Sanofi Provides Update on Phase 3 Studies of Two Investigational Compounds

Paris, France - June 3, 2013 - Sanofi (EURONEXT: SAN and NYSE: SNY) today announced topline results of two Phase 3 clinical studies of its investigational compounds iniparib and otamixaban respectively.

Iniparib
The randomized Phase 3 ECLIPSE trial of iniparib in squamous non-small cell lung cancer (Sq NSCLC) did not meet its primary endpoint. In the study, newly diagnosed, metastatic Sq NSCLC patients treated with iniparib plus chemotherapy did not achieve improvement in overall survival compared to patients who received chemotherapy alone. There were no clinically meaningful differences in the main safety parameters between the two arms.

The topline results of a Phase 2 study of iniparib in platinum-resistant ovarian cancer do not support further development of iniparib in this patient population. Following these findings, Sanofi has decided to terminate the internal development program with iniparib. As a consequence, the intangible assets related to iniparib will be fully impaired on the June 30, 2013 consolidated balance sheet. The related charge will have an estimated net impact of US $285 million after tax on consolidated net income (or approximately € 219 million). This non-cash charge will have no impact on Business Net Income.

Otamixaban
Topline results of the completed Phase 3 study of the investigational anticoagulant otamixaban showed the study did not meet its primary endpoint of superiority over current therapy. In the TAO study (Treatment of non-ST elevation Acute coronary syndrome with otamixaban), due to efficacy lower than expected, otamixaban did not show superior benefit/risk to the combination of unfractionated heparin (UFH) +/- eptifibatide (a GP IIb/IIIa inhibitor) in non-ST elevation acute coronary syndrome (NSTE-ACS) patients planned for early invasive strategy. The primary endpoint of the Phase 3 TAO study was the reduction of all-cause mortality or new heart attacks.

Following the results of the TAO study the company has decided to discontinue the investigational program with otamixaban, an injectable factor Xa inhibitor.

The results of both of these studies will be presented at upcoming scientific meetings and submitted for publication in peer-reviewed journals.

About the Phase 3 ECLIPSE trial of Iniparib
In this NSCLC study, previously untreated patients received iniparib in combination with gemcitabine/carboplatin versus gemcitabine/carboplatin alone. The study enrolled 780 patients with metastatic (stage IV) Sq NSCLC at more than 140 sites in 16 countries. Patients were randomized to receive a standard chemotherapy regimen of carboplatin AUC 5 on Day 1 and gemcitabine 1000 mg/m² on Day 1 and 8 of each 21-day cycle, with or without iniparib 5.6 mg/kg on Day 1, 4, 8 and 11. Patients in the study received this treatment as first-line chemotherapy in the metastatic setting. The primary endpoint of the trial was overall survival. Secondary endpoints were progression-free survival and response rate.
Iniparib (BSI-201; SAR240550) is a benzamide (4-iodo-3-nitrobenzamide) that is structurally related to nicotinamide. Iniparib was initially designed as a poly (ADP-ribose) polymerase (PARP) 1 inhibitor based on the benzamide structure. Recent research has demonstrated that iniparib cannot inhibit PARP1 at pharmacologic concentrations.

About the Phase 3 TAO study of Otamixaban
This multicenter, phase 3, randomized, double-blind active-controlled trial evaluated otamixaban compared to unfractionated heparin (UFH) plus epftifibatide (a GP IIb/IIIa platelet inhibitor) in patients with NSTE-ACS who were treated with dual oral antiplatelet therapy and an invasive strategy. Over 13,000 moderate- to-high-risk patients in 55 countries were randomized to receive UFH plus downstream epftifibatide (started before PCI and continued as per label) or otamixaban (0.08 mg/kg intravenous bolus at randomization then 0.100 or 0.140 mg/kg per hour intravenous infusion).

Otamixaban is an investigational, rapid-onset/offset, direct selective injectable inhibitor of the blood clotting factor Xa, a key component of the body’s blood clotting cascade that was in Phase 3 clinical development with the just completed TAO study in NSTE-ACS. Otamixaban was the first intravenous factor Xa anticoagulant tested against UFH +/- GP IIb/IIIa inhibitor on the occurrence of death or new heart attack.

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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