BLACK HILLS REGIONAL EYE INSTITUTE

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Study Name	Study Rationale	Study Candidates
Alexion (ALXN2040-GA-201) ***Dry AMD*** **Current Enrollment:** **ACTIVE**	A PHASE II, DOUBLE-MASKED, PLACEBO-CONTROLLED, DOSE RANGE FINDING STUDY OF DANICOPAN IN PATIENTS WITH GEOGRAPHIC ATROPHY (GA) SECONDARY TO AGE-RELATED MACULR DEGENERATION.	≥ 60 years, treatment naïve, vaccinated against meningococcal infections, total GA lesion area of 0.5 to 17.76 mm2 (~0.2-to-7-disc area [DA]) per eye measured by FAF. If GA is multifocal, at least one focal lesion must be ≥ 0.5 mm^2(~0.2 DA). Study Eye VA range of 84 to 24 letters; 20/20 to 20/320 using ETDRS charts at 4m, axial length ≤ 26.0 mm, or spherical equivalent refractive error ≤ 6.0 diopter of myopia.
Alluvium (BP43445) ***DME*** **Current Enrollment:** **ACTIVE**	A PHASE II, MULTICENTER, RANDOMIZED, DOUBLE MASKED, ACTIVE COMPARATOR-CONTROLLED STUDY TO INVESTIGATE THE EFFICACY, SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF RO7200220 ADMINISTERED INTRAVITREALLY IN PATIENTS WITH DIABETIC MACULAR EDEMA	≥ 18 years and treatment naïve or washout period of 8-16 weeks. Diagnosed with diabetes mellitus (Type 1 and Type 2) and center-involving macular edema associated with DR as well as vision loss due to the DME. CST of ≥ 325 µm. BCVA letter score of 73 to 19 letters (both inclusive; 20/40 − 20/400). HbA1c < 12% at screening.
Ascent (RGX-314-3101) **Wet AMD** **Current Enrollment:** **ENROLLING**	A RANDOMIZED PARTIALLY MASKED, CONTROLLED PHASE 3, CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF RGX-314 GENE THERAPY INPARTICIPANTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (nAMD).	Between ≥ 50 years and ≤ 89 years. ETDRS BCVA letter score between ≤ 78 and ≥ 40 in study eye at visit 1. CNV lesion size < 10-disc areas (~2.54mm^2). Pseudophakic study eye. Diagnosis of CNV secondary to AMD in the study eye, must have received prior anti-VEGF treatment to control a recently active CNV lesion and who demonstrated a response to those injections. Study eye with wet AMD diagnosed < 4 years from Screening Visit 1. Spherical equivalent of the refractive error in the study eye demonstrating ≤ −8.00 diopters or an axial length < 26 mm.

Atmosphere (RGX-314-2104) ***Wet AMD*** **Current Enrollment:** **ENROLLING**	A RANDOMIZED PARTIALLY MASKED, CONTROLLED PHASE 2B/3 CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF RGX-314 GENE THERAPY INPARTICIPANTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (nAMD).	Between ≥ 50 years and ≤ 89 years. ETDRS BCVA letter score between ≤ 78 and ≥ 40 in study eye at visit 1. CNV lesion size < 10-disc areas (~2.54mm^2). Pseudophakic study eye. Diagnosis of CNV secondary to AMD in the study eye, must have received prior anti-VEGF treatment to control a recently active CNV lesion and who demonstrated a response to those injections. Study eye with wet AMD diagnosed < 4 years from Screening Visit 1. Spherical equivalent of the refractive error in the study eye demonstrating ≤ −8.00 diopters or an axial length < 26 mm.

