



Journal of Clinical Oncology Publishes Phase III Results of ZALTRAP[®] (aflibercept) VELOUR Study in Previously Treated Metastatic Colorectal Cancer

Paris, France – October 8, 2012 – Sanofi (EURONEXT: SAN and NYSE: SNY) today announced that detailed results from the pivotal Phase III VELOUR study evaluating ZALTRAP[®] (aflibercept) Injection for Intravenous Infusion for the treatment of patients with previously treated metastatic colorectal cancer were published in the October 2012 edition of the Journal of Clinical Oncology (JCO).

ZALTRAP is a recombinant fusion protein that binds to Vascular Endothelial Growth Factor (VEGF)-A, VEGF-B, and placental growth factor (PlGF). In the VELOUR trial evaluating metastatic colorectal cancer patients previously treated with an oxaliplatin-containing regimen, ZALTRAP in combination with the FOLFIRI chemotherapy regimen (5-fluorouracil, leucovorin, irinotecan) showed a statistically significant improvement in overall survival, progression-free survival, and the overall tumor response rate versus placebo plus FOLFIRI.

“We want to express our appreciation to the authors and the editorial board of the JCO for publishing the results of the VELOUR trial,” said Debasish Roychowdhury, M.D., Senior Vice President and Head of Sanofi Oncology. *“The scrutiny of the FDA review and peer review processes should provide physicians confidence in the results of VELOUR, as they make important decisions for their patients.”*

The VELOUR data supported the regulatory approval of ZALTRAP by the U.S. Food and Drug Administration (FDA) on August 3, 2012 after a Priority Review. In the US, ZALTRAP is approved with the US proper name ziv-aflibercept for use in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI) for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. ZALTRAP is under review at the European Medicines Agency and other regulatory agencies worldwide.

About the VELOUR Phase III Study

The VELOUR trial showed that in patients previously treated with an oxaliplatin-containing regimen, adding ZALTRAP to FOLFIRI significantly improved median survival from 12.06 months to 13.50 months (HR=0.817 (95% CI 0.714 to 0.935; p=0.0032), an 18 percent relative risk reduction. A significant improvement in progression-free survival from 4.67 months to 6.90 months (HR=0.758 95% CI 0.661 to 0.869; p=0.00007), a 24 percent relative risk reduction, was also observed. The overall response rate in the ZALTRAP plus FOLFIRI arm was 19.8% vs. 11.1% for FOLFIRI (p=0.0001).

The most common adverse reactions (all grades, $\geq 20\%$ incidence) reported at a higher incidence (2% or greater between-arm difference) in the ZALTRAP-FOLFIRI arm, in order of decreasing frequency, were leucopenia, diarrhea, neutropenia, proteinuria, AST increased, stomatitis, fatigue, thrombocytopenia, ALT increased, hypertension, weight decreased, decreased appetite, epistaxis, abdominal pain, dysphonia, serum creatinine increased, and headache. The most common Grade 3-4 adverse reactions ($\geq 5\%$) reported at a higher incidence (2% or greater between-arm difference)



in the ZALTRAP-FOLFIRI arm, in order of decreasing frequency, were neutropenia, diarrhea, hypertension, leucopenia, stomatitis, fatigue, proteinuria, and asthenia.

The Phase III VELOUR study was a multinational, randomized, double-blind trial comparing FOLFIRI in combination with either ZALTRAP or placebo in the treatment of patients with metastatic colorectal cancer (mCRC). The study randomized 1,226 patients with mCRC who previously had been treated with an oxaliplatin-containing regimen. The primary endpoint was an improvement in overall survival. Secondary endpoints included progression-free survival, overall response rate, and safety.

About ZALTRAP® (aflibercept)

ZALTRAP is a recombinant fusion protein that acts as a soluble receptor that binds to Vascular Endothelial Growth Factor-A (VEGF-A), VEGF-B and placental growth factor (PlGF). Under the terms of their collaboration agreement, Sanofi and Regeneron share equally the global profits of ZALTRAP after Regeneron's obligation to repay its share of development expenses. In the U.S., ZALTRAP is a registered trademark of Regeneron Pharmaceuticals, Inc.

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. One of the deadliest cancers, colorectal cancer was responsible for more than 600,000 deaths globally in 2008 alone.

According to the American Cancer Society, it is estimated that more than 143,000 new cases of colorectal cancer will be diagnosed in 2012, and more than 51,000 people will die from it in the US. Approximately 60 percent of colorectal cancer cases are diagnosed at the locally advanced or metastatic stage. Although survival for early stage disease is relatively high, once colorectal cancer metastasizes to distant organs, five-year survival is estimated to be 12 percent.

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 to help them live healthier and longer lives. We believe in the value of partnerships that combine our internal scientific expertise with that of industry and academic experts. Our portfolio includes 10 marketed products and more than 15 investigational 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).

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.

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