

Clinical Research Trials Prema Abraham, MD

Age Related Macular Degeneration Studies

Principal Investigator: “A Phase 2, randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreal injections of E10030 (anti-PDGF pegylated aptamer) given in combination with Lucentis in subjects with neovascular age-related macular degeneration”. OPHTHOTECH CORP., New York, New York. 2010 – Present.

Principal Investigator: “An Open-Label, Long-term, Safety and Tolerability Extension Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration”. Regeneron Pharmaceuticals, Tarrytown, New York. 2010 – Present.

Principal Investigator: “A Phase 3, double-masked, multicenter, randomized, active treatment-controlled study of the efficacy and safety of 0.5 mg and 2.0 mg Ranibizumab administered monthly or on an as-needed basis (PRN) in patients with subfoveal neovascular age-related macular degeneration”. Genentech, Inc., South San Francisco, California. 2009 – Present.

Sub-Investigator: “Ranibizumab for treating submacular vascularized PED – A prospective pilot study”. Southern California Desert Retina Consultants, Palm Springs, California. 2009 – Present.

Principal Investigator: “A Randomized, Double Masked, Active Controlled Phase 3 study of the efficacy, safety, and tolerability of repeated doses of intravitreal VEGF Trap in subjects with neovascular age-related macular degeneration”. Regeneron Pharmaceuticals, Tarrytown, New York. 2007 – Present.

Principal Investigator: “An open-label, long-term, safety, and tolerability study of intravitreal VEGF Trap-eye in subjects with neovascular age-related macular degeneration”. Regeneron Pharmaceuticals, Tarrytown, New York. 2007 – Present.

Principal Investigator: “A Phase 3, randomized, double-masked, parallel-assignment study of intravitreal bevasiranib sodium, administered every 8 or 12 weeks as maintenance therapy following three injections of Lucentis® compared to Lucentis® monotherapy every 4 weeks in patients with exudative age-related macular degeneration (AMD)”. Opko Helath, Inc., Miami, Florida. 2007 – 2009.

Principal Investigator: “A phase 1, open-label study to investigate the safety, tolerability, and pharmacokinetic profile of single and repeated doses of JSM6427 following administration by intravitreal injection in patients with

neovascular age-related macular degeneration". Jerini Ophthalmic, New York, New York. 2007 – 2009.

Principal Investigator: "A 24-month randomized, double-masked, multi-center, phase IIIb study assessing safety and efficacy of verteporfin (Visudyne®) photodynamic therapy administered in conjunction with ranibizumab (Lucentis™) versus ranibizumab (Lucentis™) monotherapy in patients with subfoveal choroidal neovascularization secondary to age-related macular degeneration", Novartis Pharmaceuticals Corporation, East Hanover, New Jersey. 2006 – 2010.

Principal Investigator: "A Phase IV, open-label, multi-center, trial of maintenance intravitreal injections of Macugen® (Pegaptanib Sodium) given every 6 weeks for 48 weeks in subjects with subfoveal neovascular age-related macular degeneration (AMD) initially treated with a different modality resulting in maculopathy improvement", OSI Eyetech, New York, New York. 2006 – 2008.

Principal Investigator: "A Randomized, Controlled Study of the Safety, Tolerability, and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients with Neovascular Age-Related Macular Degeneration", Regeneron Pharmaceuticals, Tarrytown, NY. 2006 – 2008.

Principal Investigator: "A Randomized, Double-Masked, Multicenter, Phase I/II study of the safety of PTK787 administered in conjunction with Photodynamic Therapy with Visudyne® to patients with predominantly classic, minimally classic, and occult with no classic Subfoveal CNV secondary to Age-Related Macular Degeneration", Novartis Pharmaceuticals Corporation, East Hanover, New Jersey. 2006 – 2007.

Principal Investigator: "A Phase I, Open-Label, Single-Dose, Sequential, Dose-Escalation Study of Intravitreal Administration of AG-013958 in Subjects with Subfoveal CNV associated with Age-Related Macular Degeneration", Pfizer, Inc. San Diego, CA. 2006 – 2007.

