# RETINA RESEARCH CENTER NEWS

**SPRING 2014**

RRC RETINA RESEARCH CENTER

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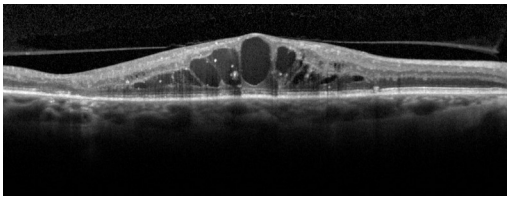
- ***Pfizer B1261009***
- ***DRCR U***
- ***DRCR V***
- ***Ophthotech Fovista***


## Novel Treatment Routes for the Treatment of Diabetic Macular Edema



Diabetic retinopathy is the leading cause of blindness in American adults. The current standard of care treatments for diabetic retinopathy are laser photocoagulation and intravitreal injections. Although effective, laser photocoagulation does not always resolve retinal swelling and can also lead to partial peripheral vision loss. Intravitreal injections of anti-VEGF and corticosteroids are effective, but last only one to six months depending on the patient and severity of retinopathy.

Pharmaceutical companies are now working on developing alternate drug delivery mechanisms to treat diabetic macular edema.

We are currently enrolling patients into a Phase IIb trial conducted by Ampio Pharmaceuticals to evaluate Optina, an oral agent taken twice per day to treat diabetic macular edema. Optina is a low dose of Danazol™, an FDA approved treatment for endometriosis and fibrocystic breast disease.

Ampio PHARMACEUTICALS

Pfizer is conducting a Phase II trial comparing the efficacy and safety of oral PF-04634817, a chemokine CCR2/5 receptor antagonist, to Lucentis® in treatment of diabetic macular edema. We are currently the only site enrolling patients for this trial in the United States.

Pfizer

We are beginning a Phase II trial with Aerpio Therapeutics investigating AKB-9778 (a Tie2 activator) administered daily subcutaneously as monotherapy or adjunctive therapy to Lucentis®.

aerpio therapeutics

If these drugs prove to be effective, this could lead to longer treatment intervals as well as possibly avoiding or reducing the need for laser or injection therapy. For more information about these trials please contact Ivana Gunderson at 512-279-1251 or igunderson@e-retina.net.

## DRCR (Diabetic Retinopathy Clinical Research Network) trials

The Diabetic Retinopathy Clinical Research Network (DRCR.net) is a collaborative network dedicated to facilitating multicenter clinical research of diabetic retinopathy, diabetic macular edema and associated conditions. The DRCR.net supports the identification, design, and implementation of multicenter clinical research initiatives focused on diabetes-induced retinal disorders. Currently, Retina Research Center is conducting the following two DRCR trials.

Protocol U: Short-Term Evaluation of Combination Corticosteroid (Ozurdex) + Anti-VEGF (Lucentis®) Treatment for Persistent Diabetic Macular Edema Following Anti-VEGF Therapy in Pseudophakic Eyes.

**Key Inclusion**:

- Visual acuity 20/32—20/320
- At least 6 prior intravitreal anti-VEGF injections
- Pseudophakia

Protocol V: Treatment for Center-Involved Diabetic Macular Edema in Eyes with Very Good Vision.

**Key Inclusion**:

- Center-involved DME as confirmed by spectral domain OCT
- Visual acuity 20/25 or better

DRCR.net

**Kristen Jarzombek, a fourth year medical student at UTMB, completed her ophthalmology elective with Dr. Berger and Dr. Jhaveri in February 2014. She plans to pursue a career in anesthesiology.**

## The Institute for Retina Research

On September 6, 2013, The Institute for Retina Research received its 501 (c)(3) as a non-profit foundation. The foundation was established by Dr. Berger and Dr. Jhaveri in order to benefit our patients, staff, and future doctors. Donations will be used to:

- Help the RRC to be the first, and often only research center in the area to offer novel treatments for various retinal diseases
- Conduct independent research
- Provide travel grants and stipends for staff and students to attend educational meetings
- Defray teaching expenses associated with training future medical professionals

**If you or your foundation are interested in making a tax-deductible contribution, please visit our website at www.e-retina.net or click HERE.**

## From a future ophthalmologist…

"I wanted to thank you again. I matched into Ophthalmology at Medical College of Georgia in Augusta, GA and an internship year at Spartanburg Regional Transitional Year in Spartanburg, SC, close to my residency. I am very excited to begin and am very grateful to you for your support in helping me achieve my career goals. I hope all is going well in your practice."

Steven Glenn, MD

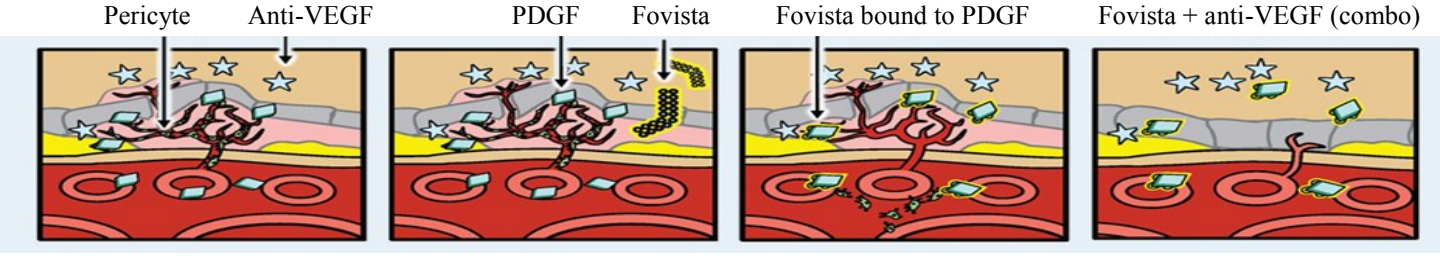
# New Approach to Treating Wet ARMD

Retina Research Center is involved in a Phase III clinical trial using Fovista™ for the treatment of choroidial neovascularization associated with age-related macular degeneration (wet AMD).