Coast (OPT-302-1005) ***Gene therapy w/ nAMD Neovascular Age Related Macular Degeneration*** **Current Enrollment:** **ACTIVE**	A PHASE III, MULTICENTER, DOUBLE MASKED RANDOMIZED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INTRVITREAL OPT-302 IN COMBINATION WITH AFLIBERCEPT ALONE, IN PARTICIPANTS WITH NEOVASVULAR AGE-RELATED MACULAR DEGENERATION.	≥50 years of age with active subfoveal CNV lesion or juxtafoveal CNV lesion (1-199 µm from the fovea) with foveal involvement (demonstrated by leakage on FA and/or IR fluid or SRF on SD-OCT) that is secondary to AMD. An ETDRS BCVA score between 60 and 25 (inclusive) letters. CNV ≥ 50% lesion area, total lesion size of ≤ 30.5 mm^2. Can be classic or occult CNV. Occult CNV must measure < 10 mm^2.
Elevatum (ML43435) ***DME*** **Current Enrollment:** **ACTIVE**	A PHASE IV, MULTICENTER, OPEN-LABEL, SINGLE-ARM STUDY TO INVESTIGATE FARICIMAB (RO6867461) TREATMENT RESPONSE IN TREATMENT-NAÏVE, UNDERREPRESENTED PATIENTS WITH DIABETIC MACULAR EDEMA	≥ 18 years, IVT treatment-naïve in the study eye, who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander. Diagnosed and receiving treatment for diabetes mellitus (type 1 or type 2), HbA1c ≤10%, DME involving center of the macula, CST of ≥325 µm, BCVA letter score of 73 to 20 letters (both inclusive).
Gale (APL2-GA-305) ***Dry AMD*** ***Gale (Derby extension)*** **Current Enrollment:** **ACTIVE**	A PHASE 3, OPEN-LABEL, MULTICENTER, EXTENSION STUDY TO EVALUATE THE LONGTERM SAFETY AND EFFICACY OF PEGCETACOPLAN IN SUBJECTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION	Participated in APL2-103 (NCT03777332) or completed the treatment at month 24 of either APL2-303 (Derby, NCT03525613) or APL2-304 (Oaks, NCT03525600). Clarity of ocular media, adequate pupillary dilation, and fixation.

Iveric (ISEE2009) ***Dry AMD*** **Current Enrollment:** **ACTIVE**	AN OPEN-LABEL EXTENSION (OLE) PHASE 3 TRIAL TO ASSESS THE SAFETY OF INTRAVITREAL ADMINISTRATION OF AVACINCAPTAD PEGOL (COMPLEMENT C5 INHIBITOR) IN PATIENTS WITH GEOGRAPHIC ATROPHY WHO PREVIOUSLY COMPLETED PHASE 3 STUDY ISEE2008	≥ 50 years, diagnosed with GA inside and/or outside of the fovea who completed Study ISEE2008 through month 24.
Photon (VGDTe-HDDME-1934) ***DME*** **Current Enrollment:** **ACTIVE**	A RANDOMIZED, DOUBLE-MASKED, ACTIVE-CONTROLLED PHASE 2/3 STUDY OF THE EFFICACY AND SAFETY OF HIGH-DOSE AFLIBERCEPT IN PATIENTS WITH DIABETIC MACULAR EDEMA	≥18 years, diagnosed with type 1 or type 2 diabetes mellitus 2. DME with central involvement in the study eye with CRT ≥300 µm (or ≥320 µm). Decreased vision due to DME. BCVA early treatment diabetic retinopathy study (ETDRS) letter score of 78 to 24 (20/32 to 20/320). IOP ≤ 25 mmHg in the study eye.
Pulsar (20968) ***Wet AMD*** **Current Enrollment:** **ACTIVE**	A RANDOMIZED, DOUBLE-MASKED, ACTIVE-CONTROLLED PHASE 3 STUDY OF THE EFFICACY AND SAFETY OF HIGH-DOSE AFLIBERCEPT IN PATIENTS WITH DIABETIC MACULAR EDEMA	≥ 50 years, total area of CNV must comprise > 50% of total lesion area in study eye, total lesion size < 12-disc areas ($30.5mm^{2,}$ including blood, scars, and neovascularization), IOP < 25mmHg in the study eye. BCVA letter score 78 to 24 (20/32 to 20/320) in study eye, decreased vision primarily due to wet AMD in the study eye, presence of IRF and/or SRF affecting central subfield (1mm diameter centered on the fovea).

