Regeneron Submits Biologics License Application to FDA for VEGF Trap-Eye for Treatment of Wet Age-Related Macular Degeneration

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TARRYTOWN, N.Y., Feb. 22, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the company submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD). Under the Prescription Drug User Fee Act (PDUFA), the goal for a standard review time from submission to FDA action is ten months. Regeneron's submission includes a request for Priority Review, which, if granted, would shorten the FDA's targeted goal for review time under PDUFA to six months.

"There have been significant advances in the treatment of wet AMD in recent years. However, the need for monthly intravitreal injections to obtain optimal vision gains has resulted in a significant burden for physicians, patients, and their caregivers," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We are extremely proud to have conducted the largest global Phase 3 clinical program in patients with wet AMD, which demonstrated that patients treated with VEGF Trap-Eye 2 mg every two months, following three loading doses, were able to be dosed with fewer injections over one year without compromising efficacy. We look forward to working closely with the FDA to bring this potentially important new medicine to patients with wet AMD."

The VEGF Trap-Eye BLA is based on the positive results from two Phase 3 trials, the North American VIEW 1 trial and the global VIEW 2 trial. In these trials, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed 2 milligrams (mg) every two months (following three loading doses), successfully met the primary endpoint of non-inferiority, compared to the current standard of care, ranibizumab 0.5 mg dosed every month. The primary endpoint analysis was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The ocular adverse events were balanced across all treatment groups in both studies. There were no notable differences in non-ocular adverse events among the study arms.

About the VIEW Program

The VIEW (**V**EGF Trap-Eye: **I**nvestigation of **E**fficacy and Safety in **W**et AMD) program consists of two randomized, double-masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). The VIEW 1 study, which randomized 1217 patients, is being conducted in the United States and Canada by Regeneron under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration. The VIEW 2 study, which randomized 1240 patients, is being conducted in Europe, Asia Pacific, Japan, and Latin America by Bayer HealthCare. The study designs are essentially identical. The primary endpoint evaluation was conducted at 52 weeks.

In each of the studies, VEGF Trap-Eye was evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of 0.5 mg monthly, 2.0 mg monthly, or 2.0 mg every two months (following three monthly loading doses), as compared with intravitreal ranibizumab administered 0.5 mg every month during the first year of the studies.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye who maintained visual acuity at the end of one year, compared to ranibizumab patients. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity. Maintenance of vision was defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS eye chart.

The following table summarizes the VIEW 1 and VIEW 2 results for the primary and the first secondary endpoint pre-specified for testing:

	Ranibizumab 0.5mg monthly	**VEGF Trap-Eye 0.5mg monthly**	**VEGF Trap-Eye 2mg monthly**	**VEGF Trap-Eye 2mg every 2 months**
Maintenance of vision* (% patients losing				