

## Meeting Minutes



|                                           |                                                                |               |                                          |
|-------------------------------------------|----------------------------------------------------------------|---------------|------------------------------------------|
| <b>Institution:</b>                       | University Retina – Lemont                                     |               |                                          |
| <b>Meeting Date:</b>                      | June 05, 2026                                                  |               |                                          |
| <b>Meeting Time</b>                       | 8:30 AM Central Time                                           |               |                                          |
| <b>Meeting Type:</b>                      | Virtual Platform Teleconference (Remote)<br>Open to the Public |               |                                          |
| <b>Members in Attendance:</b>             | <b>Member</b>                                                  | <b>Voting</b> | <b>Member Type</b>                       |
|                                           | Bavaret, Tammy                                                 | Yes           | Chair: Biosafety Expert/HGT Expert       |
|                                           | Campbell, Mark                                                 | Yes           | Core Member: Biosafety Expert/HGT Expert |
|                                           | Rastein, Daniel                                                | Yes           | Core Member: Biosafety Expert/HGT Expert |
|                                           | Helm, Allen                                                    | Yes           | Local Unaffiliated Member                |
|                                           | Bivona, John                                                   | Yes           | Local Unaffiliated Member                |
|                                           | Barcewicz, Maggie                                              | No            | Site Contact                             |
| <b>Invited Members Not in Attendance:</b> | None                                                           |               |                                          |
| <b>Guests:</b>                            | None                                                           |               |                                          |
| <b>Staff:</b>                             | Parrish, Wendy<br>Payne, Kaylie                                |               |                                          |

**Call to Order:** The IBC Chair called the meeting to order at 8:31 AM. 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

**Previous Meeting Minutes:** None

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### New Business:

|                                |                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PI:</b>                     | Sheth, Veeral                                                                                                                                                                                                                                                                                                                                      |
| <b>Sponsor:</b>                | AbbVie Inc.                                                                                                                                                                                                                                                                                                                                        |
| <b>Protocol:</b>               | M23-415<br>An Operationally Seamless Phase 2b/3, Multicenter, Randomized, Masked, Sham-controlled Study to Evaluate the Efficacy and Safety of Surabgene Lomparvovec (Suravec) Delivered via Suprachoroidal Space (SCS) Injection Targeting Subjects with Diabetic Retinopathy without Center Involved-Diabetic Macular Edema (CI-DME) (NAAVIGATE) |
| <b>Review Type:</b>            | Initial Review                                                                                                                                                                                                                                                                                                                                     |
| <b>NIH Guidelines Section:</b> | 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 Lomparvovec (sura-vec; ABBV-RGX-314) in participants with diabetic retinopathy without center involved-diabetic macular edema. Sura-vec is a replication-defective, recombinant adeno-associated virus (AAV) expressing a soluble binding fragment specific to Vascular Endothelial Growth Factor (VEGF). The investigational product (IP) is administered by injection of sura-vec into the suprachoroidal space (SCS) or sham needle-less control injection.

**Biosafety Containment Level (BSL):** The study agent surabgene lomparvovec 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. The administration of this agent in a clinical setting further requires compliance with OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

### 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.
    - The Committee discussed the photos of the preparation room. The Site confirmed the clean bench has been removed and preparation will take place on a benchtop or tray. The Committee stipulated the Site provide an updated photo of the preparation space.
    - In response to a question from the Committee, the Site confirmed their priming process while preparing the IP. The Facility Details xForm will be administratively revised to include a description of the Site's priming process.
    - The Committee suggested the Site consider moving the fire extinguisher to a different location in the preparation room.
    - The Committee discussed the photos of the exam rooms, and recommended placing smaller portable eyewash bottles in a dedicated space separate from other bottles. The Site noted they will also consider purchasing additional eyewash bottles.
    - The Committee suggested the Site consider installing a plumbed eyewash station on the premises.
    - The Committee discussed the photos of the biohazardous waste storage area. The Site confirmed the layout of the area and access to the space. The Site further confirmed there are silicone trays under the Vendor-provided boxes and the carpet has been removed. The Committee stipulated the Site provide updated photo(s) of the area showing placement of biohazard signage and no carpet.
    - The Site confirmed reusable ocular speculums are used, and are sanitized with a disinfectant wipe prior to being sent for sterile processing. The Committee had no concerns.
    - The Committee recommended that the Site confirm the proposed disinfectant has a label claim confirming efficacy against non-enveloped viruses.

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- The Site confirmed that the annual OSHA training includes bloodborne pathogen training. The Committee had no concerns.
- The Biohazard Sign will be administratively revised to define the AAV acronym.

**Motion:** A motion of Approval with Stipulations 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:
  - The Committee stipulated that the Site provide an updated photo of the preparation room showing the benchtop preparation space with clean bench removed by 7/5/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site provide an updated photo of the biohazardous waste storage area showing placement of biohazard signage and no carpet by 7/5/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

**Review of Incidents:** Nothing to report.

**IBC Training:** Nothing to report.

**Reminder of IBC Approval Requirements.**

**Adjournment:** The IBC Chair adjourned the meeting at 9:22 AM.

**Post-Meeting Pre-Approval Note:** None