DRY AMD

Study: A Phase 2/3 Trial to Assess the Safety and Efficacy of Intravitreous Administration of Zimura (Anti-CS Aptamer) in Subjects With Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration
Sponsor: Ophthotech
Purpose: To evaluate the safety and efficacy of intravitreous administration of Zimura when administered in subjects with geographic atrophy (GA) secondary to dry age-related macular degeneration
Design: Randomized, Safety/Efficacy, Parallel Assignment, Double Blind
Number of Patients: 300
Inclusion Criteria: Diagnosis of non-foveal GA secondary to dry AMD
Exclusion Criteria: Retinal atrophy involving the fovea; evidence of CNV; any prior treatment for AMD or any prior intravitreal treatment for any indication in either eye, except oral supplements of vitamins and minerals; any intraocular surgery or thermal laser within 3 months of trial entry; any prior thermal laser in the macular region, regardless of indication; any ocular or periocular infection in the 12 weeks prior to entry; previous therapeutic radiation in the region of the study eye; any sign of diabetic retinopathy in either eye
Information: Desiree.Beutelspacher@Ophthotech.com

Study: SPECTRI/CHRROMA: A Study Investigating the Safety and Efficacy of Lampalizumab Intravitreal Injections in Patients With Geographic Atrophy Secondary to AMD
Sponsor: Hoffmann-La Roche
Purpose: To conduct a study evaluating the efficacy and safety of lampalizumab administered by intravitreal injections in patients with geographic atrophy (GA) secondary to age-related macular degeneration
Design: Randomized, Safety/Efficacy, Parallel Assignment, Double Blind
Number of Patients: 936
Inclusion Criteria: Well demarcated area(s) of GA secondary to AMD with no evidence of prior or active choroidal neovascularization in both eyes
Exclusion Criteria: History of vitrectomy surgery, submacular surgery, or other surgical intervention for AMD; previous laser photocoagulation for CNV, DME, RVO, and proliferative diabetic retinopathy; previous intravitreal drug delivery
Information: global.rochegegenentechtrials@roche.com

Study: TOGA: Clinical Study to Evaluate Treatment With ORACEA for Geographic Atrophy
Sponsor: Paul Yates, MD, PhD/MEDARVA
Purpose: To evaluate the efficacy and safety of ORACEA in the treatment of geographic atrophy due to dry age-related macular degeneration
Design: Randomized, Parallel Assignment, Double Blind
Number of Patients: 286
Inclusion Criteria: Best-corrected visual acuity of 20/20 - 20/400 in the study eye; geographic atrophy of ≥0.5 and ≤7.0 MPS disc areas
Exclusion Criteria: History of or active presence of choroidal neovascularization secondary to exudative age-related macular degeneration in the study eye; history of or active presence of choroidal neovascularization secondary to exudative AMD in the non-study eye requiring any treatment within 12 months prior to Day 0
Information: kh7v@virginia.edu

Study: A Study of Lampalizumab Intravitreal Injections Administered Every Two Weeks or Every Four Weeks to Patients With Geographic Atrophy
Sponsor: Genentech
Purpose: To investigate the exposure-response and safety of lampalizumab administered intravitreally every 2 weeks (Q2W) or every 4 weeks (Q4W) for 24 weeks in patients with geographic atrophy (GA) secondary to AMD
Design: Randomized, Safety/Efficacy, Parallel Assignment, Single-blind
Number of Patients: 100
Inclusion Criteria: Patients aged 60-89 years with well-demarcated area of GA secondary to AMD in the absence of choroidal neovascularization
Exclusion Criteria: History of vitrectomy surgery, submacular surgery, or other surgical intervention for AMD; previous subfoveal focal laser photocoagulation; laser photocoagulation in the study eye; previous intravitreal drug administration; GA in either eye due to causes other than AMD
Information: global.rochegegenentechtrials@roche.com

Study: Evaluation of Oral Minocycline in the Treatment of Geographic Atrophy Associated With AMD
Sponsor: National Eye Institute
Purpose: To see if minocycline is safe for people with GA and if it helps preserve their vision
Design: Randomized, Safety/Efficacy, Parallel Assignment, Double Blind
Number of Patients: 66
Inclusion Criteria: Participant must have evidence of early or intermediate AMD as defined by characteristic presence of drusen and/or pigmentary changes; participant must be able to swallow capsules
Exclusion Criteria: Participant is on ocular or systemic medications known to be toxic to the lens, retina or optic nerve (eg, ethambutol, chloroquine, or hydroxychloroquine); participant has a condition that would preclude participation in the study
Information: meg.gordon@nih.gov

Study: Evaluation of Lipoic Acid as a Treatment for Geographic Atrophy
Sponsor: University of Pennsylvania
Purpose: To determine if there are safety/tolerability concerns seen when higher doses of alpha lipoic acid are taken by subjects 65 years of age or older
Design: Safety, Single Group, Open Label 15
Exclusion Criteria: Blood pressure greater than 190/100 at the baseline visit; pulse greater than 100 at the baseline visit; acute and ongoing systemic infection; history of dementia; participant has a condition that, in the opinion of the investigator, gives them an unstable medical status; participant has geographic atrophy and the investigator believes the participant is a candidate for enrollment into the planned Phase 2 trial for geographic atrophy
Information: benjamin.kim@uphs.upenn.edu

