Trial: A Phase 4, Open Label, Multi-Center, Study of Maintenance Intravitreous Injections of Pegaptanib Sodium (Macugen) Given Every 6 Weeks for 48 Weeks in Subjects With Subfoveal Neovascular Age-related Macular Degeneration (AMD) Initially Treated With a Modality Resulting in Maculopathy Improvement

Purpose: The purpose of this study is to explore the safety and efficacy of pegaptanib (OSI/Eyetech and Pfizer, New York, New York) given as maintenance therapy in patients who have had initial success with another AMD treatment. Patients must have one, but not more than three prior treatments for neovascular AMD.
Sponsor: Eyetech Pharmaceuticals and Pfizer
Design: Interventional, treatment, nonrandomized, open label, uncontrolled, single-group assignment
Number of patients: 1,000
Inclusion/exclusion criteria: Ages ≥ 50 year, female, subfoveal choroidal neovascularization (CNV) secondary to AMD, at least one but not more than three prior treatments for AMD. Exclusion criteria: Subfoveal scar or subfoveal atrophy, significant media opacities, including cataract, which might interfere with visual acuity.
Status: This study is currently recruiting patients.
Information: Macugen information 866-622-8433 or Retina Research Institute of Texas, LLC, Abilene, Texas.

Trial: A Phase 3b/4 Randomized, Double-Masked, Active Controlled, Dose-Ranging, Multi-Center Comparative Trial, in Parallel Groups, to Compare the Safety and Efficacy of Intravitreal Injections of Pegaptanib Sodium Given Every 6 Weeks for 102 Weeks, to Pegaptanib Sodium Plus Photodynamic Therapy (PDT) With Visudyne, in Patients With Exudative AMD

Purpose: The purpose of the trial is to compare whether pegaptanib sodium in combination with PDT with verteporfin (Visudyne; Novartis, East Hanover, NJ) is safe and effective in slowing down the leakage of fluid within the eye and thereby stabilizing or improving vision when compared to pegaptanib alone. Patients must be recently diagnosed with predominantly classic wet AMD and must be eligible for PDT.
Sponsor: Eyetech Pharmaceuticals and Pfizer
Design: Interventional, treatment, randomized, double-masked, active-control, parallel-assignment, safety/efficacy study.
Number of patients: 360
Inclusion/exclusion criteria: Ages ≥ 50 years, both genders, subfoveal CNV due to AMD with predominantly classic lesion composition BCVA in the study eye between 20/40 and 20/200. Exclusion criteria: Any prior PDT with verteporfin to the study eye. Any previous AMD thermal laser therapy to the study eye.
Status: This study is currently recruiting patients.
Information: Macugen information 866-622-8436.

Trial: An Exploratory Randomized, Double-Masked, Multi-Center Comparative Trial, in Parallel Groups, to Explore the Safety and Efficacy of Three Different Doses of Intravitreous Injections of Pegaptanib Sodium (Anti-VEGF Pegylated Aptamer) Given Every 6 Weeks for 102 Weeks, in Patients With Subfoveal Neovascular AMD

Purpose. The purpose of this trial is to compare the ability of three different doses of pegaptanib sodium to safely and effectively minimize fluid leakage within the eye, thereby stabilizing or improving vision in patients with wet AMD. The study will also examine the effects of pegaptanib sodium on the cornea and sensory retina of patients with wet AMD.
Sponsor: Eyetech Pharmaceuticals and Pfizer
Design: Interventional, treatment, randomized, double-masked, dose-comparison, parallel-assignment, safety/efficacy study.
Number of patients: 262
Inclusion/exclusion criteria: Ages ≥ 50 years, both genders, subfoveal CNV due to AMD, BCVA in the study eye between 20/40 and 20/320. Normal electroretinogram, and corneal endothelial cell density of 1500 cells/mm^2 or more. Exclusion criteria: Any prior PDT with Visudyne or thermal laser to the study eye.
Status: This study is currently recruiting patients.
Information: Macugen information 866-622-8436.

