Jevtana® (cabazitaxel) Injection Approved by U.S. FDA After Priority Review

- First and only therapy to provide significant survival benefit in second-line metastatic hormone-refractory prostate cancer -

Paris, France – June 17, 2010 – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the U.S. Food and Drug Administration (FDA) has granted marketing authorization for Jevtana® (cabazitaxel) Injection in combination with prednisone for the treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-containing treatment regimen.

Jevtana, a microtubule inhibitor, in combination with prednisone was approved based on results from the Phase 3 TROPIC clinical study involving 755 patients with mHRPC previously treated with a docetaxel-containing treatment regimen. Results from this trial demonstrated a statistically significant 30% \( \text{HR}=0.70 \) (95% CI: 0.59-0.83); \( P<0.0001 \) reduction in risk of death from mHRPC among patients taking Jevtana in combination with prednisone compared with an active chemotherapy regimen consisting of a standard dose of mitoxantrone and prednisone. Investigator-assessed tumor response rates using Response Evaluation Criteria in Solid Tumors (RECIST) were 14.4% and 4.4% for cabazitaxel-treated and mitoxantrone-treated patients respectively, \( p=0.0005 \). No complete responses were observed on either arm.

“This is truly a significant announcement for the prostate cancer community, addressing an unmet medical need. With the approval of Jevtana, health care professionals now have a new treatment option for patients with the most advanced stage of prostate cancer and for whom there have been few options,” said Oliver Sartor, M.D., TROPIC North American principal investigator, Piltz Professor for Cancer Research at Tulane Medical School, New Orleans. “Jevtana in combination with prednisone is the only FDA approved regimen to significantly improve overall survival in patients previously treated with docetaxel-based chemotherapy regimen.”

“This is a proud time for sanofi-aventis Oncology. Phase III study results with Jevtana were significant for a prostate cancer compound since it successfully demonstrated a survival benefit compared to active control in a second-line treatment setting,” said Debasish Roychowdhury, M.D., Senior Vice President, Global Oncology, sanofi-aventis. “Jevtana builds on sanofi-aventis Oncology’s long legacy of providing innovative oncology medicines to patients around the world.”

In the TROPIC Study, the most common (≥ 10%) adverse reactions (grade 1-4) were neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysguesia, 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. 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 patients and three (less than 1%) mitoxantrone-treated patients. The most common fatal adverse reactions in Jevtana patients were infections (n=5) and renal failure (n=4). One death was due to diarrhea-induced dehydration and electrolyte imbalance.

**About Jevtana® (cabazitaxel) Injection**

Jevtana 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. Jevtana is expected to be available as a marketed product in the United States this summer. A registration dossier of Jevtana is also under regulatory review by other regulatory authorities, including the European Medicines Agency.

**Important Safety Information for Jevtana (cabazitaxel) Injection**

Please see the accompanying full prescribing information for Jevtana, or visit: [http://products.sanofi-aventis.us/jevtana/jevtana.pdf](http://products.sanofi-aventis.us/jevtana/jevtana.pdf).

### 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 cabazitaxel concentrations.
  - JEVTANA should not be given to patients with hepatic impairment.
- JEVTANA can cause fetal harm when administered to a pregnant woman.

**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, dysguesia, 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.

**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**

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.

Sanofi-aventis U.S. offers reimbursement support services and patient assistance programs through our PACT+ program to help provide eligible patients in financial need with access to therapies prescribed by their healthcare professionals. For more information, please call 1-800-996-6626.

**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.

**Contacts:**

Marisol Peron
Tel: +33 (0) 1 53 77 45 02
Mobile: +33 (0) 6 08 18 94 78
E-mail: marisol.peron@sanofi-aventis.com

Emmy Tsui
Tel: 1 - (908) 981-6573
E-mail: emmy.tsui@sanofi-aventis.com