INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, November 24, 2026**
Time:	9:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Northside Hospital, Atlanta, GA
Principal Investigator:	**Melhem Solh, MD**
Protocol:	AstraZeneca AB, **D8316C00001**
NCT Number:	NCT07735637
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase III, Open-label, Multicentre, Randomised Study Comparing Consolidation Treatment with AZD0120, an Autologous Dual Targeting Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible (TE NDMM) (DURGA-6)

1. Call to order:

The Meeting was called to order at 9:00 am 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 one local member unaffiliated with the institution. Also present were two 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 by a self-inactivating 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:

Vote	Determination
X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed the qualifications of the Principal Investigator and had no concerns.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that the HSC Laboratory is located across the street from the dosing location in a separate building. The Committee recommended that the address of the HSC Laboratory be updated to reflect this on the Site Map [and on the Site Inspection Checklist].
2. An Institutional Representative confirmed that the 4th floor BMT Unit does not have plumbed eyewash stations, but has many easily accessible prefilled eyewash bottle stations available on the floor.

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:

Vote	Determination
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 9:11 am Eastern Time.

15. Post-meeting notes:

None.

Documents reviewed:

Agenda
Protocol, Version 1.0, dated 03-26-2026
Investigator's Brochure, Edition 2.0, dated 05-11-2026
Investigational Medicinal Product Handling, Version 1.0, dated 08-31-2026
Biological Risk Assessment and Summary, dated 09-30-2026
Site Map, BMT Unit, 4th Floor, dated 01-29-2024
Site Map, HSC Laboratory, dated 06-01-2026
Site Inspection Checklist, GMHC, expires 01-29-2028, updated 11-13-2026
Site Inspection Checklist, Autoclave Addendum, expires 04-20-2028
Photos, HSC Lab, BMT Unit, dated 04-23-2026
Biohazard Sign, Genetically Modified Human Cells, dated 11-13-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 11-13-2026
SOP Addendum, Biosafety for Autologous Cells, dated 11-13-2026
Training, Shipping Certification, expires 01-2028
CV, Solh, M., signed 06-02-2025