Title: A Randomized, Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age-Related Macular Degeneration (nAMD).

ACHIEVE Research Study/Research Study/Wet AMD Study

Condition: Neovascular Age-Related Macular Degeneration (nAMD)

Eligible Subjects will be randomly assigned into one of the three study arms:

Investigational Treatment Arm A: Screening/Active run-in period of up to 6 weeks. An intravitreal injection of ranibizumab (Lucentis®) at the first visit, followed by an intravitreal injection of ranibizumab (Lucentis®) approximately 4 weeks later, if eligible. Surgical visit on Day 1 to receive a subretinal dose of the study drug in the study eye, if eligible. Postoperative safety visits on Day 2 and Day 8. Additional dose of ranibizumab (Lucentis®) to be given 2 weeks after surgery. Subjects will return for site visits at specified intervals for approximately 5 years. Additional doses of intravitreal ranibizumab (Lucentis®) may be given if recommended by the study doctor.

Investigational Treatment Arm B: Screening/Active run-in period of up to 6 weeks. An intravitreal injection of ranibizumab (Lucentis®) at the first visit, followed by an intravitreal injection of ranibizumab (Lucentis®) approximately 4 weeks later, if eligible. Surgical visit on Day 1 to receive a subretinal dose of the study drug in the study eye, if eligible. Postoperative safety visits on Day 2 and Day 8. Additional dose of ranibizumab (Lucentis®) to be given 2 weeks after surgery. Subjects will return for site visits at specified intervals for approximately 5 years. Additional doses of intravitreal ranibizumab (Lucentis®) may be given if recommended by the study doctor.

Control Arm: Screening/Active run-in period of up to 6 weeks. An intravitreal injection of ranibizumab (Lucentis®) at the first visit, followed by an intravitreal injection of ranibizumab (Lucentis®) approximately 4 weeks later, if eligible. There is no surgery in this arm. Subjects will return at Week 2 and will receive intravitreal ranibizumab (Lucentis®). For Week 2 through Week 54, subjects will return for monthly study visits and may receive an intravitreal injection of ranibizumab (Lucentis®). For Week 54 through Year 5, subjects will come every six months for a study visit and may receive an intravitreal injection of ranibizumab (Lucentis®). Subjects may receive additional doses of intravitreal ranibizumab if recommended by the study doctor.

Final Visit for all Arms A, Arm B and Control Arm: Year 5

Sponsor: AbbVie, Inc.

Royal Oak Site:

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