

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, December 3, 2025
Time: 8:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Senda Ajroud-Driss, MD
Protocol: UniQure biopharma B.V., **AMT-162-001**
NCT Number: NCT06100276
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1/2, Multicenter, Single Ascending Dose Study to Evaluate the Safety, Tolerability, and Exploratory Efficacy of Intrathecally Administered Gene Therapy AMT-162 in Adult Participants with SOD1 Amyotrophic Lateral Sclerosis (SOD1-ALS)

1. Call to order:

The Meeting was called to order at 8:18 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:

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. Approval of previous meeting minutes:

Minutes Approved - YES: 6 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-1 containment facilities and practices plus Standard Precautions** are required for AMT-162, since it consists of an adeno-associated viral (AAV) vector being administered in a clinical setting. 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 AMT-162 locally**, provided that other biosafety criteria for study closure are also 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: 6 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.

Points of Discussion:

1. The Committee recommended that current Biological Safety Cabinet (BSC) and Compounding Aseptic Containment Isolator (CACI) certification reports be submitted to IBC Services when available.
2. The Committee recommended that the BSCs and CACI be labeled with a biohazard sticker or sign during study agent preparation. The Biosafety Officer noted that the [REDACTED] follows stringent standards for ISO cleanrooms and generally avoids affixing items to equipment and walls.
3. The Committee discussed that the entrance door to the cleanroom is labeled with a biohazard sign and determined this to be acceptable if equipment inside the room cannot be labeled.
4. The Committee recommended that an emergency eyewash sign be posted above the plumbed eyewash station located outside of the dosing rooms if one is not already present and that an updated photo showing the posted signage be provided to IBC Services.

11. Site requirements:

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

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:27 am Central Time.