

April 5, 2012

## **Sanofi and Regeneron Announce Regulatory and Clinical Update for ZALTRAP® (aflibercept)**

- ZALTRAP BLA for Metastatic Colorectal Cancer Granted Priority Review by FDA**
- ZALTRAP Phase III Study in Prostate Cancer Did Not Meet Primary Endpoint**

PARIS and TARRYTOWN, N.Y., April 5, 2012 /PRNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) and Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review of the Biologics License Application (BLA) for the investigational agent ZALTRAP® (aflibercept) concentrate for solution for infusion in combination with the irinotecan-fluoropyrimidine-based chemotherapy in patients with metastatic colorectal cancer (mCRC) previously treated with an oxaliplatin-containing regimen. A Priority Review designation is given to drugs if preliminary estimates indicate that the drug product, if approved, has the potential to provide a treatment where no adequate therapy exists or a significant improvement compared to marketed products. Under Priority Review, the target date for an FDA decision on the ZALTRAP BLA is August 4, 2012. The filing was based on the Phase III VELOUR study in patients with metastatic colorectal cancer previously treated with an oxaliplatin-containing regimen.

"Sanofi and Regeneron are committed to the continued development of ZALTRAP and we are very pleased that the FDA has chosen to grant Priority Review to ZALTRAP in metastatic colorectal cancer," said Debasish Roychowdhury, M.D., Senior Vice President and Head, Sanofi Oncology. "We look forward to working closely with the FDA to potentially bring an important new option to patients with this difficult disease."

Separately, the companies today announced the results from the Phase III VENICE trial evaluating the addition of the investigational agent ZALTRAP to a regimen of docetaxel and prednisone for the first-line treatment of metastatic androgen-independent prostate cancer. The study did not meet the pre-specified criterion of improvement in overall survival (OS). The safety profile was generally consistent with previous studies of ZALTRAP in combination with docetaxel.

The companies are conducting a detailed analysis of the VENICE data, and full results will be presented at an upcoming medical meeting.

### **About the VELOUR Phase III Study**

The VELOUR study was a multinational, randomized, double-blind trial comparing ZALTRAP versus placebo in combination with FOLFIRI in the treatment of patients with mCRC after failure of an oxaliplatin-based regimen. The study enrolled 1,226 patients with mCRC. The primary endpoint was an improvement in overall survival. Secondary endpoints included progression-free survival, response to treatment, and safety.

### **About the VENICE Phase III Study**

The main objective of the multinational VENICE study (VEGF Trap Administered with Docetaxel in metastatic androgen-independent prostate cancer) was to evaluate the efficacy and safety of the investigational agent ZALTRAP® (aflibercept) concentrate for intravenous infusion as a first-line treatment in combination with docetaxel and prednisone. The trial randomized 1,224 patients with metastatic androgen-independent prostate cancer to receive either docetaxel, prednisone and ZALTRAP or docetaxel, prednisone and placebo. The primary endpoint was improvement in overall survival. Secondary endpoints included Prostate Specific Antigen (PSA) measurement, pain measurement, progression-free survival, and safety.

### **About ZALTRAP® (aflibercept) and the Clinical Development Program**

ZALTRAP, also known in the scientific literature as VEGF Trap, is an investigational angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds multiple 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 (aflibercept) has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their native receptors.

Sanofi submitted a regulatory application for marketing approval of ZALTRAP for the treatment of previously-treated patients with metastatic colorectal cancer to the European Medicines Agency (EMA) in the fourth quarter of 2011.

### **About Sanofi Oncology**

Based in Cambridge, Massachusetts, USA and Vitry, France, Sanofi Oncology is dedicated to translating science into effective therapeutics that address unmet medical needs for cancer and organ transplant patients. Starting with a deep understanding of the disease and the patient, Sanofi Oncology employs innovative approaches to drug discovery and clinical development, with the ultimate goal of bringing the right medicines to the right patients. We believe in the value of partnerships that combine our internal scientific expertise with that of industry and academic experts. Our commitment is to help patients live healthier and longer lives through novel science and innovative therapies, with a portfolio that includes 11 marketed products and more than 15 compounds in clinical development, including small molecules and biological agents.

## **About Sanofi**

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi 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, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products in the United States, one for the treatment of neovascular (wet) age-related macular degeneration and another for the treatment of a rare inflammatory condition. Additionally, Regeneron has three regulatory applications pending before the U.S. Food and Drug Administration (FDA) and 10 drug candidates in clinical development. More information and recent news releases are available on the Regeneron web site at [www.regeneron.com](http://www.regeneron.com).

## **Sanofi 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's 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, 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 product candidates, the absence of guarantee that the product 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, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi 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 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, including without limitation ZALTRAP, unforeseen safety issues resulting from the administration of products and product candidates in patients, 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 products and drug candidates, competing drugs that may be superior to Regeneron's products and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, 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, 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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