INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, October 8, 2025**
Time:	12:00 pm Central Time
Location:	Zoom Teleconference
Institution:	Texas Retina Associates, Dallas, TX
Principal Investigator:	**Ashkan Abbey, MD**
Protocol:	Sanofi US Services Inc., **DFI18231**
NCT Number:	N/A
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1/2, study to evaluate the safety, tolerability, and efficacy of one-time intravitreal dose of SAR446597 in participants with geographic atrophy secondary to age-related macular degeneration

1. Call to order:

The Meeting was called to order at 12:00 pm Central 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 two 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-1 containment facilities and practices plus Standard Precautions** are required for SAR446597 since it consists of an AAV vector being administered by injection in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of SAR446597 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 absorbent material be placed on the countertop during study agent preparation and that Section 3.3 of the Biosafety SOP Section be revised to reflect this.
2. The Committee recommended that absorbent material be placed inside the Ziploc-style bag during study agent transport and that Section 3.4.1 of the Biosafety SOP be revised to reflect this.
3. The Committee recommended that photos of the biohazardous waste containers in the dosing rooms be provided to IBC Services.
4. An Institutional Representative confirmed that the hallways in which the study agent is transported are carpeted and that contaminated sections of the carpet are removed in the event of a spill. The Committee recommended that Section 3.6 of the Biosafety SOP and Site Inspection Checklist (#17) be revised to reflect this.

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 12:09 pm Central Time.