INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, August 6, 2025**
Time:	12:00 pm Pacific Time
Location:	Zoom Teleconference
Institution:	University of Southern California, Los Angeles, CA
Principal Investigator:	**Heinz-Josef Lenz, MD**
Protocol:	AMAL Therapeutics S.A., **KISIMA-02**
NCT Number:	NCT05846516
Meeting Type:	Continuing Review of Protocol and Site
Title:	A phase 1b study to evaluate the safety, tolerability and preliminary efficacy of ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in patients with KRAS G12D/G12V mutated pancreatic ductal adenocarcinoma.

1. Call to order:

The Meeting was called to order at 12:00 pm Pacific Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Seven voting members were present, including two local members unaffiliated with the institution. 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 could not confirm if the public posting was made and agreed to follow-up with IBC Services about this. If a public posting was not made, the Committee recommended that the meeting notice be posted publicly for one week after the meeting, in accordance with the NIH's recommendation that these meetings be made open to the public if possible.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 7 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-2 containment facilities and practices** are required for VSVGP154, since it consists of a replication-competent vesicular stomatitis virus. 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 VSV-GP154 locally**, provided all 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: 7 NO: 0 ABSTAIN: 0

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 Biosafety SOP Section 5.1.4.ii be rewritten as “Ensure the surface remains wet for a contact time of 10 minutes,” for the bleach section and “Ensure the surface remains wet for a contact time of 3 minutes,” for the Peridox RTU section.
2. An Institutional Representative confirmed that a sharps container is placed within the Biological Safety Cabinet (BSC) during study agent preparation. The Committee recommended that the Photos document be updated to indicate that a sharps container is placed within the BSC during study agent preparation.
3. The Committee recommended that a photo of the hard-sided, sealable internal transport container (intermediate container) be submitted to IBC Services.
4. The Committee recommended that the Institution obtain permission from the [redacted] to take a representative photo of a dosing room and to provide this photo to IBC Services.
5. The Committee recommended that the Institution provide more information about what happens with the occlusive dressing used to cover infusion site (e.g., does the subject dispose of it at home?).
6. The Committee noted that there are several plumbed eyewash stations in the area where dosing will occur. However, the Committee recommended that the Institution confirm whether or not prefilled disposable eyewash bottles are available in the dosing room during administration of the study agent to the subject.
7. The Committee recommended that the Institution confirm how often the plumbed eyewash stations in the preparation and dosing areas are flushed.
8. The Committee recommended that the Institution confirm how often bleach solution is prepared (e.g. freshly-prepared on a daily basis).
9. The Committee recommended that the Institution confirm if the study-agent specific biohazard sign is posted as required during preparation and dosing of the study agent.
10. An Institutional Representative confirmed that the study agent is not transported externally to the dosing area after preparation.

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: 7 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 12:29 pm Pacific Time.