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Phase III Study Showed Lucentis Improved Vision in Patients with Branch Retinal Vein Occlusion

Study Showed Early and Sustained Improvement in Vision Through Six Months

Roche announced today that the Phase III study BRAVO showed Lucentis (ranibizumab injection) improved vision, as measured by the primary endpoint of mean change from baseline in best-corrected visual acuity at six months, in patients with macular edema due to branch retinal vein occlusion. The safety profile of Lucentis was consistent with previous experience and no new adverse events related to Lucentis were observed in the study. Retinal vein occlusion (RVO) is a common cause of vision loss that occurs when blood flow through a retinal vein becomes blocked, such as by a blood clot.

BRAVO evaluated the safety and efficacy of six monthly injections of Lucentis compared to monthly sham injections. The two doses of Lucentis studied showed a statistically significant improvement in best-corrected visual acuity (the best vision a person can achieve with an eyeglass or contact lens prescription) at six months compared to sham. Full results will be presented at the Retina Congress, September 30 to October 4, 2009, in New York.

William M. Burns, Head of Roche's Pharmaceuticals Division, said "RVO is a devastating disease. We are excited that another pivotal study has demonstrated the important role Lucentis can play in improving vision in people with difficult-to-treat eye disease, and look forward to the results of CRUISE, a Phase III trial in central-RVO in the third quarter of this year."

About RVO

Retinal vein occlusion (RVO) occurs when blood flow through a retinal vein becomes blocked, causing swelling (macular edema) and hemorrhages in the retina, which may result in vision loss. Sudden blurring or vision loss in all or part of one eye is common with RVO. RVO can affect people across a wide range of ages, from young, working-aged adults to the elderly.

There are two main types of RVO: branch-RVO, which affects an estimated 684,000 people, and central-RVO, which affects an estimated 211,000 people in the United States.¹ Branch-RVO occurs when one of the branches of the main vein of the eye becomes blocked. Central-RVO occurs when the main vein of the eye, located at the optic nerve, becomes blocked.

About BRAVO (FVF4165g)

BRAVO is a multicenter, randomized, double-masked, sham injection-controlled Phase III study, designed to assess the safety and efficacy of Lucentis in treating macular edema secondary to branch-RVO. Patients (n=397) were enrolled at 93 clinical trial sites across the United States.

The 12-month study consists of a six-month, sham-controlled treatment period, followed by a six-month observation period (during which all participants were eligible to receive Lucentis as needed). During the first six-month period, participants received monthly injections of one of two different doses (0.3 mg or 0.5 mg) of Lucentis (n=265) or monthly sham injections (n=132). The study was not designed to compare the two doses of Lucentis. Rescue laser treatment was available starting at month three to all patients meeting pre-specified criteria. The primary endpoint was the mean change from baseline in best-corrected visual acuity score at six months compared to sham.

About Lucentis

Lucentis is a vascular endothelial growth factor (VEGF) inhibitor approved by the U.S. Food and Drug Administration (FDA) for the treatment of neovascular (wet) age-related macular degeneration (AMD). Lucentis is the only FDA-approved treatment for wet AMD proven to improve or maintain vision. In wet AMD clinical trials, Lucentis administered monthly demonstrated an improvement in vision of three lines or more on the study eye chart in up to 41 percent of patients at two years. Nearly all patients (90 percent) in those trials treated monthly with Lucentis maintained vision.

Lucentis is designed 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. In RVO, angiogenesis and hyperpermeability can lead to macular edema, the swelling and thickening of the macula, which is the portion of the eye responsible for fine, detailed central vision.

In the United States Lucentis is being sold by Genentech Inc, a wholly-owned member of the Roche Group, and outside of the United States Lucentis is being sold by Novartis.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2008, Roche had over 80'000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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¹ Data on file, Genentech