



## **Sanofi-aventis and Regeneron Report Top-line Results from Phase III Study with aflibercept (VEGF Trap) in Second-Line Non-Small Cell Lung Cancer**

March 10, 2011

PARIS and TARRYTOWN, N.Y., March 10, 2011 /PRNewswire/ -- Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced results from the Phase III VITAL trial evaluating the investigational agent aflibercept (VEGF Trap) for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding aflibercept to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of aflibercept to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the aflibercept arm compared to 8.9 percent in the placebo arm.

The treatment emergent adverse events (AEs) on the aflibercept arm with an incidence that was 10 percent greater than the control arm were stomatitis, weight decrease, hypertension, epistaxis and dysphonia. Grade 3 or 4 AEs that occurred at a frequency of at least 5 percent in patients who received aflibercept were fatigue, stomatitis, disease progression, hypertension, febrile neutropenia, dyspnea, neutropenia, and asthenia. AEs leading to treatment discontinuation occurred in 27.2 percent of patients in the aflibercept arm compared to 14.6 percent in the placebo arm. The types and frequencies of AEs reported in the aflibercept treatment arm were generally consistent with those reported in previous studies with anti-VEGF agents.

The companies will conduct a detailed analysis of the efficacy and safety results of the VITAL study. Full results will be presented at an upcoming medical meeting.

"Bringing new and innovative cancer therapies to patients can be incredibly challenging, especially in difficult-to-treat cancers such as second-line non-small cell lung cancer," said Debasish Roychowdhury, SVP and Head of Global Oncology Division, sanofi-aventis. "Our Phase III trials of aflibercept in metastatic colorectal cancer and hormone-refractory metastatic prostate cancer are underway to determine the clinical potential of aflibercept for patients with these advanced cancers."

### **About the VITAL Phase III Study**

The VITAL study was a multinational, randomized, double-blind trial comparing aflibercept versus placebo in combination with docetaxel patients with locally advanced or metastatic non-squamous NSCLC who have failed one platinum-based therapy. The study enrolled 913 patients who were randomized to receive intravenous (IV) docetaxel 75 mg/m<sup>2</sup> plus either IV placebo or IV aflibercept 6 mg/kg every three weeks until disease progression, unacceptable toxicity, patient's refusal or further treatment. The primary objective of the study was to demonstrate improvement in overall survival with the combination of aflibercept and docetaxel compared with placebo and docetaxel.

### **About the Aflibercept Clinical Development Program**

Sanofi-aventis Oncology and Regeneron are collaborating on a broad oncology development program, combining the investigational agent aflibercept with common chemotherapy regimens in the treatment of patients with advanced cancers. In addition to VITAL, the program includes two Phase III trials and one Phase II trial, all of which are fully enrolled:

- **VELOUR:** Second-line treatment for metastatic colorectal cancer in combination with 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) (Phase III). Final results are anticipated during the first half of 2011.
- **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 Aflibercept**

Aflibercept (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. Aflibercept has been shown to bind VEGF-A, VEGF-B and PlGF with higher affinity than their natural receptors.

### **About Non-Small Cell Lung Cancer (NSCLC)**

According to the World Health Organization, lung cancer is the leading cause of cancer-related deaths among men and women (1.4 million in 2008) world-wide.(1) Lung cancer is classified as either small cell or non-small cell (most common form).(2) Non-small cell lung cancer typically grows at a slower rate than small cell lung cancer.(3)

#### **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](http://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 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](http://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 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 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, 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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(2) American Cancer Society. Cancer Facts & Figures 2010. Atlanta: American Cancer Society; 2010.

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SOURCE Regeneron Pharmaceuticals, Inc.

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