INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

| | |
|---|---|
| **Meeting Date:** | **Friday, January 9, 2026** |
| **Time:** | 10:00 am Central Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Ascension SE Wisconsin, Milwaukee, WI |
| **Principal Investigator:** | **Bhupendra O. Khatri, MD, FAAN** |
| **Protocol:** | Cartesian Therapeutics, Inc., **RNAC-MG-002** |
| **NCT Number:** | NCT06799247 |
| **Meeting Type:** | Initial Review of Protocol and Site |
| **Title:** | A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Descartes-08 in Patients with Generalized Myasthenia Gravis (MG) |

**1. Call to order:**

The Meeting was called to order at 10:00 am Central 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 five 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 Descartes-08**,** since it consists of primary human cells modified via mRNA transfection.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of Descartes-08 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: 5 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 Biosafety SOP Section 5.1 be revised to include steps for decontaminating the water bath in the event of a spill.
2. The Committee recommended that 16 fluid ounce prefilled disposable eyewash bottles be made available in the dosing room and that a photo of the eyewash bottles be provided to IBC Services.
3. The Committee recommended that absorbent material be placed inside the internal transport container during study agent transportation.
4. The Committee recommended that updated shipping training certificates, signed by both the participant and the supervisor, be submitted to IBC Services.
5. The Committee recommended that the chair in the dosing room be relocated away from the sink to avoid potential contamination of the chair and any items placed on it.
6. The Committee recommended that the Biohazard Sign be posted on the entrance doors of the preparation and dosing rooms when study agent handling activities occur and that updated photos be provided to IBC Services.
7. The Committee recommended that the metal file cabinet drawer that may be used for temporary storage of used study agent vials be labeled with a biohazard symbol.
8. An Institutional Representative confirmed that needles may be used to withdraw the isotonic solution from its vial during study agent preparation but that needle-free devices are used when withdrawing the study agent from its vial and when transferring the study agent to an infusion bag.
9. An Institutional Representative confirmed that preparation and dosing occur in the same building on the same floor.
10. An Institutional Representative confirmed that research staff complete all required safety training and that the Principal Investigator is responsible for ensuring that staff are properly trained.
11. An Institutional Representative confirmed that the biohazardous waste storage room is only used for waste storage and there are no research activities that occur in that area.
12. An Institutional Representative confirmed that disposable linens are used in the dosing room.
13. An Institutional Representative confirmed that bleach will be used for cleaning large spills and not for routine work surface decontamination.

**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: 5 NO: 0 ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 10:32 am Central Time.