Trial: A Phase 3b, Open-Label, Multicenter 12-Month Study to Evaluate the Safety, Tolerability and Efficacy of Ranibizumab (0.3 Mg) in Patients With Subfoveal CNV Secondary to AMD

Purpose: Ranibizumab (Lucentis; Genentech, San Francisco) is a humanized recombinant monoclonal antibody fragment targeted against human vascular endothelial growth factor A. This study will assess the safety and efficacy of ranibizumab administered on an as-needed dosing regimen in patients with subfoveal CNV secondary to AMD.
Sponsor: Novartis
Design: Interventional, treatment, nonrandomized, open-label, uncontrolled, expanded-access assignment, safety/efficacy study.
Number of patients: 500
Inclusion/exclusion criteria: Ages ≥ 50 years, both genders, diagnosis of active primary or recurrent CNV secondary to AMD, including those with predominantly classic, minimally classic or occult lesions with no classic component. The total area of CNV (including both classic and occult components) encompassed within the lesion must be ≥ 50% of the total lesion area. The total lesion area must be ≤ 12 disc areas. Patients who have a BCVA score

between 73 and 24 letters, inclusive, in the study eye using Early Treatment of Diabetic Retinopathy Study (ETDRS-like) grading charts (approximately 20/40 to 20/320). Exclusion criteria: Patients who have a BCVA of <34 letters in both eyes (legally blind is defined as bilateral vision below 20/200 or<34 letters). Laser photocoagulation, treatment with intravitreal steroids, verteporfin PDT or pegaptanib sodium in the study eye within 30 days preceding day 1. Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, anecortave acetate, protein kinase C inhibitors, etc.). Other protocol-defined inclusion/exclusion criteria may apply.
Status: This study is currently recruiting patients.
Information: Novartis customer information 862-778-8300.

Trial: Genetic Factors in AMD

Purpose: This study will examine whether certain polymorphisms predispose people to develop AMD.
Sponsor: NEI
Design: Observational/screening
Number of patients: 400
Inclusion/exclusion criteria: Samples from volunteers meeting the following eligibility criteria will be included in the study. Diagnosis of advanced AMD defined by geographic atrophy and/or CNV with drusen of any size in at least one eye. (AMD cases only). Age ≥ 50 years. If sample previously donated in a different study, the patient has given their permission to use their sample (ie, marked appropriate selection in the informed consent).
Control Patients (controls): Age ≥ 70 years or. Absence of drusen or no more than five drusen <63 µm, absence of other of diagnostic criteria for AMD. Agrees to undergo study examinations. Exclusion criteria: Samples from volunteers meeting any of the following exclusion criteria will not be included. Presence of retinal disease involving the photoreceptors and/or outer retinal layers other than AMD loss such as high myopia, retinal dystrophies, central serous retinopathy, vein occlusion, diabetic retinopathy and uveitis or similar outer retinal diseases that have been present prior to the age of 50 years. Opacities of the ocular media, limitations of papillary dilation or other problems sufficient to preclude adequate stereo fundus photography. These conditions include occluded pupils due to synechiae, cataracts, vitreous haze and opacities due to ocular diseases.
Status: This study is currently recruiting patients.
Information: NEI Patient Recruitment and Public Liaison Office, 800-411-1222; e-mail: prpl@mail.cc.nih.gov.

Trial: Clinical Research of PDT for Exudative AMD Accompanied With Polypoidal Choroidal Vasculopathy