Sponsor: Paul Yates, MD, PhD/MEDARVA
Purpose: To evaluate the efficacy and safety of ORACEA in the treatment of geographic atrophy due to dry age-related macular degeneration
Design: Randomized, Parallel Assignment, Double Blind
Number of Patients: 286
Inclusion Criteria: Best-corrected visual acuity of 20/20 - 20/400 in the study eye; geographic atrophy of ≥0.5 and ≤7.0 MPS disc areas
Exclusion Criteria: History of or active presence of choroidal neovascularization secondary to exudative age-related macular degeneration in the study eye; history of or active presence of choroidal neovascularization secondary to exudative AMD in the non-study eye requiring any treatment within 12 months prior to Day 0
Information: kh7v@virginia.edu

Study: A Study of Lampalizumab Intravitreal Injections Administered Every Two Weeks or Every Four Weeks to Patients With Geographic Atrophy
Sponsor: Genentech
Purpose: To investigate the exposure-response and safety of lampalizumab administered intravitreally every 2 weeks (Q2W) or every 4 weeks (Q4W) for 24 weeks in patients with geographic atrophy (GA) secondary to AMD
Design: Randomized, Safety/Efficacy, Parallel Assignment, Single-blind
Number of Patients: 100
Inclusion Criteria: Patients aged 60-89 years with well-demarcated area of GA secondary to AMD in the absence of choroidal neovascularization
Exclusion Criteria: History of vitrectomy surgery, submacular surgery, or other surgical intervention for AMD; previous subfoveal focal laser photocoagulation; laser photocoagulation in the study eye; previous intravitreal drug administration; GA in either eye due to causes other than AMD
Information: global.rochegegenentechtrials@roche.com

Study: Evaluation of Oral Minocycline in the Treatment of Geographic Atrophy Associated With AMD
Sponsor: National Eye Institute
Purpose: To see if minocycline is safe for people with GA and if it helps preserve their vision
Design: Randomized, Safety/Efficacy, Parallel Assignment, Double Blind
Number of Patients: 66
Inclusion Criteria: Participant must have evidence of early or intermediate AMD as defined by characteristic presence of drusen and/or pigmentary changes; participant must be able to swallow capsules
Exclusion Criteria: Participant is on ocular or systemic medications known to be toxic to the lens, retina or optic nerve (eg, ethambutol, chloroquine, or hydroxychloroquine); participant has a condition that would preclude participation in the study
Information: meg.gordon@nih.gov

Study: Evaluation of Lipoic Acid as a Treatment for Geographic Atrophy
Sponsor: University of Pennsylvania
Purpose: To determine if there are safety/tolerability concerns seen when higher doses of alpha lipoic acid are taken by subjects 65 years of age or older
Design: Safety, Single Group, Open Label 15
Exclusion Criteria: Blood pressure greater than 190/100 at the baseline visit; pulse greater than 100 at the baseline visit; acute and ongoing systemic infection; history of dementia; participant has a condition that, in the opinion of the investigator, gives them an unstable medical status; participant has geographic atrophy and the investigator believes the participant is a candidate for enrollment into the planned Phase 2 trial for geographic atrophy
Information: benjamin.kim@uphs.upenn.edu
**DRY AMD**

**Study: BioCurrent Electrical Stimulation for the Treatment of Dry ARMD**

**Sponsor:** DuBois Vision Clinic

**Purpose:** To evaluate the treatment of Dry Macular Degeneration and the resulting change in vision with a very, very low current that is similar to what occurs in the body naturally

**Design:** Randomized, Safety/Efficacy, Crossover Assignment, Double Blind

**Number of Patients:** 616

**Inclusion Criteria:** Best-corrected visual acuity can be no better than 20/40 and no worse than 20/200 for each enrolled eye; confirmed diagnosis of Dry MD; vision loss attributable to Dry MD

**Exclusion Criteria:** Any retinal pathology other than Dry MD; evidence or history of wet MD; previous intravitreal injection; seizure disorders; dense cataract; eyelid pathology at the treatment sites

**Information:** telephonescreener@outlook.com

**Study: PRO-CON: IAI Versus Sham as Prophylaxis Against Conversion to Neovascular AMD**

**Sponsor:** Jeffrey S. Heier, MD/Regeneron

**Purpose:** To evaluate intravitreal aflibercept injection (IAI) versus sham as prophylaxis against conversion to neovascular age-related macular degeneration (AMD) in “high-risk” subjects

**Design:** Randomized, Parallel Assignment, Single-blind

**Number of Patients:** 128

**Inclusion Criteria:** Study eye must have a diagnosis of non-exudative age-related degeneration characterized by the presence of many intermediate sized drusen, 1 or more large drusen, and/or hyperpigmentary changes. Fellow (non-study) eye must have CNV lesion (ie, leakage on fluorescein angiography and/or subretinal, intraretinal, or sub-RPE fluid on OCT) secondary to age-related macular degeneration OR history of CNV lesion secondary to age-related macular degeneration, as confirmed by current or past treatment or current or past diagnostic imaging

