

## **JEVTANA® (cabazitaxel) for Prostate Cancer Recommended for Approval in the European Union**

**- Therapy provides significant survival benefit in second-line metastatic hormone-refractory prostate cancer in combination with prednisone or prednisolone -**

**Paris, France - January 21, 2011** - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending to grant a marketing authorization in the European Union for JEV TANA® (Cabazitaxel – 60mg concentrate and solvent for solution for infusion) in combination with prednisone or prednisolone for the treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-containing treatment regimen.

The positive opinion from the CHMP needs now to be ratified by the European Commission.

*“Sanofi-aventis welcomes the positive CHMP recommendation for the approval of JEV TANA® in the European Union,”* said Debasish Roychowdhury, M.D., Senior Vice President and Head of Global Oncology, sanofi-aventis. *“The response to JEV TANA® in the US has exceeded our expectations. The positive opinion for JEV TANA® in the European Union now strengthens sanofi-aventis Oncology’s goal of providing substantially beneficial cancer medicines to patients around the world.”*

The CHMP positive opinion is based on the submission of results from the Phase III 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 percent [HR=0.70 (95% CI: 0.59-0.83); P<0.0001] reduction in risk of death from mHRPC among patients taking JEV TANA® in combination with prednisone or prednisolone compared with an active chemotherapy regimen consisting of a standard dose of mitoxantrone and prednisone or prednisolone. In addition, the median survival of patients receiving JEV TANA® was 15.1 months, 2.4 months higher than patients receiving mitoxantrone, a statistically significant difference.

In the TROPIC Study, the most common (≥ 10%) adverse events (grade 1-4) were anemia, leukopenia, neutropenia, thrombocytopenia and diarrhea. The most common (≥ 5%) grade 3-4 adverse reactions in patients who received JEV TANA were neutropenia, leukopenia, anemia, febrile neutropenia and diarrhea.

JEV TANA® is currently approved in the United States and Brazil. JEV TANA® has also been submitted to regulatory agencies in 26 countries spanning four continents.

### **About JEV TANA® (cabazitaxel Injection)**

JEV TANA is an antineoplastic agent that acts by disrupting the microtubular network in cells. JEV TANA binds to tubulin and promotes the assembly of tubulin into microtubules while simultaneously inhibiting their disassembly. This leads to the stabilization of microtubules. JEV TANA demonstrated a broad spectrum of antitumor activity against advanced solid tumors xenografted in mice. JEV TANA is active in docetaxel sensitive tumors. In addition, cabazitaxel demonstrated activity in tumor models insensitive to chemotherapy including docetaxel.

## 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 percent 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](http://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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