INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, June 9, 2025**
Time:	9:00 am Arizona Time
Location:	Zoom Teleconference
Institution:	Mohtaseb Cancer Center & Blood Disorders (Sargon Research), Bullhead City, AZ
Principal Investigator:	**Hamdy Mohtaseb, MD**
Protocol:	Genelux Corporation, **Olvi-Vec-NSCLC-025**
NCT Number:	NCT06463665
Meeting Type:	Initial Review of Protocol and Site
Title:	A randomized phase 2 study assessing the efficacy and safety of Olvimulogene Nanivacirepvec followed by Platinum-doublet Chemotherapy + physician's choice of immune checkpoint inhibitor compared with Docetaxel in patients with Non-Small-Cell Lung Cancer after first progression while on front-line immune checkpoint inhibitor-based maintenance (VIRO-25 Study)

1. Call to order:

The Meeting was called to order at 9:00 am Arizona Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three voting members were present, including one local member 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 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 Olvi-Vec since it consists of an attenuated, conditionally replicative vaccinia virus administered in a clinical setting.

The Committee determined that IBC oversight will continue for **6 months after the last subject's last dose of Olvi-Vec locally**, provided that other biosafety criteria for study closure are also 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: 3 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

Point of Discussion:

1. The Committee recommended that a list or addendum of the Principal Investigator's specific clinical trial experience be submitted to IBC Services.

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 a sink is not available in the preparation room and that sinks are available in the dosing rooms. The Committee recommended that Site Inspection Checklist Item 21 be revised to indicate that a sink is not available in the preparation room and that sinks are available in the dosing rooms.
2. An Institutional Representative confirmed that the sink that staff members will use to wash their hands after preparation is located in the [redacted]. The Committee recommended that the Site Map be revised to note the handwashing sink that will be used by staff members after preparing the study agent.
3. An Institutional Representative noted that full containers of biohazardous waste are currently stored for pickup by the commercial biohazardous waste hauler in [redacted]. The Committee recommended that the Institution store full containers of biohazardous waste in a room specifically designed for this purpose. An Institutional Representative agreed to this arrangement and identified the [redacted] on the Site Map that will be used for storage of full containers of biohazardous waste. The Committee recommended that the Site Map be updated accordingly and photos of the inside and outside of this room be submitted to IBC Services.
4. An Institutional Representative confirmed that the study agent will be vortexed within the Biological Safety Cabinet (BSC). The Committee recommended that Site Inspection Checklist Item 10 be revised to indicate that aerosol-generating activities are performed inside of a BSC.
5. The Committee recommended that Biosafety SOP Section 3.3 be revised to read as, "…The needle safety mechanism is engaged, the needle is removed and discarded immediately into a sharps container and a new capped dosing needle is placed onto the syringe. The study agent syringe is double-bagged and paced in a transport container."
6. The Committee noted the IATA Shipping Training Certification for a study staff member that is dated June, 2024 should be valid for two years. However, the Certification indicates that this training is set to expire June, 2025. The Committee recommended that staff members be retrained on shipping biologicals prior to certification expiration dates or the dates on certifications be updated to reflect accurate/valid expiration dates.

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: 3 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:20 am Arizona Time.