Purpose: The purpose of this study is to evaluate and conduct an exploratory comparison of the efficacy and safety of indocyanine green angiography-guided PDT and fluorescein angiography-guided PDT for exudative AMD accompanied with PCV.
Sponsor: Ophthalmic PDT Study Group
Design: Interventional, treatment, randomized, single-masked, active, control, parallel-assignment, safety/efficacy study.
Number of patients: 190
Inclusion/exclusion criteria: Japanese patients aged 50 years old or older, exudative AMD with subfoveal PCV, eyes with PCV meets the definite criteria of PCV issued from Japanese study group of Polypoidal Choroidal Vasculopathy, PCV lesion with subfoveal hemorrhage or exudation, Lesion size (GLD) of less than 12 MPS Disc area measured by FA and IA, decimal BCVA of 0.1-0.5 at baseline period. Exclusion criteria: Patients who have RPE tear, vitelliform retinal dystrophy, and central Serous Chorioretinopathy. Patients who have other ocular disease with irreversible VA Study eyes unable to be taken fundus photos of CNV. Study eyes received surgery operation within 2 months of the participation to this study or nd:YAG operation within one month. Pathological myopia, PCV with clearly identified subsensory retinal CNV (on the retinal pigment epithelium) at the baseline examination, study eyes which have received any treatments for CNV, such as PDT, transpupillary thermotherapy, laser photocoagulation, and so on. Patients who have any physical problem for using angiography or PDT (such as systemic debility, significant diabetes mellitus, significant heart disease, and so on). Medical history of porphyria, porphyrin sensitivity, or hypersensitivity to sunlight or bright light. Patients with medical history of hypersensitivity to ingredients of Visudyne. Patients with medical history of hypersensitivity to ingredients of fluorescein or indocyanine green injection. Patients with hypersensitivity to iodine. Patients judged inappropriate for this study by the investigator.
Status: This study is currently recruiting patients.
Information: Fukushima Medical University School of Medicine, Japan; Tomohiro Iida, MD +81-24-547-1299 iidat@fmu.ac.jp; Masaaki Saito, MD, +81-24-547-1303; amasaaki@fmu.ac.jp; Tomohiro Iida, MD, Principal Investigator. Sapporo City general hospital, Sapporo, 060-8604, Japan; Recruiting Muneyasu Takeda, MD; +81-11-726-2211; Hiroko Imaizumi, MD, +81-11-726-2211; Muneyasu Takeda, MD, Principal Investigator. Surugadai Nihon University Hospital, Tokyo, 101-8309, Japan; Recruiting. Mitsuko Yuzawa, MD, +81-3-3295-1711; Ryuzaburo Mori, MD, +81-3-3295-1711; Mitsuko Yuzawa,

MD, Principal Investigator. Kyorin University, Tokyo, 181-8611, Japan; Recruiting. Annabelle Okada, MD, +81-3-422-5511; Seijo Yamaoka, MD, +81-3-422-5511; Annabelle Ayame, MD, Principal Investigator

Trial: A Safety and Efficacy Study of Squalamine Lactate for Injection (MSI-1256F) for *Wet* AMD

Purpose: The trial objective is to evaluate the safety and efficacy of two doses of Squalamine lactate for Injection administered as intravenous infusions weekly for 4 weeks followed by maintenance doses every 4 weeks through week 104 compared with the safety and efficacy in the control group.
Sponsor: Genaera Corporation
Design: Interventional, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study, phase 3.
Number of patients:
Inclusion/exclusion criteria: Patients with a diagnosis of wet AMD. Excluded are patients with treatment for wet AMD in the affected eye in the past 3 months
Status: The expected completion is June 2008. The study is recruiting patients.
Information: Jamila Watkins: 800-299-9156 or e-mail: jwatkins@genaera.com.

Trial: A Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients With Neovascular AMD

Purpose: The effect of intravitreally administered VEGF Trap in patients with wet AMD. To assess the ocular and systemic safety and tolerability of repeated intravitreal doses of VEGF Trap in patients with subfoveal CNV due to AMD.
Sponsor: Regeneron Pharmaceuticals
Design: Intervention, phase 2, interventional, treatment, randomized, double-blind, dose comparison, parallel-assignment, safety/efficacy study.
Number of patients. 150
Inclusion/exclusion criteria: age ≥ 50 years. both genders, subfoveal CNV secondary to AMD, central retinal (including lesion) thickness ≥ 300 µm as measured by OCT. Early Treatment of Diabetic Retinopathy Study (ETDRS) BCVA of 73 letters to 34 letters. Exclusion criteria: History of any vitreous hemorrhage within 4 weeks prior to day 1, aphakia, significant subfoveal atrophy or scarring. Prior treatment with the following in the study eye, subfoveal thermal laser therapy, submacular surgery or other surgical intervention for the treatment of AMD. Extrafoveal laser coagulation treatment within 12 weeks prior to day 1, PDT within 12 weeks prior to visit 2 (day 1), pegaptanib sodium within 8 weeks of visit 2 (day 1). Juxta-scleral steroids or anecortave acetate within 24 weeks (6 months) prior to visit 2 (day 1). Intravitreal administration of triamcinolone acetonide or other steroids within 24 weeks prior to visit 2 (day 1), unless no visible residue of drug substance can be seen in the vitreous cavity using indirect ophthalmoscopy. Prior systemic or intravitreal treatment with VEGF Trap, ranibizumab or bevacizumab (Avastin; Genetech, San Francisco). Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this phase 2 study.
Status: This study is currently recruiting patients.
Information: Regeneron at VEGF.Trap@regeneron.com

