Regeneron Reports First Quarter 2011 Financial and Operating Results

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TARRYTOWN, N.Y., May 3, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced financial results for the first quarter of 2011 and provided an update on development programs and upcoming milestones.

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 U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

In February 2011, Regeneron 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). In April 2011, the FDA accepted the BLA for filing and granted the Company's request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

Also in February 2011, data from the Phase 3 VIEW 1 and VIEW 2 trials of VEGF Trap-Eye in patients with wet AMD and the Phase 3 COPERNICUS trial in macular edema due to central retinal vein occlusion (CRVO) were presented at the Bascom Palmer Eye Institute's Angiogenesis, Exudation and Degeneration 2011 meeting. Results of the Phase 2 DA VINCI trial of VEGF Trap-Eye in diabetic macular edema (DME) were also presented.

In April 2011, Regeneron and Bayer HealthCare announced positive top-line results for VEGF Trap-Eye in the Phase 3 GALILEO study in patients with macular edema due to CRVO. The positive results from the GALILEO study confirmed the results of the similarly designed COPERNICUS study that were announced in December 2010. In GALILEO, the primary endpoint at week 24 was achieved: 60.2% of patients receiving 2 milligrams (mg) of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections (p