## **RETINA TODAY**

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### Retina Today Has a New Online Home

Bryn Mawr Communications, publisher of *Retina Today*, is pleased to announce a new online home for the publication: RetinaToday.com. Although the web address will be familiar to users, there are many significant upgrades on the site designed to expand the utility of *Retina Today*'s educational content.

In addition to an aesthetic overhaul, the redesigned website features digital content shared from the Retina channel on EyeTube.net, the second most viewed channel on the site in 2013 and 2014. Users will still be able to read the complete archives of the print publication on RetinaToday.com dating back to 2006; in addition, by combining print and video mediums into 1 location, the new website harnesses the reach and power of each

site, in turn offering a broader and more comprehensive perspective on the issues that matter most to clinical practice—all in an intuitive and easy-to-navigate format.

Following an emerging trend in publishing to offer a multimedia content presentation, print and video content is seamlessly integrated into 9 different "Centers" on RetinaToday.com that reflect popular content categories: AMD, Business, Diabetic Retinopathy, Disease & Pathophysiology, Imaging & Visualization, Medical Retina, Pediatric, Pipeline, and Retina Surgery. Under each Center, content can be filtered between articles, videos, or both. Additionally, the website features a search engine powered by Google, which allows users to quickly find the exact content they are seeking.

### Aflibercept Approved for Treatment of Diabetic Macular Edema

The US Food and Drug Administration (FDA) approved aflibercept (Eylea, Regeneron) for treatment of diabetic macular edema (DME), according to a company press release. Days later, European regulators also approved the drug for treatment of DME.

The drug's recommended dosage is 2.0 mg every 8 weeks following 5 monthly loading doses. It is the first anti-VEGF agent approved by the FDA for DME with a recommendation for less-than-monthly dosing.

Regulatory agencies relied on 1-year data from the VIVID-DME and VISTA-DME trials, which compared aflibercept 2.0 mg monthly, aflibercept 2.0 mg every 8 weeks (following 5 monthly loading doses), and asneeded laser. The primary efficacy endpoint for the studies was the mean change from baseline in best corrected visual acuity (BCVA) at week 52. The 2 studies were similarly designed. VIVID recruited 466 patients and VISTA recruited 406 patients.

At 1 year, patients in the aflibercept groups had a statistically significant improvement in BCVA versus patients in the laser group. The visual acuity gains in the aflibercept groups were similar, demonstrating no added benefit to monthly dosing versus bimonthly dosing.

Rates of adverse events (AEs), ocular serious AEs, nonocular serious AEs, and arterial thromboembolic events were

similar across the aflibercept groups and the laser group.

This is the third approved indication for aflibercept in the United States. The drug received FDA approval for neovascular age-related macular degeneration (AMD) in 2011 and macular edema secondary to central retinal vein occlusion (CRVO) in 2012.

- Eylea (afflibercept) injection receives FDA approval for treatment of diabetic macular edema [press release].
   Tarrytown, NY: Regeneron; July 29, 2014.
- Eylea (affilbercept) injection receives EU approval for the treatment of diabetic macular edema [press release]. Tarrytown, NY: Regeneron; August 11, 2014.

# Dexamethasone Intravitreal Implant Approved in Europe for Diabetic Macular Edema

The European Union's Committee for Medicinal Products for Human Use recommended extending the marketing authorization for the dexamethasone intravitreal implant (Ozurdex, Allergan) to treat adult patients with vision loss due to DME who are pseudophakic or are recalcitrant to or unsuitable for noncorticosteroid therapy, according to a company press release.<sup>1</sup>

This is the third marketing authorization for the drug in the European Union. The drug also has marketing authorization for macular edema in patients with retinal vein occlusion and for inflammation due to noninfectious uveitis in the posterior segment.

Allergan announces Ozurdex (dexamethasone 700 mcg intravitreal implant in applicator) receives European
positive opinion for the treatment of diabetic macular edema [press release]. Irvine, CA: Allergan; July 25, 2014.

## **RETINA TODAY**

### Use of Bevacizumab in Retinopathy of Prematurity Led to Better Refractive Outcomes

Use of bevacizumab (Avastin, Genentech) in patients with retinopathy of prematurity (ROP) was associated with less frequent development of very high myopia and better overall refractive outcomes versus laser, according to a study published in *JAMA Ophthalmology*.<sup>1</sup>

Investigators in the BEAT-ROP study, a prospective, stratified, randomized, controlled, masked, multicenter clinical trial, randomized preterm infants with ROP to bevacizumab monotherapy or laser therapy. Patients underwent cycloplegic retinoscopic refraction at a mean age of 2.5 years. Of all study eyes (n = 300), 255 eyes in 131 infants were analyzed, and refractions were available for 211 eyes.

