

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, November 20, 2025  
**Time:** 9:00 am Pacific Time  
**Location:** Zoom Teleconference  
**Institution:** Swedish Health Services, Seattle, WA  
**Principal Investigator:** Philip Mease, MD, MACR  
**Protocol:** AstraZeneca AB, D8313C00001  
**NCT Number:** NCT06897930  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** Phase 1b/2 Study of AZD0120, a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects with Refractory Systemic Lupus Erythematosus (SLE)

### 1. Call to order:

The Meeting was called to order at 9:22 am Pacific 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 fourteen 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 AZD0120 since it consists of autologous T cells modified using a lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of AZD0120 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.

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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 SOP Addendum, Biosafety for Autologous Cells Section 2.1 be moved to Section 5.2 (Exposures) in SOP, Biosafety for Genetically Modified Human Cells or that a new section at the end of the SOP Addendum be created since this section specifically describes how to handle skin and eye exposures to the study agent.
2. The Committee recommended that SOP Addendum, Biosafety for Autologous Cells Section 2.1 be revised to remove the language pertaining to wiping skin with diluted bleach in the event of an exposure to intact skin.
3. The Committee recommended that SOP Addendum, Biosafety for Autologous Cells Section 3.2.6 be revised accordingly if there is a possibility that the needle will be capped after preparation and prior to dosing.
4. The Committee recommended that SOP Addendum, Biosafety for Autologous Cells Section 3.2.6 be revised to remove the language pertaining to massaging the infusion bag during thawing as the Sponsor documents specifically state that massaging the bag should be avoided as it may cause a decrease in cell viability.
5. The Committee recommended that Site Inspection Checklist Item #15 be changed to "Yes" since biohazardous waste containers are available in rooms where the study agent is handled.
6. The Committee recommended that a photo of the water bath, labeled with a biohazard symbol, on a cart or a countertop in the preparation and dosing room be provided to IBC Services.

### **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 9:26 am Pacific Time.