# RETINA RESEARCH CENTER NEWS

**WINTER 2013**

RRC RETINA RESEARCH CENTER

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- ***GSK BAM114341***
- ***iDEAL***
- ***Lpath Nexus***

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- **DRCR T**


## Comparative Study of Diabetic Macular Edema Treatment

Retina Research Center is participating with Diabetic Retinopathy Clinical Research Network (DRCRnet) in a major clinical trial comparing the efficacy and safety of intravitreal Eylea®, Avastin® and Lucentis® for the treatment of diabetic macular edema. This clinical trial has been named Protocol T.


**$1950.00**

Patients are **eligible to participate** in this trial if they meet the following criteria:

1. Visual acuity 20/30—20/320 in the study eye
2. Diabetic macular edema in the study eye
3. No anti-VEGF treatment for DME within 12 months and no other treatment for DME within 4 months

The study participation will last two(2) years. Participants will be evaluated for treatment every 4 weeks throughout the first year of the study and then every 4 to 16 weeks during the second year.

If the **non-study eye** is going to be treated for **any condition** which requires treatment with an anti-VEGF agent, the non-study eye must be treated with the same anti-VEGF drug as the study eye.


**$265.00**

**DRCR will provide the drug for BOTH EYES throughout the duration of trial participation.**


**$1850.00**

To refer a patient for participation in **PROTOCOL T**, please send a referral form to **512-454-5853** with Protocol T written on the top. You may also email any of the people indicated under **Contact Us**.

# JETREA® Receives FDA Approval for the Treatment of Symptomatic Vitreomacular Adhesion


Retina Research Center and Dr. Brian Berger participated in two Phase III clinical trials with Thrombogenics (MIVI-TRUST and Oasis) examining the use of ocriplasmin for the treatment of symptomatic vitreomacular adhesion including small macular holes. Retina Research Center had ten (10) patients who randomized into the first Phase III trial, which concluded during the summer of 2010. For the second Phase III clinical trial with Thrombogenics, Retina Research Center had eight (8) patients randomize. There are currently six (6) patients ongoing in this trial.

On October 17, 2012, the FDA approved JETREA® (ocriplasmin) Intravitreal Injection, 2.5 mg/mL for the treatment of symptomatic vitreomacular adhesion. JETREA® made its official United States launch on January 14, 2013 at the price of $3950.00 per vial.

Dr. Berger and Dr. Jhaveri have begun treating their patients with JETREA® in office. The medication is a single dose administered intravitreally. JETREA now provides a non-surgical alternative for the treatment of symptomatic vitreomacular adhesion.

## Lux Biosciences Uveitis Trial Fails Phase III Trial

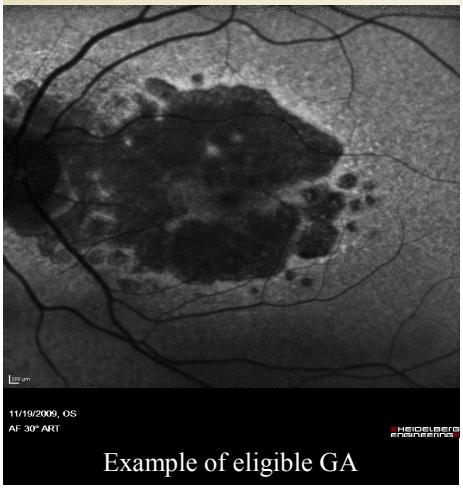
On December 29, 2012, it was announced that the Lux Phase III clinical study using Luveniq (voclosporin) for the treatment of non-infectious Uveitis conducted by Lux Biosciences did not meet its primary endpoint of change from baseline in vitreous haze at 12 weeks or at the time of treatment failure, if earlier. As a result, Lux does not expect to move forward with its sub-mission of regulatory approval applications for non-infectious Uveitis in the United States and Europe.

## University of Texas Medical Branch Elective Student

Sarah White, a 4th year medical school student from University of Texas Medical Branch completes her ophthalmology elective with Dr. Berger and Dr. Jhaveri this month. Sarah intends to specialize in emergency medicine.

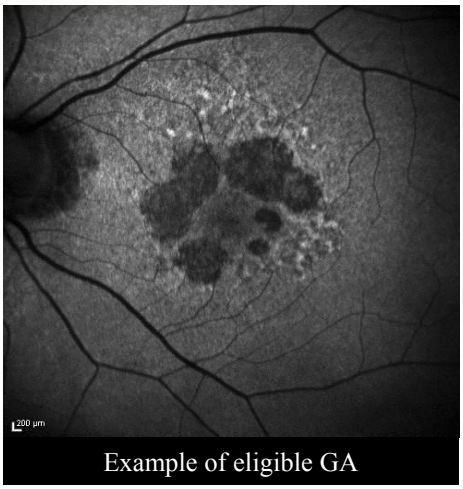
John Dryden completed his ophthalmology elective with Dr. Berger and Dr. Jhaveri in November 2012. John begins the Navy Health Services Collegiate Program this Fall.

