Meeting Minutes

Meeting Date: July 22, 2025 at 1:30 PM Central Time

Meeting Type: Teleconference (Remote)
Meeting open to the Public

Members in Attendance:

Noriea, Nicholas
Helm, Allen
Bivona, John
Foreman, Robert
Reed, Craig
Rastein, Daniel

Members Not in Attendance: None

Guests: Bhagat, Davis; Lyon, Alice

Staff: Smith, Jennifer

Institution: Northwestern University Feinberg School of Medicine

Call to Order: The meeting was called to order at 1:32 PM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Lyon, Alice, MD
Sponsor:	AbbVie Inc
Protocol:	RGX-314-3101 A Randomized, Partially Masked, Controlled, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT)
Review Type:	Annual Review
NIH Guidelines Section:	III-C

Trial Summary: RGX-314-3101 (also known as M23-409) is a Phase 3, multi-center, partially masked, randomized, active-controlled, parallel arm study sponsored by AbbVie Inc and designed to investigate the efficacy and safety of the study agent ABBV-RGX-314 administered as a single subretinal injection in participants with neovascular age-related macular degeneration (nAMD). ABBV-RGX-314 (also known as RGX-314) is a recombinant adeno-associated viral vector (rAAV) serotype 8, containing a transgene that encodes for soluble anti-vascular endothelial growth factor (VEGF) antigen-binding fragment (Fab) protein.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.
- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report, 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 Site noted that the agent dosing room has moved to the adjacent OR due to the location of the surgical microscope. The Site confirmed the new dosing room is setup in the same manner with the same features and general arrangements. The Chair noted the dosing location would be updated. The Committee had no concerns or questions.
    - The Committee noted that the BBP Training certificate on file will expire soon and the Site confirmed that they will send an updated certificate once the training has been completed
    - The Site confirmed that the study agent may be stored in the refrigerator and is typically shipped on site when it is time for dosing. The Site further noted that they are still finalizing arrangements for refrigerated storage. The Chair noted that Sabai will follow up with the Site to confirm storage location once finalized. The Chair polled the Committee for any concerns in the event Sabai granted administrative approval of any new storage location, if applicable, if the new storage is consistent with the currently approved arrangements. The Committee had no concerns or questions.
    - The Site confirmed the storage location is access controlled and biohazard labeling is present
    - The Committee reminded the Site not to stack empty unused waste containers

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by majority vote. There were no abstentions on voting.

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

Reminder of IBC Approval Requirements.

Adjournment: 2:20 PM

Post-Meeting Pre-Approval Note: None