**Exclusion Criteria:** Evidence of neovascular AMD in the study eye at time of enrollment or anytime in the past. The reading center must confirm that there is no evidence of neovascular AMD in the study eye prior to enrollment; serous PED of any size in the study eye, as determined by the reading center; previous treatment with vaperopirin PDT, anti-VEGF therapy, laser, external beam radiation or other AMD therapy in the study eye

**Information:** anowak@eye.boston.com

**Study: PRELUDE: A Study to Evaluate the Safety and Clinical Response of Subretinal Administration of CNTO 2476 in Participants With Geographic Atrophy**

**Sponsor:** Janssen Research & Development, LLC

**Purpose:** To evaluate the safety and performance profile of a modified surgical procedure and custom delivery devices and also to assess the effects on visual acuity of a single subretinal administration of CNTO 2476.

**Design:** Randomized, Parallel Assignment, Double Blind

**Number of Patients:** 285

**Inclusion Criteria:** Confirmed diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) confirmed within 28 days prior to initial randomization by the central reading center; study eyes will have a best corrected visual acuity (BCVA) of 20/80 to 20/800 [Early Treatment Diabetic Retinopathy Study (ETDRS) log of the minimum angle of resolution (logMAR) value 0.6–1.6]. BCVA in the treatment eye must be worse than the BCVA in the fellow eye at screening.

**Exclusion Criteria:** Participant has a history of geographic atrophy ("wet") AMD in the treatment eye, including any evidence of retinal pigment epithelium rips or evidence of subretinal or choroidal neovascularization. History or evidence of neovascular AMD in the fellow eye is allowed, if anti-vascular endothelial growth factor (VEGF) therapy has not been required for at least 8 weeks prior to Screening; geographic atrophy secondary to any causes other than AMD in either eye

**Information:** eyestudy@ucsf.edu

**Study: METForMIN: Metformin for the Minimization of Geographic Atrophy Progression in Patients With AMD**

**Sponsor:** University of California, San Francisco

**Purpose:** To determine whether metformin, an FDA-approved drug for the treatment of type II diabetes, is a safe and effective treatment to decrease the progression of geographic atrophy in non-diabetic patients with age-related macular degeneration

**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Single-blind

**Number of Patients:** 100

**Inclusion Criteria:** Subject must have evidence of advanced dry AMD, defined by the characteristic presence of drusen and/or pigmentary changes, as well as geographic atrophy; subject must have clear ocular media and adequate pupillary dilation; study eye must have best corrected visual acuity (BCVA) of 20/20-20/400

**Exclusion Criteria:** Subjects with insufficient baseline size of geographic atrophy, less than 1.25 mm² (0.5 Macular Photocoagulation Study Disc Areas). GA is defined as one or more well-defined and often circular patches of partial or complete depigmentation of the RPE, typically with exposure of underlying choroidal blood vessels. Even if much of the RPE appears to be preserved and large choroidal vessels are not visible, a round patch of RPE partial depigmentation may be classified as early GA. The GA in the study eye must be able to be photographed in its entirety, and it must not be contiguous with any areas of peripapillary atrophy, which can complicate area measurements.

**Information:** eyestudy@ucsf.edu

**WET AMD**

**Study: Dorzolamide-timolol Drops With Injections to Treat AMD, RVO or DME**

**Sponsor:** Wills Eye

**Purpose:** This study seeks to evaluate the effect of topical aqueous suppression on the anatomic and functional response to intravitreal anti-vascular endothelial growth factor (VEGF) injections in non-responders with wet age-related macular degeneration

**Design:** Single Group

**Number of Patients:** 15

**Inclusion Criteria:** Patient of Wills Eye
Hospital Retina Service and/or Mid Atlantic Retina, volunteer patients age 18 years and older, healthy enough to participate in the study, willing and able to consent to participation in the study, diagnosis of wet age-related macular degeneration, prior treatment with at least 4 injections of anti-VEGF agents in the past 6 months and persistent intraretinal and/or subretinal fluid on SD-OCT at each visit during this period, Injection of the same anti-VEGF agent for at least two visits prior to study enrollment, Fixed interval between at least two visits prior to study enrollment.

Exclusion Criteria: History of uveitis, any ophthalmic surgery within previous 6 months, including cataract extraction, any history of vitreomacular traction, history of any glaucoma surgery, systemic diuretic or corticosteroid usage, any contraindication (bradycardia, decompensated heart failure, or reactive airway disease) for topical use of a beta-blocker, Any history of sulfonamide allergy.

Information: research@midatlanticretina.com

Study: STAIRWAY: Study to Evaluate RO6867461 (RG7716) for Extended Durability in the Treatment of Neovascular Age Related Macular Degeneration (nAMD)

Sponsor: Hoffman-La Roche

Purpose: This is a Phase II, multicenter, randomized, active comparator-controlled, 52-week study to investigate the efficacy, safety and pharmacokinetics of RO6867461 (RG7716) administered with extended dosing regimens in treatment-naive participants with nAMD. Only one eye will be chosen as the study eye.