Researchers measured spherical equivalent refractions in patients with zone I and zone II posterior ROP. In 52 eyes with zone I ROP randomized to bevacizumab, mean spherical equivalent refraction was -1.51 D; in 35 eyes with zone I ROP randomized to laser, mean spherical equivalent refraction was -8.44 D (P < .001). In 58 eyes with zone II posterior ROP randomized to bevacizumab, mean spherical equivalent refraction was -0.58 D; in 66 eyes with zone II ROP randomized to laser, mean spherical equivalent refraction was -5.83 D (P < .001).

Very high myopia was defined as spherical equivalent refractions of at least -8.00 D. In eyes with zone I ROP, very high myopia occurred in 2 of 52 (3.8%) eyes randomized to bevacizumab therapy and 18 of 35 (51.4%) eyes randomized to laser (P < .001). In eyes with zone II posterior ROP, very high myopia occurred in 1 of 58 (1.7%) eyes randomized to bevacizumab therapy and 24 of 66 (36.4%) eyes randomized to laser (P < .001).

Speculating on the reason for higher rates of very high myopia in eyes receiving laser, the study authors said that "this difference is possibly related to anterior segment development that is present with intravitreal bevacizumab but minimal or absent following laser treatment."

 Geloneck MM, Chuang AZ, Clark WL, et al. Refractive outcomes following bevacizumab monotherapy compared with conventional laser treat: a randomized clinical trial [published online ahead of print August 7, 2014]. JAMA Ophthalmol. doi:10.1001/jamaophthalmol.2014.2772.

### Non-Hispanic Blacks Had Higher Prevalence of Diabetic Macular Edema, Study Showed

Non-Hispanic blacks had greater risk of having DME than non-Hispanic whites, according to the results of a population-based study published in *JAMA Ophthalmology*. The study also found that non-Hispanic

blacks, patients with high HbA1c levels, and those with longer duration of diabetes were more likely to have DME.

A cross-sectional analysis of patients (n = 1038) 40 years or older with diabetes and valid fundus photographs who participated in the 2005 to 2008 National Health and Nutrition Examination Survey measured overall prevalence of DME and its prevalence according to age, race/ethnicity, and sex.

In the study population, 55 patients had DME. Based on this, researchers estimated an overall weighted prevalence for DME of 3.8% (95% CI, 2.7-4.9%), or approximately 746 000 people in the 2010 population 40 years or older. Researchers detected no difference in prevalence of DME for age or sex.

Use of multivariable logistic regression showed that the risk of having DME was higher for non-Hispanic blacks than for non-Hispanic whites (odds ratio [OR], 2.64; 95% CI, 1.19-5.84; P = .02).

Researchers found that elevated HbA1c levels (OR, 1.47; 95% CI, 1.26-1.71 for each 1%; P < .001) and longer duration of diabetes (OR, 8.51; 95% CI, 3.70-19.54 for  $\geq$ 10 vs <10 years; P < .001) were associated with DME prevalence.

1. Varma R, Bressler NM, Doan QV, et al. Prevalence of and risk factors for diabetic macular edema in the United States [published online ahead of print August 14, 2014]. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2014.2854.

### Signs of Early Age-Related Macular Degeneration Found in Young Patients

Signs of early AMD were found in 3.8% of patients under 45 years, according to a population-based study published in *Graefe's Archive for Clinical and Experimental Ophthalmology*.<sup>1</sup>

The study evaluated fundus photographs from participants (n = 4340) in the Gutenberg Health Study, a prospective, observational, single-center study in Germany. Fundus photographs from participants ages 35 to 75 were examined for evidence of hard and soft drusen, retinal pigmentary abnormalities, and evidence of geographic atrophy and neovascular AMD.

Of those in the youngest age bracket (35-44 years), evidence of early AMD, which included soft drusen and pigmentary abnormalities, was found in 3.8% of patients (95% Cl; stage 1a, 0.4% [0.3-0.5%]; stage 1b, 3.2% [2.9-3.5%]; stage 2a, 0.1% [0.1-0.2%]; stage 2b, 0% [0-0.0%]; stage 3, 0.1% [0.1-0.2%]). No signs of late AMD appeared in that age bracket.

The researchers found that incidence of AMD increased significantly with age (OR, 1.09; 95% CI, 1.08-1.10) and found no association between AMD and sex, iris color, or rural versus urban settings.

1. Korb CA, Kottler UB, Wolfram C, et al. Prevalence of age-related macular degeneration in a large European cohort: Results from the population-based Gutenberg Health Study. *Graefes Arch Clin Exp Ophthalmol*. doi: 10.1007/s00417-014-2591-9.