Trial: Study Of Combined Visudyne Therapy With Kenalog In CNV Secondary To AMD (VISTA)

Purpose: The primary objective of this study is to determine the effect of Visudyne therapy in combination with 4 mg intravitreal triamcinolone on the mean change in BCVA at month 12.
Sponsors: Manhattan Eye, Ear & Throat Hospital, Novartis, QLT Inc
Design: Interventional, treatment, randomized, single-blind, placebo-control, single-group assignment, safety/efficacy study
Number of Patients: 120
Inclusion/exclusion criteria: Age ≥ 50, subfoveal CNV secondary to AMD, area of the CNV at least 50% of the area of the total neovascular lesion, the lesion is either minimally classic or occult with no classic. If the lesion is occult with no classic then subjects must have presumed recent disease progression in the study eye in the judgment of the investigator and as defined by presence of blood associated with the lesion or vision loss or lesion growth reported or objectively recorded within the preceding 3 months before randomization to treatment. Baseline BCVA score between 73 and 19 letters on the ETDRS scale (approximately 20/40 to 20/400). Lesion size <5400 µm.
Status: This study is currently recruiting patients. Completion is expected in January 2007.
Information: Namrata Saroj, OD: 212-605-3777 or e-mail: nsaroj@retinal-research.org.

Trial: A Safety and Feasibility Study of the TheraSight Ocular Brachytherapy System for Treatment of AMD

Purpose: The study will investigate the safety and feasibility of using the TheraSight Brachytherapy System for treatment of wet AMD.
Sponsor: Theragenics Corporation
Design: Treatment, randomized, open-label, dose-comparison, single-group assignment, safety study, phase 1 and 2
Number of patients: 30

Inclusion/exclusion criteria: Age ≥ 50 years, active primary or recurrent subfoveal CNV secondary to AMD with minimally classic or occult lesion. Exclusion criteria: prior AMD therapy, including but not limited to laser and PDT. (See www.clinicaltrials.gov for comprehensive listing).
Status: This study is currently recruiting patients.
Information: Call 877-960-1234

Trial: Transpupillary Thermotherapy (TTT) Versus PDT for Treatment of CNV in AMD

Purpose: The purpose of the study is to compare PDT to TTT as a treatment method for CNV in AMD.
Sponsor: St. Erik Eye Hospital
Design: Treatment, randomized, single blind, active control, parallel-assignment, efficacy study
Number of patients: 140
Inclusion/exclusion: N/A
Status: Expected completion is April 2008. Patients are no longer being recruited.
Information: Anne C. Odergren, MD; +46 8 6723000 ext. 3066; e-mail: anne.odergren@sankterik.se

Trial: A Phase 2 Study of Implants of Encapsulated Human NTC-201 Cells Releasing Ciliary Neurotrophic Factor (CNTF) in Participants with Visual Acuity Impairment Associated with Atrophic Macular Degeneration

Purpose: This is an 18-month study to evaluate the safety and effectiveness of CNTF implants on vision in participants with atrophic macular degeneration.
Sponsor: NEI
Design: Treatment, safety/efficacy, phase 2.
Number of patients: 36
Inclusion/exclusion criteria: See www.clinicaltrials.gov for comprehensive listing.
Status: Study began January 6.
Information: NEI: 800-411-1222; or e-mail: prpl@mail.cc.nih.gov

Study: Triamcinolone Acetonide Plus Laser Therapy to Treat AMD

Purpose: This study will test the safety and effectiveness of combining PDT, with injections of the steroid triamcinolone acetonide for treating AMD.
Sponsor: NEI
Design: Treatment, efficacy, phase 3.
Number of patients: 300
Inclusion/exclusion criteria: See comprehensive listing at www. clinicaltrials.gov.
Status: This study is currently recruiting patients.
Information: NEI Patient Recruitment and Public Liaison Office: 800-411-1222 or e-mail: prpl@mail.cc.nih.gov.

