

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, September 19, 2025
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Wayne State University, Detroit, MI
Principal Investigator: Jeffrey A. Zonder, MD
Protocol: Alexion Pharmaceuticals, Inc., AZD0120-AL-201
NCT Number: NCT07081646
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1b/2 study of AZD0120 (also known as GC012F), a Chimeric Antigen Receptor T Cell therapy targeting CD19 and B cell maturation antigen in participants with relapsed or refractory AL Amyloidosis.

1. Call to order:

The Meeting was called to order at 11:11 am Eastern 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 five 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 primary human 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 one of the provided IATA/Shipping certifications is not acceptable since it does not list specific requirements or the expiration and completion dates. An Institutional Representative stated that other IATA/Shipping certifications are available and will provide IBC Services with them.
2. The Biosafety Officer noted that study staff can reach out to the shipping core to ensure that institutional requirements regarding shipping training are met.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and 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 11:18 am Eastern Time.