

Meeting Minutes

Institution:	Southeastern Retina Associates, PC		
Meeting Date:	April 16, 2026		
Meeting Time	1:30 PM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Pritchett, Christopher	Yes	Local Unaffiliated Member
	Welch, Jim	Yes	Local Unaffiliated Member
	Fung, Valerie	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	None		
Guests:	Youngblood, Tyler		
Staff:	Sreedharan, Aswathy		

Call to Order: The IBC Chair called the meeting to order at 1:31 PM Eastern Time. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

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Previous Meeting Minutes: Minutes from 3-24-26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Kleinman, Mark MD
Sponsor:	AbbVie Inc.
Protocol:	M23-415 An Operationally Seamless Phase 2b/3, Multicenter, Randomized, Masked, Sham-controlled Study to Evaluate the Efficacy and Safety of Surabgene Lomparovec (Suravec) Delivered via Suprachoroidal Space (SCS) Injection Targeting Subjects with Diabetic Retinopathy without Center Involved-Diabetic Macular Edema (CI-DME) (NAAVIGATE)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: M23-415 is a randomized, sham-controlled, masked, Phase IIb/III study sponsored by AbbVie Inc. and designed to assess the safety and efficacy of Surabgene Lomparovec (sura-vec; ABBV-RGX-314) in participants with diabetic retinopathy without center involved-diabetic macular edema. Sura-vec is a replication-defective, recombinant adenoassociated virus (AAV) expressing a soluble binding fragment specific to Vascular Endothelial Growth Factor (VEGF). The investigational product (IP) is administered by Suprachoroidal Injection.

Biosafety Containment Level (BSL): The study agent surabgene lomparovec is based on a Risk Group 1 (RG1) AAV vector that does not contain hazardous transgenes and is not handled or manufactured in the presence of a helper virus, thus biosafety level-1 (BSL-1) is the minimum recommended containment level for handling the study agent.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor’s study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
 - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during [preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and

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- use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package)
 - The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
 - The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
 - The Site confirmed that staff members receive Bloodborne Pathogens training.
 - Occupational Health Recommendations: None
 - The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.
- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
 - The Site verified that the information provided by the Chair was accurate.
 - In response to a question from the Committee, the Site confirmed that all procedure rooms have similar arrangements with cleanable surfaces, hand sanitizers, sharps and non-sharps containers.
 - In response to a question from the Committee, the Site confirmed that the doctor's office will not be used for dosing. The Site Map will be revised to update this information.
 - The Site confirmed the room used for storage was utilized as a kitchen by the previous tenant. The Site confirmed they have a separate break room, and no food or drink is stored in the storage area. The Site further confirmed this room is access controlled and used for storage only. The Committee had no concerns.
 - In response to a question from the Committee, the Site confirmed that one of the procedure rooms have a sink, and the Committee encouraged the Site to preferentially use this procedure room with the sink when it is available and logistically feasible.
 - The Committee encouraged the Site to ensure that they are comfortable with the format and style of safety training, and that all staff members have a full opportunity to review and understand the materials. The Site confirmed they have both comprehensive initial training and shorter refresher training. The Site also confirmed that study-specific training is provided to all requisite staff and that training is logged. The Committee had no concerns.
 - The Chair polled the Committee for any concerns in the event Sabai granted administrative approval for the clinic location reviewed at this meeting for two additional studies at the Site. The Chair confirmed the same study agents and handling practices reviewed today are used for the two additional studies. The Committee had no concerns or questions.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by

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unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

PI:	Kleinman, Mark MD
Sponsor:	4D Molecular Therapeutics, Inc.
Protocol:	4D-150-C004 A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-2)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: 4D-150-C004 is a Phase 3 clinical trial sponsored by 4D Molecular Therapeutics, Inc., and designed to evaluate the safety, efficacy, and durability of 4D-150 in adult participants with macular neovascularization (MNV) secondary to neovascular age-related macular degeneration (nAMD). 4D-150 is a recombinant, replication-defective adeno-associated virus (rAAV) vector utilizing AAV capsid variant 4D-R100 and carrying a single cassette expressing two anti-VEGF transgene components [miR-(VEGF-C) and codon-optimized aflibercept (coAFLB)], which are designed to inhibit angiogenesis and vascular leakage in the eyes of individuals with nAMD. The investigational product (IP) is administered by Intravitreal Injection.

Biosafety Containment Level (BSL): 4D-150 is a replication-defective rAAV vector produced without helper virus and does not encode any toxic or tumorigenic gene products. It is therefore classified as a Risk Group 1 (RG1) agent according to the NIH Guidelines and may be handled at Biosafety Level 1 (BSL-1)

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor’s study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
 - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during [preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and

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 - The Site confirmed that staff members receive Bloodborne Pathogens training.
 - Occupational Health Recommendations: None
 - The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.
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reviewed today are used for the two additional studies. The Committee had no concerns or questions.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:31 PM Eastern Time

Post-Meeting Pre-Approval Note: None