INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, August 29, 2025**
Time:	10:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Valkyrie Clinical Trials, Los Angeles, CA
Principal Investigator:	**David Berz, MD, PhD, MPH**
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 9:59 am Pacific 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 was 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: 4 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: 4 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 Institutional Representative noted that there is a handwashing sink located in the lab that staff can use after handling the study agent. The Committee recommended that site documents be updated to reflect this information.
2. The Committee noted that Biosafety SOP section 3.4.1 was updated to indicate that the study agent will be placed inside of doubled Ziploc-style bag as an additional form of containment prior to transport.
3. The Institutional Representative stated that full biohazardous waste containers are brought outside to the licensed biohazardous waste hauler for disposal at the time of collection. The Committee found this to be acceptable, and recommended that photos of the exterior doors of areas where waste is stored prior to collection be provided to IBC Services.
4. The Committee recommended that the institution confirm the eye protection worn by staff is reusable.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:17 am Pacific Time.