Principal Investigator: "A Phase IIIb, Single-Masked, Multicenter, Randomized Study to Evaluate the Safety and Tolerability of Ranibizumab in Naïve and Previously Treated Subjects with Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration", Genentech, Inc., South San Francisco, CA. 2005 – 2007.

Principal Investigator: "A Phase II, Randomized, Double-Masked, Controlled, Dose Comparison Study of Cand 5 for Intravitreal Injection for the Treatment of Subfoveal Choroidal Neovascularization Associated with Wet Age-Related Macular Degeneration", Acuity Pharmaceuticals, Philadelphia, PA. 2005 – 2007.

Principal Investigator: "Interval Dose Evaluation of Anecortave Acetate", Alcon Research, Ltd, Fort Worth Texas. 2005 – 2007.

Principal Investigator: “An Open-Label, Multicenter Extension Study to Evaluate the Safety and Tolerability of Ranibizumab in Subjects with Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration who have completed the treatment phase of a Genentech-Sponsored Ranibizumab Study”, Genentech Inc., So San Francisco, CA. 2005 – 2009.

Principal Investigator: “Anti-Human VEGF Antibody Fab for the Treatment of Subfoveal Choroidal Neovascularization in AMD 3 Monthly Dosing, BioTherapeutic Unit-Genentech, Inc., South San Francisco, California. 2004 – 2007.

Principal Investigator: “Anecortave Acetate Risk-Reduction Trial”, Alcon Research, Ltd, Fort Worth, Texas. 2004 – 2008.

Principal Investigator: “Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD”, BioTherapeutic Unit, Genentech, Inc., South San Francisco, California. 2003 – 2006.

Principal Investigator: “Minimally Classic/Occult Trial of AntiVEGF Antibody RhuFab V2 In the Treatment of Neovascular AMD”, BioTherapeutic Unit, Genentech, Inc., South San Francisco, California. 2003 – 2006.

Diabetic Macular Edema Studies

Principal Investigator: “Ranibizumab for Edema of the macula in Diabetes: Protocol 3 with High Dose – the READ 3 study”. Juvenile Diabetes Research Foundation, New York, New York. 2010 – Present.

Principal Investigator: “A phase 2 prospective, randomized, multi-center, diabetic macular edema dose ranging, comparator study evaluating the efficacy and safety of PF-04523655 versus laser therapy (DEGAS)”. Pfizer – LaJolla Laboratories, San Diego, California. 2009 – Present.

Principal Investigator: “A 52 week, masked, multi-center, randomized, controlled trial to assess the safety and efficacy of Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) Applicator system in combination with laser photocoagulation compared with laser photocoagulation alone in the treatment of subjects with Diffuse Diabetic Macular Edema.” Allergan, Irvine, California. 2007 – 2010.

Principal Investigator: “A phase 3, double-masked, multi-center, randomized, sham injection – controlled study of the efficacy and safety of Ranibizumab injection in subjects with clinically significant macular edema with center

involvement secondary to diabetes mellitus". Genentech, Inc., San Francisco, California. 2007 – Present.

Principal Investigator: "Ranibizumab for Edema of the macula in Diabetes: A phase II study (The READ-2 Study)", Johns Hopkins University, Baltimore, MD. 2006 – Present.

Principal Investigator: "A Randomized, Double-Masked, Parallel Group, Multi-center, Dose-Finding Comparison of the Safety and Efficacy of ASI-001A 0.5 µg/day and ASI-001B 0.2 µg/day Fluocinolone Acetonide Intravitreal Inserts to Sham Injection in Subjects with Diabetic Macular Edema", Alimera Sciences, Inc and pSivida Inc., Alpharetta, Georgia. 2006 – Present.

Principal Investigator: "Open-Label treatment for Patients Completing Study B7A-MC-MBCM", Eli Lilly and Company, Indianapolis, Indiana. 2006 – 2008.

Principal Investigator: "A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema", Diabetic Retinopathy Clinical Research Network. 2005 – 2008.

Principal Investigator: "Evaluation of Vitrectomy for Diabetic Macular Edema", Diabetic Retinopathy Clinical Research Network. 2005 – 2008.

Principal Investigator: "A Phase II, Pharmacokinetic, Randomized, Double-Masked, Controlled, Dose Comparison Study of Cand5 for Intravitreal Injection for the Treatment of Diabetic Macular Edema", Acuity Pharmaceuticals, Philadelphia, PA. 2006 – 2007.

