BLACK HILLS REGIONAL EYE INSTITUTE

Clinical Research Trials

Principal Investigator: Prema Abraham, MD

For more information, please call Retina Research Department (605)-341-2000.

Study Name	Study Rationale	Study Candidates	Current Enrollment
4FRONT-1 **4D Molecular Therapeutics, Inc. Clinical (Enrolling)**	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 . 4D-150 is a multi-mechanistic adeno-associated virus (AAV)-based gene therapy product in clinical development for the treatment of nAMD and diabetic macular edema (DME). 4D-150 is delivered as a single IVT injection.	≥50 years of age at time of consent and treatment naïve MNV secondary to nAMD in the study eye. CST ≤500µm in the study eye at Screening visit. BCVA between 25 and 78 ETDRS letters, inclusive (20/320-20/32 Snellen equivalent) in the study eye at Screening Visit. BCVA ≥34 ETDRS letters (~20/200 Snellen equivalent) in the contralateral eye at the Screening Visit	**Open**
4951-003 **KHK4951** **Kyowa Kirin Co., Ltd. (Enrollment closing on 31st Jul2025)**	A Phase 2, Multicenter, Randomized, Double- Masked, Parallel-Group Study to Assess the Efficacy and Safety of KHK4951, a Vascular Endothelial Growth Factor Receptor Inhibitor, in Patients with Diabetic Macular Edema. KHK4951 is a topical eye drop formulation of tivozanib, a VEGFR inhibitor. This Phase 2 study is designed to evaluate the efficacy, safety, and PK of KHK4951 administered alone QD or BID for 36 weeks in patients with DME.	Must be 18 years of age or older diagnosed with type-1 or 2 diabetes mellitus at the time of signing the informed consent. Macular thickening SD-OCT secondary to DME involving the center of the macula: 500 μm ≥ CST ≥ 325 μm with Spectralis (Heidelberg) at screening. CST≥ 325 μm on Day 1. BCVA ETDRS letter score of 78-35 letters(Snellen equivalent of 20/32 to 20/200) for the study eye at screening and on day 1.	**Open (Enrollment closing on 31stJul2025)**

Ascent RegenXBio 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. The long-term, stable expression of the ABBV-RGX- 314 TP following a 1-time gene therapy treatment for nAMD could potentially reduce the treatment burden of currently available anti-VEGF therapies while maintaining vision with a favorable benefit:risk profile. The main study is therefore intended to evaluate the safety and efficacy of ABBV-RGX-314 in participants with nAMD relative to an active comparator (aflibercept 2 mg [0.05 mL]) administered by intravitreal injection.	Males or females aged ≥ 50 years and ≤ 89 years. An ETDRS BCVA letter score between ≤ 78 and ≥ 40 in the study eye at Screening. Must be pseudophakic (at least 12 weeks postcataract surgery at Randomization; Screening Visit 3 in the study eye. Study eye must have a CRT < 400 µm at Week –5 (Screening Visit 2)	**Open**
Atmosphere RegenXBio (RGX-314-2104)	Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ATMOSPHERE) The long-term, stable expression of the ABBV-RGX-314 TP following a 1-time gene therapy treatment for nAMD could potentially reduce the treatment burden of currently available anti-VEGF therapies while maintaining vision with a favorable benefit:risk profile. The main study is therefore intended to evaluate the safety and efficacy of ABBV-RGX-314 in participants with nAMD relative to an active comparator (ranibizumab monthly intravitreal injection)	Aged ≥ 50 and ≤ 89 years, must have a diagnosis of choroidal neovascularization secondary to age-related macular degeneration in the study eye within the last 4 years, have received intravitreal anti-VEGF therapy for nAMD prior to Week –6 (Screening Visit 1) and been responsive, along with fluid within the parafovea. Optical coherence tomography documentation from a current image of center subfield fluid must be confirmed by the CRC. Participants must have a BCVA letter score in the study eye between ≤ 78 and ≥ 40 and be pseudophakic (status postcataract surgery) in the study eye.	**Open**

Artemis **Adverum Biotechnologies, Inc.** **ADVM-022-12**	A Multi-Center, Randomized, Double-Masked, Active-Comparator-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of *Ixoberogene soroparvovec* (Ixo-vec) in Participants with Neovascular Age-Related Macular Degeneration. The study is designed to assess the non-inferiority of a single IVT injection of Ixo-vec compared with IVT injections of aflibercept 2 mg.	At least 50 years old at Screening Visit 1 . ETDRS BCVA letter score ≥ 35 and ≤ 78 (approximate Snellen equivalent of 20/200 to 20/32) in the study eye at Screening Visit ETDRS BCVA letter score ≥35 (approximate Snellen equivalent of 20/200 or better) in the non-study eye at Screening Visit 1. 10% for participants with CST > 300 µm at Screening Visit 1 5% for participants with CST ≤ 300 µm at Screening Visit 1.	**Upcoming**
Constance **F. Hoffmann-La Roche Ltd** **MR45638**	A Phase IIIB/IV, Multicentre, Randomized, Open-Label, Two-Arm Study to investigate the Efficacy, Safety, and Durability of Faricimab administered up to every 24 weeks in patients with Neovascular Age-Related Macular Degeneration. The study will follow an open-label design, as all participants will receive 6-mg IVT faricimab during the study treatment period and there will be no masking of treatment interval.	Age 50 years at the time of signing Informed Consent Form . Active treatment-naïve MNV secondary to AMD, confirmed by the Investigator based on the presence of IRF or SRF affecting the central subfield on OCT. BCVA of 83 to 24 letters, inclusive (20/25 to 20/320 approximate Snellen equivalent, using the ETDRS protocol and addressed at the initial testing distance of 4 meters on Day 1).	**Upcoming**

Sienna **Regeneron Pharmaceuticals, Inc.** **R3918-AMD-2326**	A Multicentre, Randomized, Double-Masked, Placebo-Controlled Phase 3 Study of the Efficacy, Safety, and tolerability of Subcutaneously Administered Pozelimab in Combination with Cemdisiran or Cemdisiran alone in participants with Geographic Atrophy Secondary to Age-Related Macular Degeneration. This study will assess the efficacy and safety of pozelimab + cemdisiran combination therapy and cemdisiran monotherapy against placebo.	Male or female ≥50 years of age at the time of signing of ICF . Study eye with diagnosis of GA of the macula secondary to AMD not involving the foveal center point, BCVA of 35 letters or better using ETDRS charts (20/200 Snellen equivalent) in the study eye at screening and randomization Prior to study treatment administration, participants will be fully vaccinated against *Neisseria meningitidis* (serogroups ACWY and B), *Streptococcus pneumoniae.* Participants who have not been vaccinated against *Haemophilus influenzae* type B may receive the vaccination during the screening period and/or baseline visit.	**Upcoming**