Fovista™, a PDGF inhibitor, offers a unique and novel approach for the management of wet AMD. Foviasta™ prevents PDGF from binding to its natural receptor on pericytes, thus causing pericytes to be stripped from newly formed abnormal blood vessels. Left unprotected, the endothelial cells are highly vulnerable to the effects of anti-VEGF drugs. Because of the ability of Fovista™ to induce pericyte stripping from newly formed blood vessels, the administration of Fovista™ in combination with anti-VEGF drugs is likely to inhibit abnormal new blood vessel growth associated with wet AMD more effectively than anti-VEGF drugs alone and may also enhance neovascular regression.

In the previous Phase II study, Fovista™ administered in combination with Lucentis® demonstrated statistically significant superiority compared to Lucentis® monotherapy based on the primary endpoint of mean change in visual acuity from baseline at 24 weeks. Patients receiving the combination of Fovista™ and Lucentis® gained a mean of 10.6 letters from baseline compared to a mean gain of 6.5 for patients receiving Lucentis® monotherapy. Fovista™ exhibited a favorable safety profile.

We would appreciate you allowing us to evaluate your treatment naïve patients with new onset wet AMD. The objective of this study is to evaluate Fovista™ when administered in combination with Lucentis®. Thus all patients in this trial will still be treated with standard of care, Lucentis®




Pericyte coverage protects new vessels from anti-VEGF-inducted disruption

Fovista is designed to inhibit PDGF

Fovista inhibits PDGF, leading to pericyte stripping

Combo therapy results in enhanced anti-angiogenesis & new vessel disruption & regression

# Publications and Presentations

## BRIAN BERGER, MD

- The course of Eyes with Vitrectomy Prior to Enrollment in a Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred laser for Diabetic Macular Edema., Berger MD, Brian. Association for Research in Vision and Ophthalmology Annual Meeting, Orlando, FL, May 2014

- Demographics and Baseline Characteristics of the IDEAL Study: A Randomized Multi-center, Phase II Study of the safety, Tolerability, and Biactivity of Repeated Intravitreal Injections of ICO-007 as Monotheraoy or in Combination with Ranibizumab or Laser Photocoagulation in the Treatment of Diabetic Macular Edema with Involvement of the FoveAL Center, Sepah, Yasir; Do, Diana V.; Callanan, David; Gonzalez, Victor H.; Halperin, Lawrence; Berger, Brian B.; Hanout, Mostafa S.; Hnik, Peter; Nguyen, Quan Dong. Association for Research in Vision and Ophthalmology Annual Meeting, Orlando, FL, May 2014

- Berger BB, Gunderson I, Rickman CB, Lin J, Garzone P. An investigational therapy for geographic atrophy in age-related macular degeneration - a monoclonal antibody against amyloid beta may target a novel therapeutic mechanism in dry AMD. *Retina Today*. 2014; May.

# Enrolling Trials

**Wet Age-Related Macular Degeneration**

***Lpath NEXUS*** –A Phase II study of iSONEP as monotherapy or adjunctive therapy to Lucentis, Avastin or Eylea versus Lucentis, Avastin or Eylea alone for treatment of choroidal neovascularization secondary to wet age-related macular degeneration in treatment resistant patients.

***Ophthotech OPH1003*** –A Phase III, randomized, double-masked, study to evaluate the safety and efficacy of an intravitreal injection of Fovista™ administered in combination with Lucentis compared to Lucentis monotherapy in subjects with wet age-related macular degeneration

**Dry Age-Related Macular Degeneration**

***University of Virginia TOGA*** - A Phase III study to evaluate the efficacy of daily administration of ORACEA®, a tetracycline derivative approved for treatment of inflammatory lesions of rosacea in adults, compared to placebo on the rate of change of geographic atrophy in patients with dry age-related macular degeneration. - Enrollment will start in the near future

**Uveitis**

***XOMA X052130/ CL3-78989-005***- A study of monthly subcutaneous injections of gevokizumab in the treatment of active non-infectious intermediate, posterior, or pan–uveitis.

**Diabetic Macular Edema**

***Ampio AP-05-002*** - A Phase IIb study to evaluate two doses of oral Optina™ in adult patients with diabetic macular edema. The study drug is a low dose of Danazol™, which is marketed for the treatment of endometriosis and benign fibrocystic breast disease.

***Pfizer B1261009*** - A Phase II, double-masked, placebo-controlled, study to compare the efficacy and safety of a chemokine CCR2/5 receptor antagonist, PF-04634817, against Raninizumab (Lucentis) in patients with diabetic macular edema.

***DRCR Protocol U*** - A short-term evaluation of combination corticosteroid + Anti-VEGF treatment for persistent diabetic macular edema following Anti-VEGF therapy in pseudophakic eyes.

***DRCR Protocol V*** - A study to compare the safety and efficacy of (1) prompt focal/grid photocoagulation + intravitreal Eylea, (2) observation + deferred intravitreal Eylea, and (3) prompt intravitreal Eylea in eyes with central-involved diabetic macular edema and good visual acuity.

***Aerpio AKB-9778-CI-2003***- A study to compare the safety and efficacy of daily subcutaneous AKB-9778 administered for 3 months, as monotherpy or adjunctive to ranibizumab, in subjects with diabetic macular edema.

# Special Thanks

**A special thank you goes to all of you who have helped support our trials by referring your patients for participation.**