Design: Randomized, Parallel Assignment, Double Blind

Number of Patients: 75

Inclusion Criteria: Treatment-naive CNV secondary to AMD; subfoveal CNV or CNV lesion component; active CNV; BCVA letter score of 73 to 24 letters (inclusive).

Exclusion Criteria: CNV due to causes other than AMD; retinal pigment epithelial tear involving the macula; on fundus fluorescein angiography (FFA) subretinal hemorrhage, fibrosis or atrophy of >50% of the total lesion area and/or that involves the fovea; cataract surgery within 3 months of baseline assessments; uncontrolled blood pressure.

Information: global.rochegeventechtrials@roche.com

Study: DAWN: Dorzolamide-timolol in Combination With Anti-vascular Endothelial Growth Factor Injections for Wet Age-related Macular Degeneration

Sponsor: Wills Eye

Purpose: A previous pilot study demonstrated that commonly available glaucoma drops (dorzolamide-timolol) might decrease the amount of chronic swelling in patient with wet age-related macular degeneration who have been receiving anti-vascular endothelial growth factor (VEGF) injections. This will be a larger study where subjects are randomly assigned to receive the glaucoma drops or a placebo (artificial tears) to confirm whether this previous finding is valid.

Design: Randomized, Parallel Assignment, Single Blind

Number of Patients: 50

Inclusion Criteria: Active choroidal neovascularization (CNV) due to AMD; prior treatment with at least 4 injections of anti-VEGF agents in the past 6 months and persistent intraretinal and/or subretinal fluid on SD-OCT at each visit during this period; baseline CST ≥270 µm on SD-OCT automated retinal thickness map; injection of the same anti-VEGF agent at each of the 2 visits immediately preceding study enrollment; time interval of 5 weeks (±1 week) between visits for at least 2 visits immediately preceding study enrollment; either gender aged ≥45 years.

Exclusion Criteria: History of uveitis; presence of intraocular inflammation, significant epiretinal membrane, significant vitreomacular traction, macular hole, or vitreous hemorrhage; any ophthalmic surgery within previous 6 months, including cataract extraction; any history of vitrectomy or glaucoma surgery; current prescription eye drop usage; any contraindication for topical use of a beta-blocker; any history of sulfonamide allergy.

Information: mformoso@midatlanticretina.com

Study: ONXY: Anti-angiOpoeitin 2 Plus Anti-vascular endothelial Growth Factor as a therapY for Neovascular Age Related Macular Degeneration: Evaluation of a fiXed Combination Intravitreal Injection

Sponsor: Regeneron

Purpose: To compare the efficacy of intravitreal (IVT)-administered REGN910-3 compared to intravitreal aflibercept injection

Design: Randomized, Safety/Efficacy, Parallel Assignment, Double Blind

Number of Patients: 360

Inclusion Criteria: Men or women ≥50 years of age with active subfoveal choroidal neovascularization secondary to age-related macular degeneration, including juxtapfoveal lesions that affect the fovea as evidenced by fluorescein angiography in the study eye as assessed by a central reading center; best-corrected visual acuity by ETDRS letter score of 73 to 24 (Snellen equivalent of 20/40 to 20/320) in the study eye

Exclusion Criteria: Evidence of choroidal neovascularization due to any cause other than age-related macular degeneration in either eye; prior intravitreal injection of anti-VEGF in the study eye; evidence of diabetic macular edema or diabetic retinopathy (defined as more than 1 microaneurysm) in either eye in diabetic patients

Information: clinicaltrials@regeneron.com

Study: Study of DS-7080a for the Treatment of Neovascular AMD

Sponsor: Daiichi Sankyo Inc.

Purpose: To test DS-7080a, a monoclonal antibody, as a new treatment for neovascular age-related macular degeneration

Design: Randomized, Safety/Efficacy, Parallel Assignment, Open Label

Number of Patients: 45

Inclusion Criteria: Active primary subfoveal CNV lesions secondary to AMD; CNV ≥50% of total lesion size in study eye; central sub-field thickness > 315 µm on SD-OCT in the study eye

Exclusion Criteria: Presence of RPEI tears or rips involving the macula in the study eye; history of any vitreous hemorrhage within 4 weeks prior to screening visit; the presence of causes of CNV other than AMD; prior vitrectomy

Information: ssaigal@oraclinical.com
WET AMD

**Study: A Phase I/II Safety, Tolerability, Immunogenicity, and Bioactivity Study of DE-122 Injectable Solution for Refractory Exudative Age-Related Macular Degeneration**

**Sponsor:** Santen Inc.

**Purpose:** To evaluate the safety, tolerability, immunogenicity, and bioactivity of a single intravitreal (IVT) administration of DE-122 in subjects with refractory exudative age-related macular degeneration

