Jevtana® Improves Survival in Advanced Prostate Cancer Patients

– The Lancet *publishes landmark Phase III data from global study* –

Paris, France – October 1, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that data from the Phase III TROPIC study, which was the basis for the June 2010 U.S. Food and Drug Administration (FDA) approval of Jevtana® (cabazitaxel) Injection, was published in the October 2 issue of *The Lancet* in an article titled "Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial." The data demonstrated that Jevtana® in combination with prednisone reduced the risk of death by 30% in men with metastatic castration-resistant prostate cancer (also known as metastatic hormone refractory prostate cancer, or mHRPC) whose disease progressed following treatment with docetaxel-based chemotherapy.

"We are proud to have been involved in the development of this drug, which will offer new hope to men with advanced prostate cancer who have exhausted other treatment options," said Johann de Bono, M.D., study investigator, The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, London, United Kingdom. *"This is one of only a small handful of drugs shown to prolong the life of men with advanced prostate cancer."*

For patients with metastatic prostate cancer, hormone therapy is frequently the first treatment offered. Patients who no longer respond to hormone therapy often receive chemotherapy – a staple of treatment for more than 10 years. However, some patients receiving chemotherapy over time develop resistance, and their disease continues to progress. Before Jevtana®, no available second-line treatment options were proven to provide an overall survival benefit in mHRPC patients. The combination of Jevtana® and prednisone is the first and only therapy to have shown a significant survival benefit for patients with mHRPC previously treated with a docetaxel-containing regimen in this setting.

"*Sanofi-aventis Oncology is tackling cancer on all fronts to provide new solutions that make a difference in patients' lives,"* said Debasish Roychowdhury, M.D., Senior Vice President, Head of Global Oncology, sanofi-aventis. *"The publication of this pivotal trial in* The Lancet *underscores the importance of the study, which is the first to demonstrate an overall survival advantage in patients with hormone refractory prostate cancer whose disease has progressed following treatment with a docetaxel-containing treatment regimen."*

Results of the TROPIC study showed that the combination of Jevtana® and prednisone significantly reduced the risk of death by 30% [HR=0.70 (95% CI: 0.59-0.83); P<0.0001], with a clinically meaningful improvement in median overall survival of 15.1 months versus 12.7 months in the mitoxantrone combination arm. Patients who received Jevtana® and prednisone also experienced a significant increase in median progression-free survival (2.8 months versus 1.4 months in patients treated with mitoxantrone and prednisone) [HR=0.74 (95% CI: 0.64-0.86); P<0.0001]. In addition, patients in the Jevtana® combination arm showed a significantly higher rate of tumor response (14.4 [95% CI: 9.6-19.3; P<0.001])

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compared with those in the mitoxantrone combination arm (4.4 [95% CI: 1.6-7.2; P<0.001]), as well as a significant improvement in median time to tumor progression (8.8 months versus 5.4 months; [HR=0.61 (95% CI: 0.49-0.76); P<0.001]).

In the TROPIC Study, the most frequent hematological grade 3 or higher adverse events were neutropenia, leukopenia, and anemia. The most common non-hematological grade 3 or higher adverse event was diarrhea, which was managed expectantly. Grade 3 peripheral neuropathy was uncommon (reported in three [1%] patients in each group). The most common adverse reactions leading to treatment discontinuation in the Jevtana® group were neutropenia and renal failure. Treatment discontinuations due to adverse drug reactions occurred in 18% of patients who received Jevtana® and 8% of patients who received mitoxantrone. Deaths due to causes other than disease progression within 30 days of last study drug dose were reported in 18 (5%) Jevtana®-treated patients and 3 (less than 1%) mitoxantrone-treated patients. The most common fatal adverse reactions in Jevtana® patients were neutropenia and clinical consequences/sepsis (n=7) and cardiac function (n=5). One death was due to diarrhea-induced dehydration and electrolyte imbalance.

About the TROPIC Trial

TROPIC was conducted in 146 trial sites in 26 countries, including the U.S. This multicenter, Phase III, randomized registrational trial assessed 755 mCRPC patients whose disease had progressed following treatment with docetaxel-based chemotherapy.

