Updated Phase 3 Survival Results with Cabazitaxel in Patients with Advanced Hormone-Refractory Prostate Cancer, Presented at ASCO

- Results Demonstrated 28% Improvement in Overall Survival -

Paris, France - May 27, 2010 - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today the updated results from the Phase 3 trial, TROPIC, that demonstrated the investigational drug cabazitaxel plus prednisone/prednisolone, significantly improved overall survival, versus an active chemotherapy combination of mitoxantrone plus prednisone/prednisolone, in patients with metastatic hormone-refractory (castration-resistant) prostate cancer whose disease progressed following treatment with docetaxel-based chemotherapy.

"It is impressive to see the updated results continue to demonstrate an improvement in overall survival compared with that achieved with a standard chemotherapy regimen," said Marc Cluzel, M.D., Ph.D, Executive Vice-President, Research & Development, sanofi-aventis. *"These are encouraging results in a difficult-to-treat stage of prostate cancer."*

Updated results of the primary end point (overall survival) – to be presented at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6 – will show that the combination of cabazitaxel and prednisone/prednisolone significantly reduced the risk of death by 28% [HR=0.72 (95% CI: 0.61-0.84); P<0.0001] with an improvement in the median overall survival of 15.1 months vs. 12.7 months in the mitoxantrone combination arm.

The most frequent grade 3/4 hematological adverse events with cabazitaxel were neutropenia (81.7%) assessed by laboratory values, leukopenia (68.2%), anemia (10.5%), and febrile neutropenia (7.5%); the most frequent grade 3/4 non-hematological adverse events were diarrhea (6.2%), fatigue (4.9%), and asthenia (4.6%). Discontinuation of treatment due to adverse events occurred in 18.3% of patients in the cabazitaxel arm and 8.4% of patients in the mitoxantrone arm. Most frequent treatment-emergent adverse events leading to discontinuation in the cabazitaxel arm were neutropenia (2.4%), hematuria (1.3%), diarrhea (1.1%) and fatigue (1.1%). Grade 3/4 peripheral neuropathy occurred in 0.5% of patients in the cabazitaxel arm vs. 0.3% in the mitoxantrone arm. Deaths due to adverse events were 4.9% in the cabazitaxel arm (predominantly due to neutropenia and its complications) vs. 1.9% in the mitoxantrone arm.
"Providing solutions that have a major impact on patients with cancer, such as metastatic castration-resistant prostate cancer, is the driving force behind everything we do," said Debasish Roychowdhury, M.D., Senior Vice President, Global Oncology, sanofi-aventis. *"The development of cabazitaxel is one of many investigational compounds we hope to present to the cancer community in the months and years to come."*

The TROPIC study results were chosen by the ASCO Committee to be presented on July 16-17 and July 23-24 at the Best of ASCO sessions in San Francisco, CA and Boston, MA; these meetings are held to provide wider access to cutting-edge science presented at the annual meeting.

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About the TROPIC Trial

TROPIC was conducted in 146 trial sites in 26 countries throughout the world, including the U.S. The multi-center Phase 3 randomized registrational trial assessed 755 metastatic castration-resistant prostate cancer patients whose disease had progressed following treatment with docetaxel-based chemotherapy.

The primary endpoint was overall survival. Secondary endpoints included progression-free survival, tumor response rate, tumor progression, prostate-specific antigen (PSA) response, PSA progression, pain response, and pain progression. Disease progression in this trial was defined as tumor progression, PSA progression or pain progression. Other secondary endpoints were overall safety of cabazitaxel in combination with prednisone, the pharmacokinetics of cabazitaxel and its metabolite in this patient population, and the effect of prednisone on the pharmacokinetics of cabazitaxel. Patients were randomly assigned to receive cabazitaxel plus prednisone/prednisolone or mitoxantrone plus prednisone/prednisolone (378 and 377 patients, respectively). Patients were to receive either regimen for up to a maximum of 10 cycles.

About Cabazitaxel

Cabazitaxel is an investigational compound that has been shown to be active in cell lines refractory to chemotherapies. In preclinical studies, cabazitaxel has been shown to inhibit cell division and tumor cell proliferation by binding to and stabilizing tubulin, a protein in the microtubules of cells which provides a skeleton for maintaining cell shape.
Cabazitaxel recently received priority review from the U.S. Food and Drug Administration (FDA); review is anticipated by Q3 2010. Filing for approval in the EU has been completed.

About Prostate Cancer

Worldwide, prostate cancer ranks third in cancer incidence and sixth in cancer mortality in men. In the U.S., prostate cancer remains the second most common cause of cancer death among men after lung cancer. In 2009, an estimated 192,000 new cases were anticipated in the U.S., while 27,000 men were expected to have died from the disease.

Metastatic prostate cancer indicates that the cancer has spread, or metastasized, to the lymph nodes or other parts of the body, mostly to the bones. Castration resistant/hormone-refractory prostate cancer means that the cancer has continued to grow despite the suppression of male hormones that fuel the growth of prostate cancer cells. More than 80% of all prostate cancer cases are discovered when the disease is limited to the prostate and surrounding organs, while 10-20% of patients are diagnosed when the cancer has already metastasized. For many patients with this stage of prostate cancer, their disease continues to advance despite prior chemotherapy. Currently, there are few treatment options for these patients.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit: www.sanofi-aventis.com

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-aventis' 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-aventis, 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 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-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

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