

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, June 9, 2025  
**Time:** 12:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Ochsner Clinic Foundation, New Orleans, LA  
**Principal Investigator:** Daniel H. Johnson, MD  
**Protocol:** Krystal Biotech, Inc., KB707-02  
**NCT Number:** NCT06228326  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A phase 1 study of inhaled KB707 in patients with advanced solid tumor malignancies affecting the lungs.

### 1. Call to order:

The Meeting was called to order at 12:22 pm Central 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 sixteen 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. 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 protocol and status of the study.

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

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for KB707, because it is based on HSV-1, a Risk Group 2 Herpes virus. 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 KB707 locally**, provided all other biosafety criteria required 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 Committee recommended that the address listed in the Site Inspection Checklist for the [REDACTED] updated to [REDACTED].
2. An Institutional Representative confirmed that transportation of the study agent between buildings occurs via internal walkways.
3. An Institutional Representative confirmed that there have been no issues or concerns with preparation and dosing of the study agent to subjects to date.
4. The Committee noted that the images of the nebulizer and the set-up for dosing as shown in the Sponsor's documents are helpful for biosafety review.

### **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 12:31 pm Central Time.