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# CLINICAL TRIAL UPDATE

## DRY AMD

### Study: Phase II/III Study of the Efficacy and Safety of MacuCLEAR MC-1101 in Treating Dry AMD

**Sponsor:** MacuCLEAR, Inc.

**Purpose:** To assess the efficacy, safety, and tolerability of MC-1101 for these patients

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

**Number of Patients:** 60

**Inclusion Criteria:** 20/80 or better ETDRS best-corrected visual acuity; early to intermediate nonexudative AMD

**Exclusion Criteria:** Past or current exudative AMD or central geographic atrophy in study eye; AMD Category 4 on Age-Related Eye Disease Study (AREDS) Report No. 8 AMD Categories; past or current retinal or choroidal vasculopathy in study eye

**Information:** pralston@macuclear.com

### Study: SPECTRI/CHROMA: 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.rochegenentechtrials@roche.com

### Study: BEACON: A Safety and Efficacy Study of Brimonidine Intravitreal Implant in Geographic Atrophy Secondary to AMD

**Sponsor:** Allergan

**Purpose:** To assess the safety and efficacy of the brimonidine intravitreal implant in patients with geographic atrophy due to AMD

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

**Number of Patients:** 300

**Inclusion Criteria:** Geographic atrophy due to age-related macular degeneration in the study eye; visual acuity better than or equal to 20/62 in the study eye and 20/200 in the fellow eye

**Exclusion Criteria:** Cataract surgery or LASIK in the study eye in the last 3 months; infections in either eye in the last 3 months

**Information:** **clinicaltrials@allergan.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; best-corrected visual acuity of hand motion or better in the non-study eye; clinical diagnosis of geographic atrophy secondary to non-exudative age-related macular degeneration in at least one eye (study eye); geographic atrophy lesions 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:** **klh7v@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.rochegenentechtrials@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

# DRY AMD

### Study: CLG561 Proof-of-Concept Study as a Monotherapy and in Combination With LFG316 in Subjects With Geographic Atrophy

**Sponsor:** Alcon Research

**Purpose:** To evaluate the safety and efficacy of 12 (every 28 days) intravitreal (IVT) injections of CLG561 as a monotherapy and in combination with LFG316 as compared to sham in subjects with geographic atrophy

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

**Number of Patients:** 114

**Inclusion Criteria:** Geographic atrophy in both eyes

**Exclusion Criteria:** Any medical condition (systemic or ophthalmic) that may preclude the safe administration of test article or safe participation in this study; any contraindications or hypersensitivities to any component of the LFG316 or CLG561 solution; any contraindications to IVT injections; ocular surgery in either eye within 90 days of screening; uncontrolled ocular hypertension or glaucoma in the either eye

**Information:** alcon.medinfo@alcon.com

### Study: A Trial to Assess the Safety and Efficacy of Intravitreous Administration of Zimura® (Anti-C5 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 three (3) months of trial entry; any prior thermal laser in the macular region, regardless of indication; any ocular or periocular infection in the twelve (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: 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

**Number of Patients:** 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

### 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 (i.e., 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 verteporfin PDT, anti-VEGF therapy, laser, external beam radiation or other AMD therapy in the study eye

**Information:** anowak@eyeboston.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:** 255

**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 neovascular ("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:** **https://jnj.prod.sylogent.com/scr/Home.aspx?CR106814**

### 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 $mm^2$ (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: RESCUE: Ranibizumab for Recalcitrant Wet AMD in Eyes Previously Switched From Bevacizumab and/or Ranibizumab to Aflibercept

**Sponsor:** Northern California Retina Vitreous Associates/Genentech

**Purpose:** To determine the effectiveness of ranibizumab 0.5 mg or 1.0 mg in subjects who were previously treated with bevacizumab and subsequently switched to aflibercept

**Design:** Interventional, Nonrandomized, Efficacy, Parallel Assignment, Open Label

**Number of Patients:** 8

**Inclusion Criteria:** Best-corrected ETDRS VA between 20/25 to 20/320; total area of subretinal hemorrhage and/or fibrosis comprising less than 50% of lesion; any neovascular lesion type of ARMD having previously received at least 3 doses 1.25 mg of bevacizumab and/or ranibizumab (minimum 3 monthly injections) followed by 3 monthly doses of aflibercept 2.0 mg (with last injection being within 8 weeks) with evidence of recalcitrant ARMD, defined by at least one of the following: persistent subretinal fluid with or without intraretinal cystic edema on SD-OCT and/or leakage on fluorescein angiography