**Design:** Nonrandomized, Safety/Efficacy, Single Group, Open Label

**Number of Patients:** 12

**Inclusion Criteria:** Diagnosis of subretinal or intraretinal fluid secondary to exudative age-related macular degeneration; prior treatment in the study eye with any intravitreal anti-VEGF medication; at least 1 lesion in the study eye that meets minimal pathology criteria

**Exclusion Criteria:** Use or anticipated use of any intravitreal, periocular, or photodynamic therapy in the study eye for the treatment of AMD within a specified timeframe prior to Visit 1; uncontrolled or advanced glaucoma, chronic hypotony or vitrectomy in the study eye

**Information:** clinicaltrials@santeninc.com

**Study: PREVENT: Prophylactic Ranibizumab for Exudative AMD**

**Sponsor:** Southern California Desert Retinal Consultants

**Purpose:** To determine whether quarterly injections of ranibizumab may prevent eyes with dry age-related macular degeneration from progressing to wet age-related macular degeneration

**Design:** Randomized, Efficacy, Parallel Assignment, Single-blind, Prevention

**Number of Patients:** 100

**Inclusion Criteria:** Nonexudative age-related macular degeneration (AMD) in 1 eye (study eye); history of exudative AMD in 1 eye only (fellow eye) diagnosed within 5 years of study enrollment

**Exclusion Criteria:** Presence of ocular conditions with increased risk of choroidal neovascularization (CNVM) or pigment epithelial detachment (PED), including presumed ocular histoplasmosis syndrome (POHS), traumatic choroidal rupture, angiod streaks, pathologic myopia (spherical equivalent of ≥-8 diopters or axial length of ≥25 mm), multifocal choroiditis, macular choroidal nevus, polypoidal choroidal vasculopathy (PCV), etc.

**Information:** mlalezary@deseretretina.com

**Study: X-82 to Treat Age-Related Macular Degeneration**

**Sponsor:** Tyrogenex

**Purpose:** To evaluate the safety and efficacy of X-82 in the treatment of vision loss due to wet AMD

**Design:** Randomized, Safety/Efficacy, Single Group, Double Blind

**Number of Patients:** 132

**Inclusion Criteria:** Participants must have wet AMD which has been diagnosed and treated with anti-VEGF in one or both eyes for at least 1 year prior to joining the study and has required at least three prior injections of Eylea at intervals of not greater than 6 weeks for the past three injections in the eye that is selected to be the study eye; must have demonstrated the ability to achieve a dry macula in the study eye 14 days following an injection of Eylea at Screening Visit 1; Early Treatment Diabetic Retinopathy (ETDRS) Best Corrected Visual Acuity (BCVA) of 20 letters (20/400) or better in both eyes

**Exclusion Criteria:** Previous vitrectomy to the study eye; choroidal neovascularization (CNV) due to causes other than AMD; proliferative diabetic retinopathy in either eye

**Information:** denis@tyrogenex.com

**Study: AVENUE: A Proof-of-Concept Study of RG7716 in Participants With Choroidal Neovascularization (CNV) Secondary to AMD**

**Sponsor:** Hoffman-La Roche

**Purpose:** To evaluate the safety, tolerability, pharmacokinetics, and efficacy of RG7716 in participants with subfoveal CNV

**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Double Blind

**Number of Patients:** 271

**Inclusion Criteria:** Subfoveal CNV lesions of all types, secondary to AMD; active CNV

**Exclusion Criteria:** CNV due to causes other than AMD; subretinal hemorrhage, fibrosis, or atrophy involving either the fovea or more than 50% of the total lesion area; cataract surgery within 3 months of baseline

**Information:** global.rochegenentechtrials@roche.com

**Study: DRAW: A Pharmacokinetic Study of Intravitreal Afibercept Injection in Vitrectomized and Non-vitrectomized Eyes With Wet Age-Related Macular Degeneration**

**Sponsor:** University of Nebraska/Regeneron

**Purpose:** To study the way that afibercept injection behaves in the eye and in the body of patients with wet macular degeneration, in patients who have had previous vitreous removal surgery

**Design:** Nonrandomized, Pharmacokinetics, Single Group, Open Label

**Number of Patients:** 15

**Inclusion Criteria:** Active neovascular AMD, with no history of treatment in the study eye; patients with non-vitrectomized eyes; patients with vitrectomized eyes; phakic and pseudophakic eyes are allowed in the study; willing and able to provide written informed consent after the nature of the study has been explained, and prior to any research-related procedures

**Exclusion Criteria:** Presence of other retinal vascular diseases (diabetic retinopathy, vein occlusion) that could affect the VEGF levels within the eye; known hypersensitivity to afibercept; autoimmune disease of the anterior segment or posterior chamber including chronic keratoconjunctivitis sicca, uveitis, iritis/scleritis, blepharitis of either eye; infectious conjunctivitis, keratitis, or endophthalmitis of either eye

