BLACK HILLS REGIONAL EYE INSTITUTE

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Study Name	Study Rationale	Study Candidates	Current Enrollment
4FRONT-2 **4D Molecular Therapeutics, Inc.** **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 . 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 or previously treated MNV secondary to nAMD in the study eye. If previous treatment in study eye, cannot be more than 4 IVT injections and initial diagnosis should not be more than 6 months prior to the screening visit. 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. Must demonstrate clinical response to aflibercept and functional stability in the study eye from Screening week -5 to week -1 and at day 1.	**Currently Enrolling**
Aquarius **Adverum Biotechnologies, Inc.** **ADVM-022-13**	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 vector genome compared to IVT injections of aflibercept 2 mg Q 8 W.	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 1. ETDRS BCVA letter score ≥35 (approximate Snellen equivalent of 20/200 or better) in the non-study eye at Screening Visit 1. Must demonstrate a meaningful anatomic response to anti-VEGF therapy from Screening Visit 1 to Day 1.	**Upcoming**

Journey **Perceive Bio** **PBI-AMD-002**	Phase 1/2a Study of VOY-101 in subjects with Advanced Non-Neovascular Age-Related Macular Degeneration. This study has a prospective, open-label, multi-center, two-part design to evaluate a single, unilateral intravitreal (IVT) injection of VOY-101 in subjects with geographic atrophy (GA), the advanced form of non-neovascular age-related macular degeneration (AMD). Phase 1 followed a standard dose escalation model to establish safety and tolerability of VOY-101 and determine the recommended Phase 2a dose (RP2D). This does is being used in the randomized Phase 2a part of the study to evaluate the safety and efficacy of VOY-101 in the study eye compared to untreated fellow eye.	≥ 60 years of age at the time of consent. Must be able to self-administer eye drops or have a caregiver capable of administering eye drops. Subjects must be at elevated genetic risk at the AMD-associated Chromosome 1 (Chr1) locus. In Phase 2a both eyes need to meet inclusion criteria: BCVA ≥ 25 letters (Snellen 20/320) in both eyes. Well-demarcated GA that meet criteria based on fundus autofluorescence (FAF) imaging. Any IVT drug delivery within 3 months prior to baseline visit is exclusionary.	**Currently Enrolling**
Sienna Regeneron Pharmaceuticals, Inc. R3918-AMD-2326	A Multicenter, 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 evaluate the effect of systemic complement component 5 (C5) inhibition on geographic atrophy (GA) lesion growth over 52 weeks and evaluate the effect of systemic C5 inhibition on functional measures of GA disease progression.	Male or female ≥50 and ≤85 years of age at the time of signing consent. Study eye with diagnosis of GA of the macula secondary to AMD, Total GA area in the study eye measuring between ≥2.5 mm2 and ≤17.5 mm2 determined by screening images. BCVA of 55 letters or better using ETDRS charts (20/80 Snellen equivalent) in the study eye at screening and randomization. Prior to start of study treatment administration, participants must be fully vaccinated against Neisseria meningitidis (serogroups ACWY and B), Streptococcus pneumoniae. Prior or current IVT treatment of any kind for any indication in the study eye must be ≥6 months prior to starting study treatment (randomization visit).	**Currently Enrolling**

Gallop **Apellis Pharmaceuticals, Inc.** **APL3007-GA-201**	A Phase 2, Randomized, Placebo-Controlled, Multicenter, Masked Study to evaluate the Efficacy, Safety, Tolerability, and Pharmacodynamics of multidose APL-3007 in Combination with Syfovre/Pegcetacoplan (APL-2) in patients diagnosed with Geographic Atrophy Secondary to Age-Related Macular Degeneration. This study will evaluate the efficacy of multidose APL-3007 and Syfovre/pegcetacoplan (APL-2) on retinal pigment epithelium (RPE) lesion area as assessed by spectral domain optical coherence tomography (SD-OCT) in patients diagnosed with GA secondary to age-related macular degeneration (AMD). All participants will receive a total of 2 injections for each administration of APL-3007 or placebo. In addition to subcutaneous injection of APL-3007 or placebo, all participants will receive a single IVT injection of Syfovre/pegcetacoplan (APL-2) or a sham IVT injection for each treatment administration according to their randomized group.	≥60 years of age at the time of signing consent. Clinical diagnosis of GA of the macula secondary to AMD in one or both eyes, as determined by the investigator. The study eye must meet all inclusion criteria. If both eyes meet the inclusion criteria, the eye with better normal luminance visual acuity at the screening visit will be designated as the study eye. If both eyes have the same visual acuity, the right eye will be used as the study eye. NL-BCVA of 50 letters or better using ETDRS charts (approx. 20/100 Snellen equivalent). The GA lesion in at least 1 eye (designated as the study eye) must meet criteria determined by the central reading center. Prior treatment for GA in the study eye using Syfovre at 6-8 weeks interval for at least 6 months but no more than 24 months will be included if the participant has at least 2 Syfovre injections in the 6 months before screening.	**Upcoming**