BLACK HILLS REGIONAL EYE INSTITUTE

Clinical Research Trials
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Study Name	Study Rationale	Study Candidates	Current Enrollment
Comino (GR41986) ***CRVO***	A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, ACTIVE COMPARATORCONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FARICIMAB IN PATIENTS WITH MACULAR EDEMA SECONDARY TO CENTRAL RETINAL OR HEMIRETINAL VEIN OCCLUSION	Age ≥18, diagnosis of moderate BDR or worse, PDR, DME, NEARMD, GA, myopic choroidal neovascularization, dx no longer than 4 months prior to screening, BCVA of 73 to 19 letters (20/40 to 20/400 approximate Snellen equivalent, CST ≥ 325um as measured on Spectralis SD-OCT	**Open**
Gleam (KS301P104) ***DME***	A Prospective, Randomized, Double-masked, Active Comparator-controlled, Multi-center, Two-arm, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal KSI-301 Compared with Intravitreal Aflibercept in Participants with Visual Impairment Secondary to Treatment-naïve Diabetic Macular Edema (DME)	Treatment-naïve DME w/ vision loss and center involvement dx within 9 months of screening BCVA ETDRS letter score ≤ 78 and ≥ 25 (20/25 to 20/320 Snellen) in the SE at screening and confirmed at Day 1 CST of ≥ 320 microns on SD-OCT as determined by the Reading Center at the screening visit, HbA1c of ≤12%	**Open**

Beacon ***(KS301P103)*** ***RVO***	A Prospective, Randomized, Double-masked, Active Comparator-controlled, Multi-center, Two-arm, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal KSI-301 Compared with Intravitreal Aflibercept in Participants with Visual Impairment Due to Treatment-naïve Macular Edema Secondary to Retinal Vein Occlusion (RVO)	Treatment-naïve macular edema and visual impairments of ⩽ 6 months secondary to CRVO or BRVO. Participants with HRVO will also be considered eligible for this study and will be included as a CRVO. BCVA ETDRS letter score ≤ 80 and ≥ 25 (20/25 to 20/320 Snellen) in the SE at screening and confirmed a Day 1. CST of ⩾ 320 microns on Heidelberg Spectralis as determined by Reading center at the screening visit. Decrease in vision in the SE determined by the investigator to be primarily the result of ME secondary to RVO.	**Open**
Ocuphire **(OPI-APXDR-201)** ***NPDR***	*Randomized, Placebo-Controlled, Double-Masked Study of the Safety and Efficacy of Orally Administered APX3330 in Subjects with Moderately Severe to Severe Non-Proliferative Diabetic Retinopathy and Mild Proliferative Diabetic Retinopathy*	≥ 18 yrs of age, At least one eye with DR graded at least mod severe to severe NPDR or mild PDR (confirmed by a central reading center) in which PRP and IVT injections of an anti-VEGF agent can be safely deferred for ≥ 6 months, BCVA letter score of ⩾ 60 letters (Snellen ≥ 20/63) in the SE, BMI between 18-40	**Open**
Amgen (20170542) ***Neovascular Age Related Macular Degeneration*** ***Wet AMD***	A Randomized, Double-masked, Phase 3 Study of ABP-938 Efficacy and Safety Compared to Aflibercept (Eylea®) in Subjects with Neovascular Age-related Macular Degeneration (1 year)	Age 50 + Active treatment naïve CNV lesions secondary to nAMD; BCVA between 73 and 34 ETDRS letters (20/40 – 20/200); Presence of intra and/or subretinal fluid; CRT ≥ 300 μm in SE, FE cannot be Tx w/in 6 mo of Randomization	**Open**

RegenXBio (RGX-314-2101) ***Gene therapy w/ nAMD Neovascular Age Related Macular Degeneration***	A Randomized, Partially Masked, Controlled, Phase 2b Clinical Study to Evaluate the Safety and Efficacy of RGX-314 Gene Therapy in Participants with nAMD (2 years)	Age 50-89, BCVA 40 to 78 at screening, Dx of subfoveal CNV secondary to AMD along w/ fluid w/in parafovea (3-mm center of the macula), CNV lesion size needs to be less than 10-disc areas	**Upcoming**
Balaton (GR41984) ***Macular Edema Secondary to Branch Retinal Vein Occlusion (BRVO)***	A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Macular Edema Secondary to Branch Retinal Vein Occlusion	Age $\geq$ 18 years old; Foveal Center-Involved Macular Edema Due to BRVO, Diagnosed No Longer Than 3 Months Prior to Screening; BCVA of 73 to 19 letters (20/40-20/400); CST $\geq$ 325 µ on Spectralis	**Open**
SCD411-CP101 ***Wet AMD***	A Phase III Randomized, Double-Masked, Parallel Group, Multicenter Study to Compare the Efficacy, Safety, Tolerability, Pharmacokinetics,and Immunogenicity between SCD411 and Eylea®in Subjects with Neovascular Age-related Macular Degeneration	Age 50 +, OU must be Tx naïve, BCVA 73 to 35 letters (20/40 – 20/200) and FE cannot be <35 letters, CRT equal to or >300	**Open**
Pulsar (20968) *BAY 86-5321 / aflibercept* ***Wet AMD***	A Randomized, Double-Masked, Active-Controlled, Phase 3 Study of the Efficacy and Safety of High Dose Aflibercept in Patients With Neovascular Age-Related Macular Degeneration	Age 50+, total area of CNV must comprise > 50% of total lesion area in SE, BCVA letter score 78 to 24 (20/32 to 20/320) in SE, presence of IRF and/or SRF affecting central subfield	**Open**
Iveric (ISEE2008) ***Dry AMD***	A PHASE 3 MULTICENTER, RANDOMIZED, DOUBLE-MASKED, SHAM CONTROLLED CLINICAL TRIAL TO ASSESS THE SAFETY AND EFFICACY OF INTRAVITREAL ADMINISTRATION OF ZIMURA™ (COMPLEMENT C5 INHIBITOR) IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION	Age 50 +, GA area $\geqslant$ 2.5 and $\leqslant$ 17.5 mm, if GA is multifocal at least 1 lesion should measure $\geqslant$ 1.25 mm, GA in part w/in 1500 microns from foveal center, BCVA SE 20/25 to 20/320, IOP = to or $\leqslant$ 21, Must be Tx naïve	**Open**
NGM/Catalina (NGM621-GA-201) ***Dry AMD***	A Phase 2 Multicenter, Randomized, Double-Masked, Sham-Controlled Study of the Safety and Efficacy of Intravitreal Injections of NGM621 in Subjects with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD) (Catalina).	Age 55 +, BCVA letters of 34 or better (20/200 Snellen equivalent or better) in SE, total GA area must be $\geqslant$ 2.5 and $\leqslant$ 17.5 mm, if GA is multifocal at least 1 lesion must be $\geqslant$ 1.25 mm, the entire GA lesion	**Open**

		must be completely visualized on the macula centered image and imaged in its entirety, not contiguous w/ any areas of peripapillary atrophy.	