**Exclusion Criteria:** History of prior vitrectomy surgery; previous treatment with photodynamic therapy, radiation, or any other intravitreal drug delivery

**Information:** **alcon.medinfo@alcon.com**

### Study: A Phase 3 Safety and Efficacy Study of Fovista (E10030) Intravitreous Administration in Combination With Lucentis Compared to Lucentis Monotherapy

**Sponsor:** Ophthotech Corp.

**Purpose:** To evaluate the safety and efficacy of intravitreal administration of Fovista administered in combination with Lucentis compared to Lucentis monotherapy in subjects with subfoveal choroidal neovascularization secondary to AMD

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

**Number of Patients:** 622

**Inclusion Criteria:** Subfoveal choroidal neovascularization (CNV) due to AMD with some classic component; presence of sub-retinal hyper-reflective material (SD-OCT)

**Exclusion Criteria:** Any prior treatment for AMD in the study eye prior to the Day 1 visit, except oral supplements of vitamins and minerals; any prior intravitreal treatment in the study eye prior to the Day 1 visit, regardless of indication (including intravitreal corticosteroids); any intraocular surgery or thermal laser within three (3) months of trial entry; any prior thermal laser in the macular region

**Information:** **Karen.Lewis@ophthotech.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 one eye (study eye); history of exudative AMD in one 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, angioid 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@desertretina.com**

## WET AMD

### Study: Efficacy and Safety of RTH258 Versus Aflibercept

**Sponsor:** Alcon

**Purpose:** To compare RTH258 ophthalmic solution for intravitreal (IVT) injection at two dosage levels to aflibercept solution for IVT injection (2 mg) in subjects with untreated active choroidal neovascularization secondary to AMD

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

**Number of Patients:** 1,600

**Inclusion Criteria:** Active CNV lesions secondary to AMD in the study eye; intra and/or subretinal fluid affecting the central subfield of the study eye; BCVA between 78 and 23 letters, inclusive, in the study eye using Early Treatment Diabetic Retinopathy Study (ETDRS) testing

**Exclusion Criteria:** Any active intraocular or periocular infection or active intraocular inflammation in either eye; fibrosis or geographic atrophy; any approved or investigational treatment for neovascular AMD (other than vitamin supplements) in the study eye at any time; any history or evidence of a concurrent intraocular condition in the study eye

**Information:** **alcon.medinfo@alcon.com**

### Study: X-82 to Treat AMD

**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: DRAW: A Pharmacokinetic Study of Intravitreal Aflibercept Injection in Vitrectomized and Non-vitrectomized Eyes With Wet AMD

**Sponsor:** University of Nebraska/Regeneron

**Purpose:** To study the way that aflibercept 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 aflibercept; 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: 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: Study of the Intravitreal Implantation of NT-503-3 Encapsulated Cell Technology (ECT) for the Treatment of Recurrent Choroidal Neovascularization (CNV) Secondary to AMD

**Sponsor:** Neurotech Pharmaceuticals

**Purpose:** To compare NT-503-3 ECT to Eylea injected intravitreally every 8 weeks in the prevention of vision loss due to recurrent CNV secondary to AMD

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

**Number of Patients:** 170

**Inclusion Criteria:** Diagnosis of active (recurrent or persistent) subfoveal CNV lesions secondary to AMD in the study eye; prior Intravitreal Anti-VEGF injections

**Exclusion Criteria:** Significant subretinal hemorrhage; significant scar and/or fibrosis; suspected polypoidal choroidopathy, or pigment epithelial tears or rips; inadequate response to anti-VEGF therapy

**Information:** **c.johnson@neurotechusa.com**

### Study: Effect of Squalamine Lactate Ophthalmic Solution, 0.2% in Subjects With Neovascular AMD

**Sponsor:** Ohr Pharmaceutical

**Purpose:** To evaluate anatomical and functional effect of combination therapy of Squalamine Lactate Ophthalmic Solution, 0.2% administered twice daily with monthly ranibizumab intravitreal injections in patients with choroidal neovascularization due to AMD

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

**Number of Patients:** 20

**Inclusion Criteria:** A diagnosis of choroidal neovascularization secondary to age-related macular degeneration (AMD) with choroidal neovascularization (CNV) comprising at least 50% of the total lesion area in the study eye; central retinal thickness ≥ 300 µm and presence of subretinal fluid or cystoid edema by OCT; BCVA of 20/40 to 20/320 by ETDRS Protocol