Principal Investigator: "Reduction in the Occurrence of Center-Threatening Diabetic Macular Edema", Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, Indiana. 2004 – 2008.

Principal Investigator: "Protein Kinase C β Inhibitor – Diabetic Retinopathy Study 2", Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, Indiana. 2001 – 2005.

Retinal Vein Occlusion Studies

Principal Investigator: "A randomized, double masked, controlled phase 3 study of the efficacy, safety and tolerability of repeated intravitreal administration of VEGF Trap-Eye in subjects with macular edema secondary to central retinal vein occlusion". Regneron Pharmaceuticals, Tarrytown, New York. 2009 – Present.

Principal Investigator: "An open-label, multicenter extension study to evaluate the safety and tolerability of Ranibizumab in subjects with Choroidal

Neovascularization (CNV) secondary to age-related macular degeneration (AMD) OR macular edema secondary to retinal vein occlusion (RVO) who have completed the treatment phase of a Genentech-Sponsored Ranibizumab study.” Genentech, Inc. South San Francisco, California. 2008 – Present.

Principal Investigator: “A six-month, phase 3, multicenter, masked, randomized, sham-controlled trial to assess the safety and efficacy of 700 ug and 350 ug Dexamethasone posterior segment drug delivery system (DEX PS DDS) applicator system in the treatment of patients with macular edema following central retinal vein occlusion or branch retinal vein occlusion”. Allergan, Irvine, California. 2007 – 2008.

Principal Investigator: “A phase 3, multicenter, randomized, sham-injection controlled study of the efficacy and safety of Ranibizumab injection compared with sham in subjects with macular edema secondary to branch/central retinal vein occlusion”. Genentech, Inc., San Francisco, California. 2007 – 2010.

Other Studies

Principal Investigator: “A randomized, placebo controlled, double-masked, multicenter trial of microplasmin intravitreal injection for non-surgical treatment of focal vitreomacular adhesion”. ThromboGenics Inc., New York, New York. 2009 – Present.

Principal Investigator: “A randomized, double-blind placebo-controlled study to evaluate the ocular safety of SCH 530348 in subjects participating in the Schering-Plough P04737 study (TRA secondary prevention ocular safety study)”. Schering-Plough Research Institute, Kenilworth, New Jersey. 2008 – Present.

Sub-Investigator: “A phase 1 Study of the Safety and Efficacy of multiple intravitreal injections of Ranibizumab in subjects with choroidal neovascularization secondary to causes other than age-related macular degeneration”. Jeffery Heier, MD, Ophthalmic Consultants of Boston, Boston, MA. 2006 – 2009.

Principal Investigator: “Clinical Evaluation of the Safety of Next Generation Ophthalmic Irrigating Solution (NGOIS) Compared to BSS PLUS for Use During Surgery for Removal of Epimacular Membrane Vitrectomy”, Alcon Research, Ft. Worth, Texas. 2006 – 2007.

“The Family (Genetic) Study of Macular Degeneration, J. Seddon, J., and Abraham, P., Preceptor, Harvard Medical School, Boston, Massachusetts. 1999 – 2000.

“Induced Refractive Change Following Scleral Buckling Procedures”, Brinton, G.S. and Abraham, P., Preceptor, University of Utah, Department of Ophthalmology, Salt Lake City, Utah. 1992 – 1994.

“Chemical Induction of Locomotion in the In Vitro Brainstem-Spinal Cord Preparation”, Garcia-Rill, E. and Abraham, P., Preceptor, Department of Neuroanatomy, University of Arkansas School of Medicine, Little Rock, Arkansas. 1986 – 1988.

“Development of Pedunculo-pontine Nucleus: I. In Vivo”, Garcia-Rill, E., Preceptor, Department of Neuroanatomy, University of Arkansas School of Medicine, Little Rock, Arkansas. 1986 – 1987.

“Determination of Bound Iodine in Human Milk, Market Milk and Commercial Infant Formulae”, Anderson, H., Preceptor, University of Missouri Research Reactor, Columbia, Missouri. 1982 – 1983.