Phase II Trial of Sanofi JAK2 Inhibitor in Myelofibrosis Met Primary Endpoint

- New Data Presented at American Society of Hematology Annual Meeting Show Activity Against Disease and Symptom Alleviation -

Paris, France – December 9, 2012 – Sanofi (EURONEXT: SAN and NYSE: SNY) announced today new Phase II data showing that treatment with a novel, investigational, selective JAK2 inhibitor (SAR302503) reduced spleen size and improved constitutional symptoms in patients with intermediate-2 or high-risk primary or secondary myelofibrosis (MF), a hematologic malignancy with unmet medical needs.[1] The data were presented today during the 2012 Annual Meeting of the American Society of Hematology in Atlanta, Ga., December 8-11, 2012.

"*The results observed in our trial with SAR302503 are encouraging,"* said Moshe Talpaz, M.D., Professor, Department of Internal Medicine, University of Michigan and lead investigator of the study. "*New treatment options are needed to fulfill existing treatment gaps for patients with these debilitating blood disorders, and specifically targeting the JAK2 enzyme appears to offer a promising approach."*

Results from this Phase II trial support the two doses (400 mg and 500 mg) selected for the SAR302503 Phase III JAKARTA trial that is currently under way. JAKARTA enrolled 289 patients over nine months and initial results are expected in the second quarter of 2013.

"I am very pleased with how much progress has been made in the development of our JAK2 inhibitor. This study confirms the once-daily oral administration of SAR302503 identified for use in the Phase III trial in this difficult-to-treat patient population," said Debasish Roychowdhury, M.D., Senior Vice President and Head, Sanofi Oncology. *"We believe SAR302503 could provide a benefit to these patients with primary and secondary myelofibrosis and we look forward to our Phase III results next year."*

The Phase II, open label, randomized dose-ranging study evaluates the efficacy of once-daily oral doses of 300 mg, 400 mg, and 500 mg of SAR302503 for the reduction of spleen volume. The primary endpoint is change in spleen volume at the end of cycle three assessed by MRI with independent central review. Secondary endpoints include spleen response (reduction in spleen volume greater than or equal to 35 percent vs. baseline), safety and symptom response using the MPN-SAF scale.

According to the study results, treatment was associated with reductions in spleen size and other disease symptoms in 31 randomized patients.[1]

- Mean percentage reductions in spleen volume vs. baseline were 30% (n=10), 33% (n=10) and 42% (n=11), in each group, respectively
- The proportion of patients who achieved a ≥35% reduction in spleen volume by MRI was 30%, 50% and 63.6% in each group, respectively.
- The proportion of patients who achieved ≥50% reduction in the Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) score, a sum of six key constitutional symptoms (night sweats, itching, abdominal discomfort, abdominal pain, bone pain, early satiety), was similar in all dose groups (44%, 50% and 44%).

Consistent with data reported in previous trials, the most common serious (grade 3-4) hematologic adverse event was anemia with rates across the 300, 400, and 500 mg doses of 33%, 30% and 55%, respectively. Rates of grade 3-4 thrombocytopenia were 20%, 0% and 9%, respectively. The most common grade 3-4 non-hematological events were diarrhea (10%, 20%, 0%), nausea (10%, 10%, 0%) and vomiting (10%, 10%, 0%). Two patients in the 300 mg group discontinued treatment due to an adverse event (grade 3 anemia, grade 4 transaminase elevation).[1]

About Myelofibrosis

Myelofibrosis (MF) is a rare, debilitating and life-threatening progressive malignant hematologic disease characterized by abnormal blood cell production and fibrosis (scarring) within the bone marrow. Scarring in the bone marrow interferes with blood cell production; the spleen and liver try to produce and store extra blood cells, which can cause these organs to become enlarged.

Most patients with MF have greatly enlarged spleens (splenomegaly) that can result in a range of vague symptoms with dramatic impact on quality of life. These include fatigue, abdominal pain, night sweats, feeling full without eating, cough or shortness of breath and decreased physical activity. Other signs and symptoms of MF include anemia, thrombocytopenia, weight loss and severe itching.

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 JAK2 and SAR302503

JAK2 is a key enzyme for blood cell development. Mutations in JAK2 can lead to dysregulated JAK2 signaling and are thought to be a cause of MF. Patients with wild type JAK2 have also been shown to have persistent, dysregulated activation of the JAK2 signaling pathway.[2]

SAR302503 is a novel, investigational, selective inhibitor of the JAK/STAT signaling pathway that preferentially inhibits JAK2. Sanofi Oncology is developing the compound for the treatment of the three main types of myeloproliferative neoplasms: primary myelofibrosis, polycythemia vera and essential thrombocythemia. Sanofi is also studying the effect of the compound on reducing/reversing scarring in the bone marrow.

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 11 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).

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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References

1. Talpaz, et al. A Phase II randomized dose-ranging study of the JAK2-selective inhibitor SAR302503 in patients with intermediate-2 or high-risk primary myelofibrosis (MF), post-polycythemia vera (PV) MF, or post-essential thrombocythemia (ET) MF. Abstract #2837 ASH 2012
2. Abdel-Wahab, O, et al. Primary Myelofibrosis: Update on Definition, Pathogenesis, and Treatment. *Annu. Rev. Med*. 2009. 60:233–45.