**Information:** lisa.greer@UNMC.edu

**Study:**

**Design:** Nonrandomized, Pharmacokinetics, Single Group, Open Label

**Number of Patients:** 15

**Inclusion Criteria:** Active neovascular AMD, with no history of treatment in the study eye; patients with non-vitrectomized eyes; patients with vitrectomized eyes; phakic and pseudophakic eyes are allowed in the study; willing and able to provide written informed consent after the nature of the study has been explained, and prior to any research-related procedures

**Exclusion Criteria:** Presence of other retinal vascular diseases (diabetic retinopathy, vein occlusion) that could affect the VEGF levels within the eye; known hypersensitivity to afibercept; autoimmune disease of the anterior segment or posterior chamber including chronic keratoconjunctivitis sicca, uveitis, iritis/scleritis, blepharitis of either eye; infectious conjunctivitis, keratitis, or endophthalmitis of either eye

**Information:** lisa.greer@UNMC.edu
**Wet AMD**

**Study:** LADDER: Study of the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients With Subfoveal Neovascular Age-Related Macular Degeneration  
**Sponsor:** Genentech  
**Purpose:** To evaluate the efficacy and the safety of three different formulations of ranibizumab, delivered via the Ranibizumab Port Delivery System (RPDS) implant, in patients with subfoveal neovascular age-related macular degeneration  
**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Double-Blind  
**Number of Patients:** 220  
**Inclusion Criteria:** Newly diagnosed with wet AMD within 6 months of screening visit; patient must have received at least 2 ranibizumab injections within approximately 2 months prior to the screening visit; patient may have received up to 6 ITX anti-VEGF injections prior to the screening visit; demonstrated response to prior standard of care  
**Exclusion Criteria:** Study eye treatment with ITX bevacizumab within 5 months prior to the randomization visit, or with ITX aflibercept within 3 months prior to the randomization visit; history of laser photocoagulation, Visudyne, ITX corticosteroid injection, vitrectomy surgery, submacular surgery, device implantation, or other surgical intervention for AMD  
**Information:** (888) 662-6728

**Diabetic Macular Edema**

**Study:** A Phase 2 Study of RO6867461 in Participants With Center-Involving Diabetic Macular Edema (CI-DME)  
**Sponsor:** Hoffman-La Roche  
**Purpose:** This is a multiple-center, multiple-dose, randomized, active comparator-controlled, double-masked, three parallel group, 28-week study in participants with CI-DME. Only one eye will be selected as the study eye. Where both eyes meet all eligibility criteria, the eye with the worse best corrected visual acuity (BCVA) will be defined as the study eye. Participants will be randomized into each arm group (1:1:1) and total duration of the study will be approximately 32 weeks.  
**Design:** Randomized, Parallel Assignment, Double-Blind  
**Number of Patients:** 150  
**Inclusion Criteria:** Macular edema associated with diabetic retinopathy (DR), decreased visual activity (VA) attributable primarily to DME, diagnosis of diabetes mellitus (DM).  
**Exclusion Criteria:** Proliferative diabetic retinopathy (PDR), cataract surgery within 3 months of baseline, or any other previous intraocular surgery, uncontrolled glaucoma, current or history of ocular disease in the study eye other than DME, major illness or major surgical procedure within 1 month prior to Day 1, uncontrolled blood pressure, glycosylated hemoglobin (HbA1c) >10% at screening, untreated diabetes mellitus or initiation of oral anti-diabetic medication or insulin within 4 months prior to Day 1.  
**Information:** global-roche-genentech-trials@gene.com

**Study:** Dorzolamide-timolol Drops With Injections to Treat AMD, RVO or DME  
**Sponsor:** Wills Eye  
**Purpose:** This study seeks to evaluate the effect of topical aqueous suppression on the anatomic and functional response to intravitreal anti-vascular endothelial growth factor (VEGF) injections in non-responders with wet age-related macular degeneration.  
**Design:** Single Group  
**Number of Patients:** 15  
**Inclusion Criteria:** Patient of Wills Eye Hospital Retina Service and/or Mid Atlantic Retina, volunteer patients age 18 years and older, healthy enough to participate in the study, willing and able to consent to participation in the study, diagnosis of wet age-related macular degeneration, prior treatment with at least 4 injections of anti-VEGF agents in the past 6 months and persistent intraretinal and/or subretinal fluid on SD-OCT at each visit during this period, injection of the same anti-VEGF agent for at least 2 visits prior to study enrollment, fixed interval between at least 2 visits prior to study enrollment.  
**Exclusion Criteria:** History of uveitis, any ophthalmic surgery within previous 6 months, including cataract extraction, any history of vitrectomy, history of any glaucoma drop usage or prior glaucoma surgery, systemic diuretic or corticosteroid usage, any contraindication (bradycardia, decompensated heart failure, or reactive airway disease) for topical use of a beta-blocker, Any history of sulfonamide allergy.  
**Information:** research@midatlanticretina.com