**Exclusion Criteria:** Neovascularization secondary to any other condition than AMD in the study eye; blood occupying greater than 50% of the AMD lesion, or blood > 1.0 sq. mm underlying the fovea; PED without associated subretinal fluid and/or cystic retinal changes; clinical evidence of diabetic retinopathy or DME

**Information:** **1501safety@ohrpharmaceutical.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 RPEl 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**

### Study: A Phase I/II Safety, Tolerability, Immunogenicity, and Bioactivity Study of DE-122 Injectable Solution for Refractory Exudative AMD

**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 one 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: LADDER: Study of the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients With Subfoveal Neovascular AMD

**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 ITV anti-VEGF injections prior to the screening visit; demonstrated response to prior standard of care

**Exclusion Criteria:** Study eye treatment with ITV bevacizumab within 5 months prior to the randomization visit, or with ITV aflibercept within 3 months prior to the randomization visit; history of laser photocoagulation, Visudyne, ITV corticosteroid injection, vitrectomy surgery, submacular surgery, device implantation, or other surgical intervention for AMD

**Information:** (888) 662-6728

### Study: CDER: A Safety and Efficacy Study of Abicipar Pegol in Patients With Neovascular AMD

**Sponsor:** Allergan

**Purpose:** To study abicipar pegol in patients with neovascular AMD

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

**Number of Patients:** 900

**Inclusion Criteria:** Untreated or previously treated choroidal neovascularization (CNV) lesion due to AMD; BCVA of approximately 20/200 Snellen or better in the non-study eye; diagnosis of AMD in at least 1 eye; BCVA of 20/40 to 20/320 in the study eye and 20/200 or better in the other

**Exclusion Criteria:** History of vitrectomy, macular surgery, or glaucoma surgery in the study eye; cataract or refractive surgery in the study eye within the last 3 months

**Information:** clinicaltrials@allergan.com

### Study: Evaluating RXI-109 to Reduce the Progression of Subretinal Fibrosis in Subjects With NVAMD

**Sponsor:** RXi Pharmaceuticals

**Purpose:** To evaluate the safety, tolerability and clinical activity of RXI-109 administered by intravitreal injection to reduce the progression of subretinal fibrosis in subjects with advanced neovascular age-related macular degeneration

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

**Number of Patients:** 9

**Inclusion Criteria:** Subjects presenting with advanced NVAMD in the study eye with BCVA ≤20/200 potentially due to subretinal fibrosis involving the fovea; BCVA ≥20/800 in the contralateral eye and better than the study eye; ≥50 years of age; subfoveal CNV of any type

**Exclusion Criteria:** Presence of other causes of CNV including pathologic myopia, ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, and multifocal choroiditis

**Information:** clinicaloperations@rxipharma.com

### Study: Proton Radiation Therapy for Macular Degeneration

**Sponsor:** University of Florida

**Purpose:** To determine if proton radiation therapy can provide effective and safe treatment for subfoveal neovascularization membrane

**Design:** Safety, Single Group, Open Label

**Number of Patients:** 10

**Inclusion Criteria:** Patients with subfoveal neovascular membranes identified on fluorescein angiography; visual acuity (best corrected vision) 20/200 or worse in affected eye; patient must be 50 years of age or older at time of consent; patients must have had prior treatment for macular degeneration with Avastin (bevacizumab) or Lucentis (ranibizumab)

**Exclusion Criteria:** History of diabetes

**Information:** (877) 686-6009

## WET AMD

### Study: EAGLE: Evaluating Genotypes Using Intravitreal Aflibercept Injection

**Sponsor:** University of California-San Diego/Regeneron

**Purpose:** To evaluate individuals treated with intravitreal aflibercept injection (Eylea) for neovascular age-related macular degeneration

**Design:** Single Group, Open Label

**Number of Patients:** 100

**Inclusion Criteria:** Naïve neovascular wet-age-related macular degeneration (has not received treatment before)

**Exclusion Criteria:** Previous therapy in study eye for age-related macular degeneration or other retinal disease which may be used in the treatment of age-related macular degeneration; previous subfoveal focal laser photocoagulation involving the foveal center in the study eye; history of vitrectomy, submacular surgery, or other surgical intervention for age-related macular degeneration in the study eye; any concurrent intraocular condition in the study eye

**Information:** cwen@ucsd.edu

### Study: ONYX: 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 juxtafoveal 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 choridal 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**

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