Phase 3 Trial of Aflibercept in Second-Line Metastatic Colorectal Cancer to Continue as Planned at Recommendation of Independent Data Monitoring Committee

September 8, 2010

PARIS and TARRYTOWN, N.Y., Sept 08, 2010 /PRNewswire via COMTEX News Network/ -- Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) announced today that the Phase 3 VELOUR clinical trial of aflibercept (VEGF Trap) in patients with metastatic colorectal cancer (mCRC) will continue to completion as planned, with no modifications due to efficacy or safety concerns. This decision is based on the recommendation of an Independent Data Monitoring Committee (IDMC) following a planned interim analysis. Both sanofi-aventis and Regeneron management and staff remain blinded to the interim study results.

"We look forward to the final results of the trial, which are expected in the second half of 2011 with belief that the combination of aflibercept and FOLFIRI has the potential to benefit patients with this difficult-to-treat disease," said Tal Zaks, Head of Development, Global Oncology Division, sanofi-aventis.

About the VELOUR Study

The main objective of the VELOUR (Aflibercept Versus Placebo in Combination with Irinotecan and 5-FU [FOLFIRI] in the Treatment of Patients with Metastatic Colorectal Cancer after Failure of an Oxaliplatin Based Regimen) study is to evaluate the safety and effectiveness of aflibercept as a second-line treatment in combination with folinic acid (leucovorin), 5-fluorouracil, and irinotecan (FOLFIRI) in 1,226 patients with mCRC who previously had been treated with an oxaliplatin-based regimen. The primary endpoint is improvement in overall survival. Secondary endpoints include progression-free survival, response to treatment, and safety.

About the Aflibercept Clinical Development Program

Sanofi-aventis Oncology and Regeneron are collaborating on a broad oncology development program combining aflibercept (VEGF Trap) with common chemotherapy regimens in several types of cancer. In addition to VELOUR, the program includes two Phase 3 trials and one Phase 2 trial, all of which are fully enrolled:

- VITAL study: 2nd-line treatment for metastatic non-small cell lung cancer in combination with docetaxel (Phase 3). Complete results are anticipated in the first half of 2011.
- VENICE study: 1st-line treatment for hormone-refractory metastatic prostate cancer (mHRPC) in combination with docetaxel and prednisone (Phase 3). An interim analysis is expected to be conducted by an IDMC in mid-2011, with complete results anticipated in 2012.
- AFFIRM study: 1st-line treatment in mCRC in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (FOLFOX) (Phase 2). Results are anticipated in 2H 2011.

About Aflibercept

Aflibercept (VEGF Trap) is an anti-angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PIGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Aflibercept has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their natural receptors.

About Colorectal Cancer

Worldwide, colorectal cancer is the third most common cancer in men and the second in women; accounting for about 8% of all cancer deaths, making it the fourth most common cause of death from cancer. Colorectal cancer disproportionately affects people over age 65. FOLFIRI (5-fluorouracil, leucovorin, and irinotecan) is considered a standard backbone of second-line treatment in patients with advanced metastatic colorectal cancer.

About sanofi-aventis Oncology

Sanofi-aventis Oncology is targeting cancer on all fronts in an effort to address unmet medical needs for a broad range of patients. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, as well as identifying the right science early in the discovery process, the company employs innovative approaches to bring the right medicines to the right patients. There are currently more than 10 compounds in development across a broad scientific platform, including cytotoxic, antimitotic, anti-angiogenic agents, antivascular agents, monoclonal antibodies and cancer vaccines, as well as supportive care therapies. Four of these compounds are now being investigated in Phase 3 clinical studies aimed at multiple solid and hematologic tumors.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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(R) (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 and central retinal vein occlusion), 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: sanofi-aventis

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Forward Looking Statements: Regeneron Pharmaceuticals, Inc.

This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are 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 Astellas, the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. 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 (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended June 30, 2010. 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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