**Study:** Protocol V: Treatment for CI-DME in Eyes With Very Good VA Study  
**Sponsor:** Jaeb Center for Health Research  
**Purpose:** To compare the % of eyes that have lost at least 5 letters of visual acuity at 2 years compared with baseline mean visual acuity in eyes with central-involved DME and good visual acuity defined as a Snellen equivalent of 20/25 or better  
**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Single-blind  
**Number of Patients:** 702  
**Inclusion Criteria:** Best corrected E-ETDRS visual acuity letter score ≥79 (approximate Snellen equivalent 20/25 or better) at two consecutive visits within 1 to 28 days; on clinical exam, definite retinal thickening due to DME involving the center of the macula; diabetic macular edema confirmed on OCT (equivalent to CSF thickness on OCT ≥250 microns on Zeiss Stratus or gender-specific spectral domain OCT equivalent) at two consecutive visits within 1 to 28 days. (a) Investigator must verify accuracy of OCT scan by ensuring it is centered and of adequate quality  
**Exclusion Criteria:** Macular edema is considered to be due to a cause other than DME. a) An eye should not be considered eligible if: (1) the macular edema is considered to be related to ocular surgery such as cataract extraction or (2) clinical exam and/or OCT suggest that vitreoretinal interface abnormalities (e.g., a taut posterior hyaloid or epiretinal membrane) are contributing to the macular edema; an ocular condition is present such that, in the opinion of the
investigator, any visual acuity loss would not improve from resolution of macular edema (eg, foveal atrophy, pigment abnormalities, dense subfoveal hard exudates, non-retinal condition); an ocular condition is present (other than DME) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (eg, vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, etc.)

**Information:** www.jaeb.org

**Study: Phase II Combination Steroid and Anti-VEGF for Persistent DME**

**Sponsor:** Jaeb Center for Health Research

**Purpose:** To assess the short-term effects of combination steroid+anti-VEGF therapy on visual acuity and retinal thickness on OCT in comparison with that of continued anti-VEGF therapy (in eyes with persistent central-involved DME and visual acuity impairment despite previous anti-VEGF treatment)

**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Double Blind

**Number of Patients:** 125

**Inclusion Criteria:** At least 3 injections of anti-VEGF drug (ranibizumab, bevacizumab, or aflibercept) prior to randomization; within the prior 20 weeks; visual acuity letter score in study eye ≤78 and ≥24 (approximate Snellen equivalent 20/32 to 20/320); on clinical exam, definite retinal thickening due to DME involving the center of the macula; OCT CSF thickness, within 8 days of enrollment; i) On Zeiss Cirrus ≥290 microns in women; ≥305 in men ii) On Heidelberg Spectralis: ≥305 microns in women; ≥320 in men

**Exclusion Criteria:** Macular edema is considered to be due to a cause other than DME. An eye should not be considered eligible if: (1) the macular edema is considered to be related to ocular surgery such as cataract extraction or (2) clinical exam and/or OCT suggest that vitreoretinal interface abnormalities (eg, a taut posterior hyaloid or epiretinal membrane) are the primary cause of the macular edema; an ocular condition is present such that, in the opinion of the investigator, visual acuity loss would not improve from resolution of macular edema (eg, foveal atrophy, pigment abnormalities, dense subfoveal hard exudates, non-retinal condition, etc.); an ocular condition is present (other than DME) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (eg, vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, etc.)

**Information:** www.jaeb.org

**Study: Anti-VEGF Treatment for Prevention of PDR/DME**

**Sponsor:** Jaeb Center for Health Research

**Purpose:** To determine the efficacy and safety of intravitreous aflibercept injections versus sham injections (observation) for prevention of PDR or CI-DME in eyes at high risk for development of these complications

**Design:** Randomized, Safety/Efficacy, Parallel Assignment, Double Blind

**Number of Patients:** 322

**Inclusion Criteria:** No evidence of neovascularization on clinical exam including active neovascularization of the iris (small iris tufts are not an exclusion) or angle neovascularization (if the angle is assessed); no evidence of neovascularization (NV) on fluorescein angiography within the 7-modified ETDRS fields, confirmed by the central Reading Center prior to randomization. • The widest method of imaging available at the site must be used to document whether there is NV present in the periphery; however, presence of NV outside of the 7-modified ETDRS fields on ultrawide field imaging will not be an exclusion provided treatment is not planned; no center-involved diabetic macular edema (CI-DME) on clinical exam and optical coherence tomography (OCT) central subfield thickness must be below the following gender and OCT-machine specific thresholds

**Exclusion Criteria:** An eye that in the investigator’s opinion, has no chance of improving in visual acuity following resolution of macular edema (eg presence of subretinal fibrosis or geographic atrophy); presence of another ocular condition that may affect the visual acuity or macular edema during the course of the study (eg, AMD, uveitis, Irvine-Gass); evidence of active neovascularization of the iris or retina; evidence of central atrophy or fibrosis in the study eye; presence of substantial cataract, one that might decrease the vision by 3 or more lines of vision at sometime during the study; history of vitreous surgery in the study eye

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**Study: DME: Dexamethasone Intravitreal Implant for the Treatment of Persistent Diabetic Macular Edema**

**Sponsor:** Allergan/California Retinal Consultants

**Purpose:** To compare the effectiveness of using a dexamethasone steroid implant versus monthly intravitreal anti-VEGF injections for research participants with persistent diabetic macular edema

