Sanofi Reports Positive Topline Results from Pivotal Phase III JAKARTA Study for JAK2 Inhibitor in Myelofibrosis

Paris, France – May 17, 2013– Sanofi (EURONEXT: SAN and NYSE: SNY) announced today that the pivotal study, JAKARTA, examining the selective JAK2 inhibitor SAR302503 for myelofibrosis (MF), met its primary endpoint in both dose groups. The primary endpoint assessed the proportion of patients achieving ≥35% reduction of spleen volume. Consistent with data reported in previous trials, the most common adverse events were anemia, diarrhea, nausea and vomiting. Full results will be presented at an upcoming medical congress.

MF is a rare, debilitating and life-threatening hematologic malignancy characterized by abnormal blood cell production and scarring, or fibrosis, in the bone marrow.

"Patients with myelofibrosis in advanced stages are desperately ill and in need of treatments that will improve their outcomes. I am pleased with the results of JAKARTA and would like to thank the patients and the investigators in this trial," said Debasish Roychowdhury, M.D., Senior Vice President and Head, Sanofi Oncology. "*Since Sanofi's acquisition of the molecule, SAR302503 has moved from Phase I to the completion of pivotal Phase III studies in less than three years, and now we are planning regulatory filings with authorities to make this medicine available for patients.*"

SAR302503 is a novel, investigational, selective JAK2 inhibitor. Sanofi Oncology is developing SAR302503 for the treatment of the three main types of myeloproliferative neoplasms: primary myelofibrosis, including those previously treated with ruxolitinib; polycythemia vera; and essential thrombocythemia.

About JAKARTA

Conducted in 24 countries, the randomized, double-blind, placebo-controlled Phase III JAKARTA study evaluated once-daily oral SAR302503 versus placebo in 289 patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. Eligible patients with platelet counts ≥50,000/µl were randomized to receive a once-daily oral dose of either 400mg of SAR302503, 500 mg of SAR302503 or placebo for twenty-four weeks (six cycles).

The primary endpoint was the proportion of patients with a reduction in spleen volume ≥35% after 24 weeks of treatment. Key secondary endpoints include the assessment of associated symptoms as measured by total symptom score using six key symptoms as measured by the modified Myelofibrosis Symptom Assessment Form (MF-SAF) diary. Sanofi is also studying the effect of the compound on reversing fibrosis in the bone marrow. After the completion of 24 weeks of treatment or disease progression, crossover from the placebo arm to SAR302503 was allowed.

The JAKARTA study was granted a Special Protocol Assessment (SPA) by the U.S. Food and Drug Administration, signifying that the Phase III trial design, including clinical endpoints, is acceptable to support an application for the granting of marketing authorization in the U.S. More information about the trial is available at www.clinicaltrials.gov.

About JAK2 Inhibition and SAR302503

The normal functioning of the JAK/STAT pathway is key to blood cell development. Dysregulated JAK/STAT signaling is associated with the development of MF and other related myeloproliferative neoplasms (MPN), such as Polycythemia Vera (PV) and Essential Thrombocythemia (ET). Dysregulation of the JAK/STAT pathway in these diseases occurs with mutations of the JAK2 and MPL genes (notably JAK2V617F and MPLW515L). In addition, up to 50% of patients with MF are considered wild-type, meaning there is no detectable JAK2 or MPL mutations, yet do demonstrate dysregulated JAK2 signaling.

SAR302503 is a novel, investigational, JAK2 kinase inhibitor that selectively inhibits the JAK2 kinase, and in preclinical studies it has demonstrated activity against MF cells containing either JAK2V617F or MPLW515L mutation. As demonstrated in earlier Phase I and II studies, SAR302503 demonstrated activity in MF patients with both wild-type and mutated JAK2 (JAK2V617F). Results from a Phase II study in patients with intermediate-2 or high-risk MF were presented last year and final results are anticipated in Q2 2013. Another Phase II study in ruxolitinib-exposed patients who are either resistant or intolerant to ruxolitinib is ongoing.

About Myelofibrosis

Myelofibrosis (MF) is a rare, but serious blood disease characterized by abnormal blood cell production and fibrosis (scarring) within the bone marrow. Scarring in the bone marrow interferes with blood cell production, and the spleen and liver compensate by producing and storing extra blood cells, which cause an enlarged spleen. Of the mutated JAK2 associated myeloproliferative neoplasms, MF carries the poorest prognosis. Median survival for intermediate-2 and high-risk patients is approximately two and a half years; median survival for MF patients overall is approximately six years, and the 10 year risk of the disease transforming to fatal acute myelogenous leukemia (AML) is about 20%.

The exact prevalence of MF is not known. The latest research estimates that the prevalence of MF ranges from 4.2 to 5.6 per 100,000 people in the U.S., or approximately 15,000 patients. Prevalence estimates in Europe are less clear. People over age sixty are most likely to develop this disease, with men and women equally at risk.

About Sanofi Oncology

Sanofi Oncology is a global division of Sanofi based in Cambridge, Massachusetts and Vitry, France. At Sanofi Oncology, the patient is our inspiration. We are dedicated to translating science into effective therapeutics that address unmet medical needs for cancer and organ transplant patients. Through our global organization of talented and passionate employees, we are building a renewed and diversified portfolio, driven by the principles of innovation, personalization and patient access to medicines. We believe that delivering innovative treatment solutions requires collaboration with external experts, which is why we partner our own internal expertise with the best experts in scientific discovery and clinical research around the world.

About Sanofi

Sanofi, an integrated global 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).

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, 2012. 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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