



Sanofi-aventis and Regeneron Report Positive Phase III Results With ZALTRAP™ (aflibercept) in Second-line Metastatic Colorectal Cancer

April 26, 2011

PARIS and TARRYTOWN, N.Y., April 26, 2011 /PRNewswire/ -- Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the Phase III VELOUR trial evaluating the investigational agent ZALTRAP™ (aflibercept), also known as VEGF Trap, in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC).

The most frequent adverse events reported with ZALTRAP in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Full results will be presented at an upcoming medical meeting.

"We are pleased with the results of the ZALTRAP Phase III study in this group of patients," said Debasish Roychowdhury, M.D., Senior Vice President and Head, Global Oncology Division, sanofi-aventis. "We are committed to bringing ZALTRAP to patients with advanced colorectal cancer and maximizing the therapeutic potential of this unique and exciting medicine."

"These findings are exciting given the limited second-line treatment options for patients with metastatic colorectal cancer," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Research Laboratories. "Based upon these positive findings, we and sanofi-aventis plan to submit regulatory applications for marketing approval to the U.S. Food and Drug Administration and the European Medicines Agency in the second half of the year."

About the VELOUR Phase III Study

The VELOUR study was a multinational, randomized, double-blind trial comparing FOLFIRI in combination with either ZALTRAP or placebo in the treatment of patients with mCRC after failure of an oxaliplatin-based regimen. The study enrolled 1,226 patients with mCRC who previously had been treated with an oxaliplatin-based regimen. The primary endpoint was an improvement in overall survival. The study had 90 percent power to detect a 20 percent reduction in the hazard rate for overall survival using a two-sided log-rank test. Secondary endpoints included progression-free survival, response to treatment, and safety.

About ZALTRAP™ (aflibercept) and its Clinical Development Program

ZALTRAP, also known as VEGF Trap, is an investigational 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 (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-aventis Oncology and Regeneron are collaborating on a broad oncology development program, combining the investigational agent ZALTRAP with common chemotherapy regimens in the treatment of patients with advanced cancers. In addition to VELOUR, the program includes one Phase III trial and one Phase II trial, both of which are fully enrolled:

- **VENICE:** First-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel and prednisone (Phase III). An interim analysis is expected to be conducted by an Independent Data Monitoring Committee in mid 2011; final results are anticipated in 2012.
- **AFFIRM:** First-line treatment in metastatic colorectal cancer in combination with 5-fluorouracil, leucovorin and oxaliplatin (FOLFOX) (Phase II). Final results are expected during the second half of 2011.

About Colorectal Cancer

Worldwide, colorectal cancer is the third most commonly diagnosed cancer in males and the second most in females, with more than 1.2 million new cases diagnosed in 2008; colorectal cancer is also one of the deadliest cancers and was responsible for more than 600,000 deaths in 2008 alone. In Europe the overall survival rate is 43 percent, whereas in the United States it is 62 percent; these numbers drop considerably when the cancer spreads to distant organs. The risk of colorectal cancer increases with age -- in developed countries, more than 90 percent of cases are diagnosed in individuals older than age 50.

About sanofi-aventis Oncology

Based in Cambridge, Massachusetts, and Vitry, France, sanofi-aventis Oncology is translating science into effective cancer therapeutics to address unmet medical needs for patients with cancer. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, the company employs innovative approaches in drug discovery, clinical development and partnerships to bring the right medicines to the right patients with the goal of helping cancer patients live healthier and longer lives.

Sanofi-aventis Oncology is committed to the pursuit of science and innovative cancer therapies. We believe in partnership with leading experts, and combining that expertise with our own internal scientific strength and heritage. There are currently more than 10 compounds in clinical development including small molecules and biological agents.

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). For more information, please visit www.sanofi-aventis.com.

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 III 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.

Sanofi-aventis Forward-Looking Statements

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, 2010. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Regeneron 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-aventis 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. 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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