**Design:** Randomized, Efficacy, Parallel Assignment, Open Label

**Number of Patients:** 40

**Inclusion Criteria:** Clinical evidence of retinal thickening due to macular edema involving the center of the macula associated with diabetic retinopathy; previous history of anti-VEGF treatment for diabetic macular edema (DME) with documented incomplete resolution of central subfield thickening by spectral-domain optical coherence tomography (SD-OCT). At least 4 intravitreal anti-VEGF injections within the past six months prior to the baseline study visit are required for eligibility; central diabetic macular edema present on clinical examination and SD-OCT testing with central 1 mm subfield thickness greater than 300 microns as measured on SD-OCT at the baseline visit; visual acuity score greater than or equal to 19 letters (20/400) and less than or equal to 74 letters (20/32) by the ETDRS visual acuity protocol

**Exclusion Criteria:** An eye that in the investigator’s opinion, has no chance of improving in visual acuity following resolution of macular edema (eg presence of subretinal fibrosis or geographic atrophy); presence of another ocular condition that may affect the visual acuity or macular edema during the course of the study (eg, AMD, uveitis, Irvine-Gass); evidence of active neovascularization of the iris or retina; evidence of central atrophy or fibrosis in the study eye; presence of substantial cataract, one that might decrease the vision by 3 or more lines of vision at sometime during the study; history of vitreous surgery in the study eye

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**Clinical Trial Update**

**Study: Dorzolamide-timolol Drops With Injections to Treat AMD, RVO or DME**

**Sponsor:** Wills Eye  
**Purpose:** This study seeks to evaluate the effect of topical aqueous suppression on the anatomic and functional response to intravitreal anti-vascular endothelial growth factor (VEGF) injections in non-responders with wet age-related macular degeneration.  
**Design:** Single Group  
**Number of Patients:** 15  
**Inclusion Criteria:** Patient of Wills Eye Hospital Retina Service and/or Mid Atlantic Retina, volunteer patients age 18 years and older, healthy enough to participate in the study, willing and able to consent to participation in the study, diagnosis of wet age-related macular degeneration, prior treatment with at least 4 injections of anti-VEGF agents in the past 6 months and persistent intraretinal and/or subretinal fluid on SD-OCT at each visit during this period, Injection of the same anti-VEGF agent for at least 2 visits prior to study enrollment, Fixed interval between at least 2 visits prior to study enrollment.  
**Exclusion Criteria:** History of uveitis, any ophthalmic surgery within previous 6 months, including cataract extraction, any history of vitrectomy, history of any glaucoma drop usage or prior glaucoma surgery, systemic diuretic or corticosteroid usage, any contraindication (bradycardia, decompensated heart failure, or reactive airway disease) for topical use of a beta-blocker, Any history of sulfonamide allergy.  
**Information:** research@midatlanticretina.com

**Study: Minocycline to Treat Branch Retinal Vein Occlusion**

**Sponsor:** National Eye Institute (NEI)  
**Purpose:** To test the safety and effectiveness of minocycline as a treatment for branch retinal vein occlusion (BRVO).  
**Design:** Parallel Assignment, Double Blind  
**Number of Patients:** 460  
**Inclusion Criteria:** Has a clinical diagnosis of RVO in the study eye; has a CST of >300 µm in the study eye; has an ETDRS BCVA score of >5 letters read and ≤70 letters read in the study eye; is naïve to local pharmacologic treatment for RVO in the study eye.  
**Exclusion Criteria:** Any active ocular disease or infection in the study eye other than RVO; intraocular pressure >22 mmHg or uncontrolled glaucoma in study eye; any uncontrolled systemic disease that, in the opinion of the investigator, would preclude participation in the study; any evidence of neovascularization in the study eye.  
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**Study: Minocycline to Treat Central Retinal Vein Occlusion**

**Sponsor:** National Eye Institute (NEI)  
**Purpose:** To test the safety and effectiveness of minocycline as a treatment for central retinal vein occlusion  
**Design:** Randomized; Parallel Assignment; Double Blind  
**Number of Patients:** 20  
**Inclusion Criteria:** Foveal center-involved macular edema secondary to a CRVO, retinal thickness in the central subfield >350 microns as measured by optical coherence tomography; and visual acuity between 20/32 and 20/200 in the study eye  
**Exclusion Criteria:** Macular edema considered to be due to a cause other than CRVO, history of recurrent RVO, RVO present for >18 months, brisk afferent pupillary defect present in the study eye, ocular condition present such that visual acuity would not improve from resolution of ME or that might affect macular edema or alter visual acuity during the study, substantial cataract likely to be decreasing visual acuity by 3 lines or more, panretinal or sectoral scatter photocoagulation (PRP) within 4 months prior to study entry, pars plana vitrectomy within 6 months prior to study entry, major ocular surgery within 3 months prior to study entry, yttrium aluminum garnet capsulotomy performed within 2 months prior to study entry, treatment <3 months prior to study entry of intravitreal or periocular steroid injections, intravitreal anti-VEGF treatment <28 days prior to study entry  
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