Regeneron Reports Full Year and Fourth Quarter 2010 Financial and Operating Results

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TARRYTOWN, N.Y., Feb. 17, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial results for the full year and fourth quarter of 2010 and provided an update on development programs and upcoming milestones.

"2010 was a very productive year for Regeneron as we reported positive Phase 3 results in four clinical trials: two with VEGF Trap-Eye in wet age-related macular degeneration, called wet AMD, one with VEGF Trap-Eye in central retinal vein occlusion, and one with ARCALYST® for the prevention of gout flares in patients initiating uric-acid lowering therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We expect regulatory applications to be filed in the first half of 2011 for marketing approval in the U.S. and Europe for VEGF Trap-Eye in wet AMD. We also look forward to reporting results from additional Phase 3 trials in central retinal vein occlusion and gout and from two Phase 3 trials with aflibercept in cancer."

"In anticipation of potential product approvals," Dr. Schleifer added, "we are continuing to build our commercialization capabilities. We are also advancing our earlier-stage pipeline which currently includes eight fully-human monoclonal antibodies in clinical development for the treatment of various diseases and conditions including elevated LDL cholesterol, rheumatoid arthritis, atopic dermatitis, and cancer. We anticipate Phase 2 data from some of these programs in 2011."

"We entered 2011 in a strong financial position to support our development and commercialization activities," commented Murray A. Goldberg, Chief Financial Officer, "with approximately $627 million in cash and securities, following a successful public offering of Common Stock in October 2010."

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) — Ophthalmologic Diseases

VEGF Trap-Eye is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PLGF), proteins that are involved in the abnormal growth of new blood vessels. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

Phase 3 studies in wet age-related macular degeneration

In November 2010, Regeneron and Bayer Healthcare reported positive one-year data from two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). Based on these results, Regeneron plans to submit a Biologics License Application to the Food and Drug Administration (FDA) for marketing approval in the U.S. in the first half of 2011. In addition, Bayer Healthcare intends to submit regulatory applications in the first half of 2011 for marketing approval in Europe.

In VIEW 1 and VIEW 2, VEGF Trap-Eye was administered either monthly or every two months, and compared to monthly doses of ranibizumab, which is the current standard of care in wet AMD. In these studies, all regimens of VEGF Trap-Eye including VEGF Trap-Eye dosed every two months successfully met the primary endpoint of non-inferiority compared to ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. At least 94% of patients in every VEGF Trap-Eye group, including those dosed every two months, as well as those receiving ranibizumab dosed monthly, maintained visual acuity over 52 weeks. 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.

In VIEW 1 and VIEW 2, a generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD.

Phase 3 studies in central retinal vein occlusion

In December 2010, Regeneron and Bayer Healthcare reported positive initial results from the COPERNICUS study, the first of two Phase 3 studies evaluating VEGF Trap-Eye in central retinal vein occlusion (CRVO). Patients received six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 milligrams (mg) or sham control injections. In COPERNICUS, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in vision at six months compared to sham injections. In this trial, 56.1% of patients receiving VEGF Trap-Eye gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections (p