Phase 3 Trial of ZALTRAP™ (aflibercept) in Advanced Prostate Cancer to Continue as Planned at Recommendation of Independent Data Monitoring Committee

July 7, 2011

TARRYTOWN, N.Y., July 7, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the Phase 3 VENICE clinical trial evaluating the investigational agent ZALTRAP™ (aflibercept) in the first-line treatment of patients with androgen-independent (hormone-refractory) metastatic prostate cancer will continue to completion as planned, with no modifications due to efficacy or to safety concerns. This decision is based on the recommendation of an Independent Data Monitoring Committee (IDMC) following a planned interim analysis. Regeneron and Sanofi are collaborating in the development of ZALTRAP in oncology. Both Regeneron and Sanofi management and staff remain blinded to the interim study results.

"We look forward to the final results of this trial next year in the hope of providing a new therapy for patients with metastatic prostate cancer," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Research Laboratories.

About the VENICE Study

The main objective of the multinational VENICE study (Aflibercept in Combination with Docetaxel in Metastatic Androgen Independent Prostate Cancer)(1) is to evaluate the efficacy and safety of ZALTRAP as a first-line treatment in combination with docetaxel and prednisone in 1,200 patients with hormone-refractory metastatic prostate cancer. The primary endpoint is improvement in overall survival. Secondary endpoints include Prostate Specific Antigen (PSA) measurement, pain measurement, progression-free survival and safety. The trial is fully enrolled with 1,224 randomized patients, and final results are anticipated in 2012.

About ZALTRAP and the Clinical Development Program

ZALTRAP™ (aflibercept), also known as VEGF Trap, is an investigational broad-spectrum angiogenesis inhibitor with a unique mechanism of action. This fully-human fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PlGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. ZALTRAP has been shown to bind VEGF-A, VEGF-B and PlGF with higher affinity than their native receptors.

Sanofi Oncology and Regeneron are collaborating on an oncology development program, combining the investigational agent ZALTRAP™ (aflibercept) with common chemotherapy regimens in the treatment of patients with advanced cancers. In addition to VENICE, the program includes one Phase 3 trial and one Phase 2 trial:

- VELOUR study (Phase 3): second-line treatment in combination with the FOLFIRI regimen (irinotecan-5-fluorouracil-leucovorin) in patients with metastatic colorectal cancer (mCRC) previously treated with an oxaliplatin-based regimen. Positive results demonstrating significantly improved survival with ZALTRAP were presented June 25 during the ESMO World Congress on Gastrointestinal Cancer; the associated abstract (#0-0024) was published in the June 2011 supplement to *Annals of Oncology*.

- AFFIRM study (Phase 2): first-line treatment in mCRC in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (FOLFOX). Results are anticipated in the second half of 2011.

About Prostate Cancer

Worldwide, prostate cancer ranks second in cancer incidence, with approximately 900,000 new cases annually, and sixth in cancer mortality in men.(2) Latest figures show that an estimated 324,000 new cases of prostate cancer appear in the European Union every year.(3) In the U.S., prostate cancer is the leading cause of cancer in men and remains the second most common cause of cancer death among men after lung cancer.(4) The American Cancer Society estimates that in 2011 in the U.S., there will be 241,000 new cases of prostate cancer and 34,000 prostate cancer deaths.(4) For many patients with prostate cancer, their disease continues to progress despite prior treatment — including surgical and/or hormonal castration followed by chemotherapy. Metastatic prostate cancer indicates that the cancer has spread to the lymph nodes or other parts of the body, particularly the bones. Castration resistant/hormone-refractory prostate cancer means that the cancer has continued to grow despite the suppression of male hormones that fuel the growth of prostate cancer cells. An estimated 10-20% of patients with prostate cancer are diagnosed when the cancer has already metastasized.(5)

About Regeneron Pharmaceuticals, Inc.

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion, and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron

technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Forward Looking Statements

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's product and drug candidates, competing drugs that may be superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with the Sanofi Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended March 31, 2011 . Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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(1) Aflibercept in combination with docetaxel in metastatic androgen independent prostate cancer (VENICE). Available at: http://www.clinicaltrials.gov/ct2/show/NCT00519285?term=venice&rank=2

(2) International Agency for Research on Cancer. Globocan 2008. Prostate cancer incidence and mortality worldwide 2008; summary. Available at: http://globocan.iarc.fr/factsheets/cancers/prostate.asp.

(3) International Agency for Research on Cancer. Globocan 2008. Fast stats- EU. Available at: http://globocan.iarc.fr/factsheets/populations/factsheet.asp?uno=990

(4) American Cancer Society. Cancer Facts and Figures 2011.

(5) Tannok IF, de Wit R, Berry WR, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med. 2004; 351: 1502-1512.

SOURCE Regeneron Pharmaceuticals, Inc.