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RETINA RESEARCH CENTER

# Retina Research Center News: March 2015

## The Changing Paradigm for the treatment of Diabetic Macular Edema

### 36 Month Sustained Drug Delivery


In July 2006, Dr. Berger and Retina Research Center began working with Alimera Sciences on the FAME trial evaluating fluocinolone acetonide intravitreal implant for patients with diabetic macular edema, and in 2012 the extension study for the development of the new applicator. Retina Research Center enrolled 10 patients in the FAME trial and two patients into the FAME extension. On September 26, 2014, the FDA approved this drug delivery system, Iluvien®, for the treatment of patients with diabetic macular edema who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Iluvien® an injectible, non-erodible intravitreal implant that is injected using a 25 gauge applicator in a procedure very similar to the Ozurdex® delivery system. Iluvien® delivers up to 36 months of continuous, low-dose corticosteroid therapy with a single injection.

On February 24, 2015, Dr. Berger was the first physician in Austin to treat a non-study patient with Iluvien®. Dr. Berger was invited by Alimera to participate in the Iluvien® launch webinar event held on March 2,2015 for retinal surgeons across the United States. This first treatment was filmed and used to train other physicians on the use of the Iluvien® applicator and treatment procedure. On February 25, 2015, Dr. Jhaveri became the second Austin physician to treat a patient with Iluvien®. KXAN's David Scott's interview with Dr. Jhaveri and his patient about this treatment aired on March 1st and 2nd. Watch the video HERE

Doctors Berger, Jhaveri, and Chexal are excited about having a new treatment option for patients who require ongoing intravitreal injections to treat their diabetic macular edema.

# Year one Protocol T Results

On February 18, 2015, The New England Journal of of Medicine published "Aflibercept, Bevacizumab, or Ranibizumab For Diabetic Macular Edema", the year one findings from The Diabetic Retinopathy Clinical Research Network's Protocol T. Retina Research Center randomized 19 patients into this two year study comparing the relative safety and efficacy of Eylea®, Lucentis®, and Avastin® in the treatment of diabetic macular edema. The one year data analysis showed all three treatments were effective and relatively safe for diabetic macular edema causing vision impairment. When initial visual acuity loss was mild, defined as 20/32 to 20/40, there was little difference in visual acuity at 1 year among the three drugs. However, at worse levels of initial visual acuity, defined as best corrected visual acuity 20/50 or worse, aflibercept was more effective at improving vision.

# On the Horizon

If you would like for your patients to have the opportunity to participate in cutting edge research that might one day change the treatment of diabetic macular edema, Retina Research Center is currently conducting trials for diabetic macular edema using oral agents, such as Pfizer B1261009, a dual antagonist of human chemokine receptor 2 and receptor 5, and Astellas VIDI, a vascular adhesion protein (VAP-1). We are also evaluating an intravitreal injection of an integrin inhibitor with Allegro. You can find out additional information HERE or Ivana Gunderson at 512-279-1251 or igunderson@e-retina.net

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**Currently Enrolling Diabetic Macular Edema Trials**

* Allegro ALG-1001: A 24 Week Phase 2, Randomized, Double-Masked Trial Evaluating the Safety and Exploratory Efficacy of Luminate (ALG-1001) as Compared to Avastin and Focal Laser Photocoagulation.
* Astellas VIDI Protocol 8232-CL-3001: A 24 Week Phase 2, Double-Masked, Randomized, Active Controlled Study to Evaluate the Efficacy and Safety of ASP8232 in Reducing Central Retinal Thickness in Subjects with Diabetic Macular Edema.
* Pfizer B1261009: A 16 Week Phase 2, Randomized, Double-Masked Study to Compare the Efficacy and Safety of a Chemokine CCR2/5 Receptor Antagonist (PF-04634817) with that of Ranibizumab in Adult Subjects with Diabetic Macular Edema.
* DRCR Protocol V: A Phase 3 Study to Assess the Treatment for Central-Involved Diabetic Macular Edema in Eyes with Very Good Visual Acuity.
* DRCR Protocol AA: Peripheral Diabetic Retinopathy Lesions on Ultrawide-field Fundus Images and Risk of DR Worsening Over Time