

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 30, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Irene Blanco, MD, MS
Protocol: AstraZeneca Pharmaceuticals LP, 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 9:00 am Central Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. Also present were three 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 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. 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: 6

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 noted that the Biological Safety Cabinet (BSC) Certifications were certified on March 27, 2026, with an annual certification schedule. The Biosafety Officer noted that these BSCs are typically certified every six months and that they will follow up with staff members to ensure they are aware that the BSC certifying company indicated these are due annually.
2. The Committee recommended that the expiration date of the BSC Certifications be revised to “expires 03-2027” to reflect the due date noted in the document.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the 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: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:07 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 8.0, dated 10-30-2025

Protocol Clarification Letter, dated 11-17-2025

Investigator's Brochure, Edition 1.0, dated 04-17-2025

Handling, Thaw, Preparation and Administration Manual, Version 1.0, dated 03-16-2026

Handling, Receipt and Storage Manual, Version 1.0, dated 03-16-2026

Handling Manuals, Versions 1.0, Corrections Memo, dated 04-16-2026

Biological Risk Assessment and Summary, updated 06-18-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 06-17-2026

Photos, Prentice Hospital, dated 04-25-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Dosing Areas, dated 06-17-2026

Biohazard Sign, Olson MCCT, dated 06-17-2026

Biological Safety Cabinet Certifications, Olson MCCT, dated 03-27-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Autologous Cells, dated 06-17-2026

Training, Shipping Certification, expires 06-05-2027

CV, Blanco, I., signed 03-08-2026