Garland (APL2-GA-411) ***Dry AMD*** **Current Enrollment:** **ENROLLING**	A PROSPECTIVE, MULTICENTER, OPEN-LABEL, OBSERVATIONAL PHASE 4 STUDY TO EVALUATE REAL-WORLD SAFETY, TOLERABILITY, AND TREATMENT PATTERNS OF PEGCETACOPLAN (SYFOVRE) IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION.	≥60 years, treatment-naïve and prescribed pegcetacoplan, VA of 20/200 or better, diagnosis of GA secondary to AMD in one or both eyes, non subfoveal GA lesions, lesion must be visualized in its entirety on the macula centered OCT, presence of any pattern of hyperautofluorescence in the junctional zone of GA.
4951-002 (Kyowa Kirin Co., Ltd) ***Wet AMD (KHK)*** **Current Enrollment:** **UPCOMING**	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 NEOVASCULAR AGE-RELATED MACULAR DEGENERATION	≥ 50 years, treatment-naïve wet AMD with active subfoveal MNV or juxtafoveal MNV secondary to AMD with active leakage affecting the fovea in the study eye, as noted on FA. BCVA ETDRS letter score of 73 letters to 35 letters (20/40 to 20/200) for the study eye at screening and on Day 1. CST ≥ 350 µm and ≤ 450 µm at screening as assessed by the central reading center and CST ≥ 350 µm at Day 1. IOP ≤ 25 mm Hg. TSH > 0.4 mIU/L or < 5.0 mIU/L at screening. HbA1c < 8.5%.

OTX-TKI Wet AMD (Ocular Therapeutix) **Current Enrollment:** **UPCOMING**	A PHASE 3, MULTICENTER, DOUBLE-MASKED, RANDOMIZED, PARALLEL-GROUP STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INTRAVITREAL OTX-TKI (AXITINIB IMPLANT) IN SUBJECTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION	≥ 50 years, treatment naïve for wet AMD in either eye at screening. Macular choroidal neovascularization due to wet AMD with active or expected visual loss, foveal intraretinal and/or subretinal fluid is present on SD-OCT, it shall not exceed 500 µm (CSFT), BCVA ETDRS letter score of at least 54 or greater (approximately 20/80) in either eye at screening. BCVA of at least 84 ETDRS letter score (20/20) on Day 1. Have a CSFT of 350 µm or less in study eye at Day 1. A scar, fibrosis, or atrophy of < 50% of the total lesion in the study eye. IOP ≤ 25 mmHg.
NORSE EIGHT (ONS-5010-008) ***WET AMD (Outlook Therapeutics)*** **Current Enrollment:** **UPCOMING**	SAFETY AND EFFECTIVENESS OF ONS-5010 COMPARED TO LUCENTIS® IN SUBJECTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION; NORSE EIGHT	≥ 50 years, Active primary subfoveal CNV lesions secondary to AMD in the study eye, BCVA of 35 to 75 letters (ETDRS) (20/32 to 20/200) in the study eye, BCVA ≥ 20 letters read (20/400) in the fellow eye, active leakage on Fluorescein Angiogram involving the fovea, edema involving the fovea as measured by central subfield foveal thickness on SD-OCT, free of scarring, fibrosis, or atrophy involving the central foveal zone (inner most ring on OCT).
RGX-314-5101 ***WET AMD*** **Current Enrollment:** **UPCOMING**	A LONG-TERM FOLLOW-UP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF RGX-314 FOLLOWING SUBRETINAL ADMINISTRATION IN PARTICIPANTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION AND FELLOW EYE TREATMENT SUB STUDY	Long-term extension only for patients who participated in RGX-314 trials