## New Protocol Amendment for Pfizer Dry ARMD Trial



Example of eligible GA

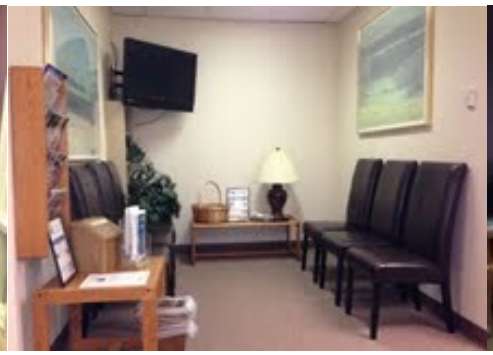
This winter, Pfizer amended the ongoing B1181003 protocol to allow the participation of patients with controlled glaucoma. This amendment also allows for the concomitant use of AREDS vitamins. The amendment will significantly expand the number of potential patients for this trial. If you have patients with geographic atrophy who were not considered due to glaucoma or an unwillingness to discontinue AREDS vitamin therapy, please reconsider their participation in this clinical trial.


Example of eligible GA

## Upgraded Amenities for Retina Research Patients

We have recently updated our facilities to enhance our Retina Research patients' office experience. Many of our dry ARMD trials involve lengthy intravenous drug infusions. We want to provide patients a comfortable environment during their time in our office.

To achieve this goal, we have added new reclining couches in the front waiting room, leather chairs in the back waiting room, an assortment of snacks for all patients to enjoy while they wait, as well as a Keurig coffee machine, work stations, and free WiFi access.


## Special Thanks

**A special thank you goes to the following for referring patients in the past 3 months who consented to enroll in a clinical trial:**

Thomas Henderson, MD; Theresa Wagner, MD; Diane Davis, OD; Laurie Sorenson, OD; Opal Amin, OD; Isaac Loose, MD; Peter Nutson, MD; George Thorne, MD; Sarah Johle, OD

**www.retinaresearchcenter.com**

## Enrolling Trials

**Wet Age-Related Macular Degeneration**

***Lpath NEXUS*** - A Phase II study of iSONEP as either monotherapy or adjunctive therapy to Lucentis or Avastin versus Lucentis or Avastin alone for choroidal neovascularization secondary to ARMD that has not adequately responded to 3-10 prior treatments.

**Dry Age-Related Macular Degeneration**

***GSK BAM114341*** - A phase II study of GSK933776, a monoclonal antibody, in patients with geographic atrophy (GA) secondary to age-related macular degeneration. Fellow eye CNV is permitted.

***Pfizer B1181003*** - A Phase II study evaluating RN6G (monoclonal antibody binding amyloid beta) in patients with geographic atrophy (GA) secondary to age-related macular degeneration.

**Uveitis**

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

**Diabetic Macular Edema**

***iCO Therapeutics and Juvenile Diabetes Foundation (iDEAL Study)*** - A Phase II study of repeated intravitreal injections of iCO-007 as monotherapy or in combination with ranibizumab or laser photocoagulation in the treatment of diabetic macular edema with involvement of foveal center.

***DRCR T*** - A comparative study of ranibizumab, aflibercept, and bevacizumab for diabetic macular edema.

## Presentations, Publications, & Appointments

**CHIRAG JHAVERI, MD**

Dr. Jhaveri received his appointment as Clinical Assistant Professor at Texas A&M University Health Science Center College of Medicine, December 2012

**BRIAN BERGER, MD**

"Key Diagnostic Signs in Posterior Uveitis," American Academy of Ophthalmology Breakfast with the Experts, Chicago, IL, November 2012

"Phase 1 Trial Targeting Tissue Factor for the Treatment of Neovascular AMD," John Wells III, MD; Christine Gonzales, MD; Brian Berger, MD; Brian Sippy, MD, PhD; Victor Gonzalez, MD; and David Johnson, MD, American Academy of Ophthalmology Annual Meeting, Chicago, IL, November 2012

"A Phase 1 Study Targeting Tissue Factor with a Single Dose of Intravitreal hI-con1 for Exudative Age-Related Macular Degeneration," Christine Gonzales, MD; John Wells III, MD; Brian Berger, MD; Brian Sippy, MD, PhD; Victor Gonzales, MD; and David Johnson, MD, American Society of Retinal Surgeons, Las Vegas, NV, August 2012