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FDA Approves Eylea

FDA Approves Eylea for Wet Age-Related Macular Degeneration

November 18, 2011 -- The U.S. Food and Drug Administration today approved Eylea (aflibercept) to treat patients with wet (neovascular) age-related macular degeneration (AMD), a leading cause of vision loss and blindness in Americans ages 60 and older.

AMD gradually destroys a person's sharp, central vision. It affects the macula, the part of the eye that allows people to see fine detail needed to do daily tasks such as reading and driving.

There are two forms of AMD, a wet form and a dry form. The wet form of AMD includes the growth of abnormal blood vessels. The blood vessels can leak fluid into the central part of the retina, also known as the macula. When fluid leaks into the macula, the macula thickens and vision loss occurs. An early symptom of wet AMD occurs when straight lines appear to be wavy.

"Eylea is an important new treatment option for adults with wet AMD," said Edward Cox, M.D., M.P.H, director of the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research. "It is a potentially blinding disease and the availability of new treatment options is important."

The safety and effectiveness of Eylea was evaluated in two clinical trials involving 2,412 adult patients. People in the study received either Eylea or Lucentis (ranibizumab injection). The primary endpoint in each study was a patient's clearness of vision (visual acuity) after one year of treatment.

Eylea is injected into the eye either every four weeks or every eight weeks by an ophthalmologist. The studies showed that Eylea was as effective as Lucentis in maintaining or improving visual acuity.

The most commonly reported side effects in patients receiving Eylea included eye pain, blood at the injection site (conjunctival hemorrhage), the appearance of floating spots in a person's vision (vitreous floaters), clouding of the eye lens (cataract), and an increase in eye pressure.

Eylea should not be used in those who have an active eye infection or active ocular inflammation. Eylea has not been studied in pregnant women, so the treatment should be used only in pregnant women if the potential benefits of the treatment outweigh any potential risks. Age related macular degeneration does not occur in children and Eylea has not been studied in children.

Other FDA-approved treatment options for wet AMD include: Visudyne (verteporfin for injection) approved in 2000, Macugen (pegaptanib sodium injection) approved in 2004, and Lucentis (ranibizumab injection) approved in 2006.

Eylea is marketed by Tarrytown, N.Y.-based Regeneron Pharmaceuticals Inc.

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