Trial: High-Resolution Ultrasound Imaging of the Retina and Choroid for Detection on AMD

Sponsors: Weill Medical College of Cornell University and the American Institute of Ultrasound in Medicine
Purpose: This study will investigate use of high frequency (20 MHz) ultrasound for imaging of the retina and choroid in patients with AMD, a prime cause of blindness. The investigation will involve use of novel post-processing methodologies to achieve maximum resolution of the fine tissue structures involved in this disease.
Design: Observational, screening, cross-sectional, defined population, retrospective/prospective study.
Number of patients: 40
Inclusion/exclusion criteria: AMD age-matched control.
Status: This study is currently recruiting patients. the completion date is June 2006.
Information: Harriet O Lloyd, MS, 212-746-6106; e-mail: hlloyd@med.cornell.edu; or Ronald H. Silverman, PhD, 212-746-6106; e-mail: ros2012@med.cornell.edu.

Trial: Double-Masked Study of Photrex (Rostaporfin) PDT in the Treatment of AMD

Purpose: The purpose of this study is to confirm the efficacy and safety of rostaporfin (Photrex) PDT in the treatment of classic and occult subfoveal CNV associated with AMD.
Sponsor: Miravant Pharmaceuticals
Design: Phase 3, randomized, double-masked, placebo-controlled, single-group assignment, efficacy study.
Number of patients: 660
Inclusion/exclusion criteria: Patients aged ≥ 50 years with at least one subfoveal CNV membrane secondary to AMD that can be demonstrated by fluorescein angiography.
Status: This study is currently recruiting patients.
Information: Miravant Pharmaceuticals, 800-685-2959 or e-mail: ctinfo@miravant.com.

Trial: Triamcinolone Acetonide as an Adjunctive to VPDT in AMD

Purpose: A 24- month study looking at the the changes in visual acuity of patients receiving PDT therapy in conjunction with intravitreal triamcinolone.
Sponsors: Canadian Retinal Trials Group, University of British Columbia, QLT Inc and Vancouver Hospital **Design**: Phase 2,3, randomized, double-masked, placebo-controlled, parallel-assignment, safety/efficacy study.
Number of patients: 120, expected completion December 2007.
Inclusion/exclusion criteria: Individuals with predominantly classic, subfoveal CNV secondary to AMD.
No previous PDT treatment in study eye. Exclusion criteria: CNV from conditions, other than AMD. Other disease that could be responsible for decreased vision.

Status: This study is currently recruiting patients.
Information: Eye Care Centre, Vancouver, British Columbia, Canada; Recruiting: Dawn Hay, RN, 604.875.4411 ext. 62544 or Melissa Witzigmann, BSc, 604-875-5285.

Trial: ADVANCE: Study of Vatalanib and Photodynamic Therapy With Verteporfin in Patients With Subfoveal CNV Secondary to AMD

