

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, October 16, 2025  
**Time:** 10:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Hackensack Meridian Health, Hackensack, NJ  
**Principal Investigator:** Martin Gutierrez, MD  
**Protocol:** AstraZeneca AB, D9660C00001  
**NCT Number:** NCT06267729  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase I/II Open Label Study to Evaluate the Safety, Cellular Kinetics, and Efficacy of AZD0754, a Chimeric Antigen Receptor (CAR) T-cell Therapy Directed Against STEAP2, in Adult Participants with Metastatic Prostate Cancer: APOLLO

### 1. Call to order:

The Meeting was called to order at 10:18 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 and the Institution's Biosafety Officer. IBC Services staff were also present. 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 Biosafety Officer 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: 5 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 AZD0754, since it consists of autologous T cells modified by a replication-defective and self-inactivating 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 AZD0754 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: 5 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.

#### **Point of Discussion:**

1. The Committee noted that the Biological Safety Cabinets are due for recertification by the end of November.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institution's Biosafety Officer.

### **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 10:22 am Eastern Time.