INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, August 26, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Oncology & Hematology Associates of West Broward (Sargon Research), Coral Springs, FL
Principal Investigator:	**Sumit Sawhney, 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 1:01 pm 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 the Principal Investigator, 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:

The Principal Investigator 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: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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. The Committee recommended that the biological safety cabinet (BSC) be labeled with a biohazard symbol.
2. An Institutional Representative confirmed that they have a rigid, leak-proof container, labeled with a biohazard sticker for internal transport of the study agent. The Committee recommended that a photo of the internal transport container be provided to IBC Services.
3. The Committee recommended not to store the broom and mop used for daily cleaning next to clean supplies in the preparation room. An Institutional Representative confirmed that the broom and mop will be moved to a different area within the room that is away from the clean supplies.
4. An Institutional Representative confirmed that the folding partition shown in the dosing room is used to separate subjects and that there is no glass door partition. The Committee recommended that the site photos be revised to remove information about the glass door separating rooms in the dosing area.
5. An Institutional Representative confirmed that there are no prefilled disposable eyewash bottles in the dosing room and that a plumbed eyewash station is located outside the dosing area. The Committee recommended that the Site Inspection Checklist, Item 22 be revised to state that an eyewash is not available in the dosing room.
6. An Institutional Representative confirmed that the dosing room chairs are non-porous and can be easily cleaned and decontaminated.
7. An Institutional Representative confirmed that no clean linens are stored in the biohazardous waste storage area.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and 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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:20 pm Eastern Time.