INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, August 29, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Maryland Oncology Hematology, PA, Rockville, MD
Principal Investigator:	**John Wallmark, MD**
Protocol:	Genprex, Inc., **ONC-003**
NCT Number:	NCT04486833
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2 Open-Label, Dose-Escalation and Clinical Response Study of Quaratusugene Ozeplasmid in Combination with Osimertinib in Patients with Advanced, EGFR-Mutant, Metastatic Non-Small Cell Lung Cancer who have Progressed after Treatment with Osimertinib (Acclaim-1 Trial)

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:

Five voting members were present, including two local members unaffiliated with the institution. Also present were one Institutional Representative 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 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: 5 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 Reqorsa®, since it consists of an LNP-encapsulated plasmid dosed via intravenous infusion. 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 Reqorsa® 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: 5 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 be revised to by removing "(defined as less than 1 mL)" as the spill volumes would likely be greater than 1 mL.
2. The Institutional Representative stated that the Biological Safety Cabinet (BSC) was re-certified in August 2025. The Committee recommended that the new BSC Certification be provided to IBC Services.
3. The Institutional Representative confirmed that the study agent specific biohazard sign is posted at the entrance to the areas where the study agent is handled. The Committee recommended that a photo of the posted biohazard sign be provided to IBC Services.
4. The Institutional Representative confirmed that a plumbed eyewash station is located next to the [redacted] in the [redacted] as well as in the [redacted] dosing area. The Committee recommended that the Site Inspection Checklist (#22) be revised to indicate this.
5. The Institutional Representative confirmed that the institution does not have prefilled disposable eyewash bottles.
6. The Committee recommended that plumbed eyewashes be flushed at least weekly and that flush logs be kept.
7. The Institutional Representative confirmed that an absorbent pad will be used when handling the infusion bag in case of leakage.
8. The Committee noted that there are no lids on top of the biohazardous waste containers, as shown in the site photos. The Institutional Representative stated that biohazardous waste containers are kept open so that they are readily available for use and that sharps and non-sharps biohazardous waste are disposed of into separate containers.
9. The Committee recommended that biohazardous waste containers have lids when not in use and be labelled with biohazard symbols. The Committee recommended that new photos of the labelled biohazardous waste containers be provided to IBC Services.
10. The Institutional Representative confirmed that booties and a face shield are worn by study staff when handling the study agent. The Committee recommended that the Biohazard Sign be revised to indicate this.
11. The Institutional Representative confirmed that a safety needle is used for study agent preparation and that the safety mechanism is used to recap the needle. The Committee recommended that site documents be revised to indicate this.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:22 pm Eastern Time.