INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Wednesday, June 25, 2025**
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: BioResearch Partner, Miami, FL
Principal Investigator: **Javier Perez-Fernandez, 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 11:10 am 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 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 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. An Institutional Representative confirmed that only safety needles will be used to prepare the study agent. The Committee recommended that Biosafety SOP Section 3.3 be revised to replace references to "non-safety needles" and how they are recapped with "safety needles" and the means by which these will be recapped, and that Site Inspection Checklist Item 13 be revised accordingly.
2. The Committee recommended that Biosafety SOP Section 3.6.2 be revised to read as, "Freshly-prepared 10% bleach solution (1 part bleach, 9 parts water), followed by a 70% Isopropyl alcohol rinse."
3. The Committee discussed Florida's Department of Health sharps regulations which note that only needles, razors or broken glass may be discarded into sharps containers. An Institutional Representative confirmed that used study agent vials will not be discarded on site, but will be retained in [redacted] in the [redacted] and then shipped back to the Sponsor. The Committee recommended that Biosafety SOP Section 4.1 be revised to read as, "Used study agent vials will be stored in [redacted] in the [redacted] and then shipped back to the Sponsor."
4. The Committee discussed the wet contact time of CaviWipes HP and determined that the 1 minute wet contact time for decontamination of work surfaces should be sufficient since this is inline with the EPA-approved label claim for vaccinia virus. However, the Committee recommended that the wet contact time for decontamination of small spills less than 1 mL be increased (e.g. "for at least 1 minute").
5. The Committee recommended that Biosafety SOP Section 5.1.4a be revised to include a longer wet contact time for the CaviWipes HP disinfectant.
6. The Committee recommended that Biosafety SOP Section 5.2 be reordered to move subsection 6 to the beginning of this section since it describes what measures to take in the event of an exposure and applies to all types of exposures.
7. An Institutional Representative confirmed that full containers of biohazardous waste are stored in the storage/preparation room. The Committee recommended that the Institution submit a wide-angle photo of this room, including where/how full biohazardous waste containers are stored.
8. The Committee noted that one staff member's IATA Shipping Training is due this month and recommended that retraining be conducted and the new Certification be submitted to IBC Services.
9. An Institutional Representative confirmed that the Institution's Exposure Control Plan is available to study staff members via computer.
10. An Institutional Representative confirmed that handwashing sinks are available in all rooms where the study agent will be handled.
11. An Institutional Representative confirmed that the [redacted] monitors the expiration dates on prefilled disposable eyewash bottles.
12. An Institutional Representative confirmed that the freezer that will be used to store the study agent is calibrated.
13. The Committee recommended that sharps containers be either secured to wall or placed in stability bracket.
14. The Committee recommended that handwashing sinks be made clear of extraneous items to prevent accidental contamination of these items.
15. An Institutional Representative confirmed that the hole in the countertop where non-sharps biohazardous waste is discarded is large enough for use personal protective equipment. The Committee noted that there is a risk that the area around the hole may become contaminated.
16. An Institutional Representative confirmed that hand soap is available near handwashing sinks.
17. The Committee noted that doors to rooms where the study agent will be handled should be self-closing per best biosafety practices as outlined in the CDC's "Biosafety in Microbiological and Biomedical Laboratories

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:56 am Eastern Time.