement.

### **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 3:15 pm Eastern Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 1.0, dated 02-11-2020

Investigator's Brochure, Edition 12, dated 03-22-2023

Product Handling Manual, Version 3.1, dated September 2021

Research Modification Evaluation, Investigator's Brochure, Edition 12

Biological Risk Assessment and Summary, updated 05-02-2023

Site Maps, updated 05-10-2023

Site Inspection Checklist, dated 05-10-2023

Photos, dated 05-10-2023

Biohazard Sign, dated 10-12-2021

Biological Safety Cabinet Certification, expires 08-2023

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

Training, Shipping Certifications, expire 2024, 2025

Continuing Review Report Form, dated 05-31-2023

Prior Meeting Minutes, Continuing, dated 09-29-2022