Patients were randomly assigned to receive cabazitaxel plus prednisone/prednisolone or mitoxantrone plus prednisone/prednisolone (378 and 377 patients, respectively), for up to a maximum of 10 cycles. 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 was defined as tumor progression, PSA progression or pain progression. Other secondary endpoints were overall safety of cabazitaxel in combination with prednisone, pharmacokinetics of cabazitaxel and its metabolite in this patient population, and the effect of prednisone on the pharmacokinetics of cabazitaxel.

The TROPIC study data were first presented at the 2010 Genitourinary Cancers Symposium sponsored by the American Society for Clinical Oncology (ASCO).

About Jevtana® (cabazitaxel) Injection

Jevtana®, a microtubule inhibitor, is approved in combination with prednisone for the treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-based treatment regimen. Jevtana® is to be administered intravenously. Jevtana® was granted fast track designation by the FDA in November 2009. The rolling new drug application (NDA) submission was completed in March 2010 and was granted priority review in April 2010; Jevtana® was approved by the FDA less than three months later. A registration dossier of Jevtana® is also under regulatory review by other regulatory authorities, including the European Medicines Agency.

Important Safety Information for Jevtana®

WARNING

- **Neutropenic deaths have been reported. In order to monitor the occurrence of neutropenia, frequent blood cell counts should be performed on all patients receiving JEVTANA®. JEVTANA® should not be given to patients with neutrophil counts of ⩽ 1,500 cells/mm3.**
- **Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the JEVTANA® infusion and administration of appropriate therapy. Patients should receive premedication.**
- **JEVTANA® must not be given to patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80.**

CONTRAINDICATIONS

- **JEVTANA® should not be used in patients with neutrophil counts of ≤ 1,500/mm3.**
- **JEVTANA® is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.**

WARNINGS AND PRECAUTIONS

- Neutropenic deaths have been reported
  - Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed
  - Primary prophylaxis with G-CSF should be considered in patients with high-risk clinical features
- Severe hypersensitivity reactions can occur
  - Premedicate with corticosteroids and H2 antagonists
  - Discontinue infusion immediately if hypersensitivity is observed and treat as indicated
- Mortality related to diarrhea has been reported
  - Rehydrate and treat with anti-emetics and anti-diarrheals as needed
  - If experiencing grade ≥3 diarrhea, dosage should be modified
- Renal failure, including cases with fatal outcomes, has been reported. Identify cause and manage aggressively.
- Patients ≥65 years of age were more likely to experience fatal outcomes not related to disease progression and certain adverse reactions, including neutropenia and febrile neutropenia. Monitor closely.
- Patients with impaired hepatic function were excluded from the randomized clinical trial
  - Hepatic impairment is likely to increase the JEVTANA® concentrations
  - JEVTANA® should not be given to patients with hepatic impairment
- JEVTANA® can cause fetal harm when administered to a pregnant woman
  - There are no adequate and well-controlled studies in pregnant women using JEVTANA®

ADVERSE REACTIONS

- Deaths due to causes other than disease progression within 30 days of last study drug dose were reported in 18 (5%) JEVTANA®-treated patients. The most common fatal adverse reactions in JEVTANA®-treated patients were infections (n=5) and renal failure (n=4)
- The most common (≥10%) grade 1–4 adverse reactions were anemia, leukopenia, neutropenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia
- The most common (≥5%) grade 3–4 adverse reactions in patients who received JEVTANA® were neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia

Please see full prescribing information for Jevtana®, including boxed **WARNING**, at http://products.sanofiaventis.us/jevtana/jevtana.pdf.

The Incidence of 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. For many patients with prostate cancer, their disease continues to progress despite prior treatment – including surgical and/or hormonal castration followed by chemotherapy. Metastatic prostate cancer indicates that the cancer has spread to the lymph nodes or other parts of the body, particularly 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. An estimated 10-20% of patients with prostate cancer are diagnosed when the cancer has already metastasized.

About sanofi-aventis Oncology

Formed in March 2010, sanofi-aventis Oncology is targeting cancer on all fronts in an effort to address unmet medical needs for a broad range of patients. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads as well as identifying the right science early in the discovery process, the company employs innovative approaches to bring the right medicines to the right

patients. There are currently more than 10 compounds in development across a broad scientific platform, including cytotoxic, antimitotic, anti-angiogenic agents, antivascular agents, monoclonal antibodies and cancer vaccines, as well as supportive care therapies. Four of these compounds are now being investigated in Phase III clinical studies aimed at multiple solid and hematologic tumors.

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).

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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