Sanofi Discontinues Clinical Development of Investigational JAK2 Agent Fedratinib (SAR302503)

Paris, France – November 18, 2013 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today the decision to halt all clinical trials and cancel plans for regulatory filings with its investigational JAK2 inhibitor, fedratinib (SAR302503).

Following a thorough risk-benefit analysis, including consultation with the U.S. Food and Drug Administration (FDA), study investigators, independent expert neurologists and neuro-radiologists, Sanofi determined that the risk to patient safety outweighed the benefit that fedratinib would bring to patients.
This decision follows recent reports of cases consistent with Wernicke's encephalopathy in patients participating in fedratinib clinical trials. The FDA directed Sanofi to put all fedratinib trials on clinical hold while the company thoroughly investigated these cases to ensure the safety of fedratinib for patients. Sanofi took immediate action requesting that study investigators discontinue fedratinib treatment for patients in the trials.
"*We are deeply disappointed to have to discontinue development of fedratinib, especially given the needs of this difficult-to-treat patient population and the earlier promise shown for this therapy, but patient safety is our top priority and drove this decision*," said Tal Zaks, MD, PhD, VP, Head of Development and Interim Head of Sanofi Oncology.

Sanofi has notified investigators of all ongoing fedratinib trials, as well as health authorities, of its decision to halt the trials. Patients currently in fedratinib trials should consult with their treating physician to determine the best alternative course of therapy for their myelofibrosis.

About fedratinib (SAR302503)

Fedratinib is a novel, investigational JAK2 inhibitor that was under development by Sanofi Oncology 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 Sanofi Oncology

Sanofi Oncology, a global division of Sanofi, is dedicated to the discovery, development and delivery of effective therapeutics that address unmet medical need for cancer patients. We are building a renewed and diversified oncology portfolio, driven by the principles of innovation, personalization and patient access to medicines. Through partnerships and collaborations with leading experts in the areas of research, clinical practice, patient experience and patient access, Sanofi Oncology aims to deliver innovative treatment solutions that provide meaningful benefit to patients around the world. We are currently marketing 10 products to address select solid tumors, hematological conditions and organ transplantation.

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).

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, 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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