



Abstract No. LBA9014

Sanofi's Investigational Semuloparin in Cancer Patients initiating Chemotherapy Shows a 64 % Risk Reduction in Life-Threatening Venous Thrombo-Embolism

- Results of Phase III SAVE-ONCO study selected for "Best of ASCO 2011" -

- Venous Thrombo-embolism Affects Up to 1 in 5 Cancer Patients and Chemotherapy Further Increases this Risk -

Paris, France - June 4, 2011 - Sanofi (EURONEXT: SAN and NYSE: SNY) announced today results of the pivotal SAVE-ONCO study which demonstrated that, in cancer patients initiating a chemotherapy regimen, investigational semuloparin significantly reduced the risk of the composite of symptomatic-deep vein thromboembolism (DVT), non-fatal pulmonary embolism (PE) or venous thromboembolism (VTE)-related death by 64%ⁱ, meeting the study primary endpoint (respectively 1.2% and 3.4% for semuloparin and placebo HR 0.36 95% CI (0.21-0.60)), $p < 0.0001$). Semuloparin reduced the risk of this type of blood clots without increasing the incidence of major bleeding over placebo (1.2% vs. 1.1%)ⁱ. The SAVE-ONCO study results were presented today in an oral presentation at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, and are selected for *the Best of ASCO**.

In VTE, blood clots usually form in deep veins (commonly referred as thrombo-phlebitis) and can migrate and potentially block blood flow in the blood vessels of the lungs (pulmonary embolism), which may result in sudden deathⁱⁱ. Often clinically silent, VTE is a life-threatening complication of cancer affecting up to one in five patients^{iii,iv}, and initiating chemotherapy further increases the risk by more than 60%^{v,vi}.

"For cancer patients initiating chemotherapy, there is currently no approved treatment for the primary prevention of venous thrombo-embolism risk," said Giancarlo Agnelli, Professor of Medicine at the University of Perugia, Italy and SAVE-ONCO principal study investigator. *"Therefore, we are encouraged by the 64% risk reduction of Life-Threatening Venous Blood Clots demonstrated in this randomized trial".*

"In many patients affected by cancer, preventing venous thromboembolism is an important clinical management issue", said Dr. Elias Zerhouni, President, Global Research & Development, Sanofi. *"We are pleased with the results achieved in this study of our selectively engineered semuloparin as shown by the SAVE-ONCO trial. Based on these results of SAVE-ONCO we plan to submit semuloparin for regulatory filing in Q3 2011".*

SAVE-ONCO, the international randomized phase 3 study enrolled 3,212 patients initiating a chemotherapy regimen for locally advanced or metastatic solid tumor (lung, colon-rectum, stomach, ovary, pancreas or bladder cancer). Patients received either a daily 20 mg subcutaneous administration of semuloparin or placebo for at least three months or until change in the chemotherapy regimen. The primary endpoint of the study was the composite of any symptomatic-DVT, non-fatal PE and VTE-related deathⁱ. Clinically relevant bleeding (bleedings requiring medical attention) was respectively 2.8% and 2.0% for semuloparin and placeboⁱ. Consistent with previous findings, there was no case of reported HIT (heparin induced thrombocytopenia) in the 3,212 studied patients. SAVE-ONCO study median treatment duration with semuloparin was approximately 3.5 monthsⁱ.



* The 2011 Best of ASCO Meetings feature the most relevant and cutting-edge science in oncology research.

About Semuloparin

Semuloparin is an investigational selectively engineered Ultra-LMWH (low molecular weight heparin) with enriched anti-thrombin binding sites, leading to anticoagulant activity mainly directed towards coagulation Factor Xa, with a minimal effect on Factor IIa. Selectively engineered semuloparin, in addition to a specific anti-Factor Xa/IIa ratio, retains biological activities that are relevant in cancer biology such as effects on TFPI (tissue factor pathway inhibitor)^{vii}. A large Phase III clinical study (SAVE-ONCO) investigating semuloparin benefit in cancer patients with locally advanced or metastatic solid tumor initiating chemotherapy has been completed. The SAVE-ONCO study assessed the efficacy and safety of semuloparin for the prevention of symptomatic- DVT, non-fatal Pulmonary Embolism and VTE-related death in cancer patients initiating a chemotherapy regimen.

About Sanofi Oncology

Based in Cambridge, Massachusetts, and Vitry, France, Sanofi Oncology is dedicated to 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 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 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, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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 labeling 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, 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, 2010. 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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ⁱ Agnelli G et al. ASCO June 3-7, 2011 Chicago. Oral Abstract #LBA9014.

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^{iv} Khorana AA et al. Thromboembolism is a leading cause of death in cancer patients receiving outpatient chemotherapy. *J Thromb Haemost* 2007;5:632-4.

^v Heit JA. Cancer and Venous Thromboembolism: Scope of the Problem. *Cancer Control*. September 2005; 12: 5-10.

^{vi} Heit JA et al. Risk Factors for Deep Vein Thrombosis and Pulmonary Embolism. *Arch Intern Med* 2000 ;160:809-15.

^{vii} Gómez-Outes A et al. New parenteral anticoagulants in development. *Ther Adv Cardiovasc Dis* 2011 5: 33-59.