Purpose: AMD is the leading cause of blindness for people over 50 in the western world, with an incidence of about 37% in patients ≥ 75 years and older. AMD occurs in two forms: dry and wet. The dry form is associated with atrophic cell death within the retina. The wet form is caused by the formation of abnormal blood vessels and growth of new blood vessels on the retina, which leak fluid and blood and cause scar tissue that results in a deterioration of sight over a period of months to years. Although the cause of AMD is unknown, some evidence suggests that angiogenic and permeability factors such as vascular endothelial growth factor (VEGF) are the stimuli that induce new and abnormal vessel formation. This study will test the safety of vatalanib in combination with verteporfin in patients with CNV forming beneath the macula due to age-related macular degeneration.
Sponsor: Novartis
Design: Multicenter, phase 1,2 study
Number of patients: 60
Inclusion/exclusion criteria: Patients aged ≥ 65 years, both genders eligible. Wet AMD, size of the lesion (if predominantly classic type) must be ≤ 5400 µm. If minimally classic type or occult only type, lesion must be ≤ 6 disc areas and must have recent disease progression. Have sight of approximately 20/40 to 20/320 Snellen (measured with a special chart). Exclusion criteria: Prior treatment in the study eye for this disease. Uncontrolled high blood pressure, despite chronic stable treatment: systolic ≥ 140 mm Hg, diastolic ≥ 90 mmHg, history of ECG abnormalities
Status: This study is currently recruiting patients.
Information:
Arizona: Retina Centres P.C, Tuscon, 85704-5614, not yet recruiting. Patricia Wilkins 520-742-0236; clinicaltrials@retinacenterspc.com. Herny Hudson, MD, Principal Investigator.
California: Retinal Consultants, San Diego, 92064, recruiting. Ruth Baer 858-451-1911; Paul Tornambe, Principal Investigator, Retina-Vitreous Associates Medical Group, Beverly Hills, 90211, recruiting. Jackie Sanguinet 310-854-6201; David Boyer, Principal Investigator.
Colorado: Porter Adventist Hospital, Eye Lab, Denver, 80210, recruiting. Sheryl Giambartolomei 303-765-3537; Brian Joondeph, Principal Investigator.
Florida: USF Eye Institute, Tampa, 33612, not yet recruiting. Sharon Millard 813-974-4627; smillard@hsc.usf.edu; Burton Goldstein, MD, Principal Investigator.
Illinois: University of Chicago, 60637, not yet recruiting. Sophie Gen 773-702-7666; William Mieler, Principal Investigator. Springfield Clinic, LLP, recruiting; Lora Walkers 217-527-4744; David Dodwell, Principal Investigator.
Maryland: Wilmer Eye Institute, Baltimore, 21287, not yet recruiting. Pam Singletary 410-614-3495; psinglet@jhmi.edu; Peter A Campochiaro, MD, Principal Investigator.
Massachusetts: Lahey Clinic Medical Center, Eye institute, Peabody, 01960, recruiting. Avon Stewart 978-538-4412; Jeff Marx, Principal Investigator. Massachusetts Eye and Ear Infirmary, Boston, 02114, not yet recruiting. Erin Peters 617-523-7900; Erin_Peters@meei.harvard.edu; Joan Miller, MD, Principal Investigator. Ophthalmic Consultant of Boston, 02114, not yet recruiting. Paul Daniel; pdaniel@eyeboston.com; Jeffrey S Heier, MD, Principal Investigator.
Minnesota: The Retina Center, Minneapolis, 55404-3810; not yet recruiting. Tanya Pierce 612-871-2292; Abdish Bhavsar, Principal Investigator.
Missouri: Eye Foundation of Kansas City at Truman Medical Center, Kansas City, 64108; not yet recruiting. Mickie Keeling 816-404-1815; Nelson Sabates, Principal Investigator.
New York: Manhattan Eye, Ear & Throat Hospital, New York, 10021; Not yet recruiting. Namrata Saroj 212-605-3777; James Klancnik, Principal Investigator.
Ohio: Cleveland Clinic Foundation, Cleveland, 44195, not yet recruiting. Laura Holody 216-445-3762; Peter Kaiser, Principal Investigator.
Oregon: Retina North West, Portland, 97210; not yet recruiting. Stephen Hobbs 503-274-2121; shobs1@retinanorthwest.com; Michael S Lee, Principal Investigator
Pennsylvania: University of Pittsburgh Medical Center Eye Center, Eye and Ear Institute, Pittsburgh, 15213, not yet recruiting. Kerie Harkleroad 412-647-7511; Thomas Friberg, Principal Investigator.
South Dakota: Black Hills Regional Eye Institute, Rapid City, 05770, not yet recruiting. Honor Evers 605-341-2000; hevers@bhrei.com; Prema Abraham, MD, Principal Investigator
Texas: Texas Retina Associates, Arlington, 76012; recruiting. Cheryl Lee 817-261-9625; clee@texasretina.com; Dave Callanan, Principal Investigator.
Utah: The Eye Institute of Utah, Salt Lake City, 84107; not yet recruiting. Ann C Bagley 801-261-2113; Michael Teske, Principal Investigator.
Washington: University of Washington Eye Center, Seattle, 98195-6485, terminated. ■