Medical Xpress

FDA approves drug to treat diabetic macular edema

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The U.S. Food and Drug Administration today announced its approval of Lucentis (ranibizumab injection) for the treatment of diabetic macular edema, or DME, an eye condition in people with diabetes that causes blurred vision, severe vision loss and sometimes blindness. A retinal specialist at The Methodist Hospital in Houston, Texas, was one of the lead investigators in the research that led to today's FDA approval.

The drug is the first and only FDA-approved medicine for DME, a condition for which the standard of care has not changed significantly in more than 25 years. To date, the usual resort in the United States has been laser surgery, which slows the rate of vision loss and helps stabilize vision, but has demonstrated only limited ability to restore lost vision.

"This approval is an important advancement in the fight against blindness for people with diabetes," said David M. Brown M.D., retinal surgeon at Methodist. "Now that it will be available, Lucentis therapy can begin to make a difference in the lives of our patients with DME."

Diabetes is the leading cause of new cases of blindness in American adults and DME is estimated to affect more than 560,000 Americans with the disease.

The FDA first approved Lucentis for treatment of wet age-related macular degeneration in 2006 and for macular edema following retinal vein occlusion in 2010. Brown and his research team were integrally involved in the research that led to these FDA approvals as well.

The approval of Lucentis in DME was based on manufacturer Genentech's Phase III trials, RIDE and RISE, two identically-designed, parallel, double-masked, three-year clinical trials, which were sham-treatment controlled for 24 months. A total of 759 patients were randomized into three groups to receive monthly treatment with 0.3 mg Lucentis (n=250), 0.5 mg Lucentis (n=252) or sham injection (control group, n = 257). In the studies, treatment with Lucentis demonstrated improved clinical outcomes including substantial visual gain for many DME patients. Results showed patients who received 0.3 mg Lucentis experienced significant, early (Day 7) and sustained (24 months) improvements in vision.

More patients who received Lucentis were able to read at least three additional lines (15 letters) on the eye chart at 24 months; had average vision gains exceeding two lines (10 letters) on the eye chart at 24 months; and were significantly more likely to maintain their vision (lose

DME is swelling of the macula, the central part of the retina responsible for sharp, central vision. DME begins with diabetes, which can cause damage to blood vessels in the eye over time. When this happens, a patient is said to have diabetic retinopathy, the most common diabetic eye disease. The damaged blood vessels can leak blood and fluid, causing swelling and blurred vision, severe vision loss and sometimes blindness.

Nearly 26 million Americans have diabetes, which has become the leading cause of new cases of blindness in adults aged 20-74. Among Americans aged 40 years and older, more than 4.2 million have diabetic retinopathy.

Lucentis is a prescription medicine for the treatment of patients with wet AMD, macular edema following RVO and DME. Lucentis is a recombinant humanized monoclonal antibody fragment (lacking an Fc

region). Lucentis is the first VEGF inhibitor specifically designed for use in the eye to bind to and inhibit VEGF-A, a protein that is believed to play a critical role in the formation of new blood vessels (angiogenesis) and the hyperpermeability (leakiness) of the vessels.

Provided by The Methodist Hospital System