

## **JEVTANA® (cabazitaxel) Approved by European Commission for Treatment of Advanced Second-line Prostate Cancer**

*– Life-extending treatment for mHRPC patients approved throughout Europe –*

**Paris, France - March 20, 2011** - Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) announced today it has received marketing authorization from the European Commission for JEVTANA® (cabazitaxel) in combination with prednisone/prednisolone for the treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-containing regimen.<sup>1</sup> JEVTANA is the first approved agent to significantly extend overall survival in mHRPC patients whose disease has progressed during or after treatment containing docetaxel (15.1 months median overall survival vs 12.7 months in the mitoxantrone arm; HR=0.70 (95% CI: 0.59-0.83); P<0.0001).<sup>1</sup>

The approval from the European Commission followed a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The decision is based on the results from the Phase III TROPIC clinical study involving 755 patients with mHRPC previously treated with a docetaxel-containing treatment regimen. The European Commission decision is applicable to the 27 Member States of the European Union (EU) as well as Iceland, Lichtenstein and Norway. JEVTANA was previously approved in the US, Israel, Curaçao and Brazil.

*“JEVTANA in combination with prednisone/prednisolone reduced the risk of death by nearly one third and extended progression-free survival compared to mitoxantrone, an active comparator,”* said Debasish Roychowdhury, M.D., Senior Vice President and Head, Global Oncology Division, sanofi-aventis. *“The European approval of JEVTANA offers new hope for patients across Europe with limited treatment options should their disease progress following first-line therapy.”*

### **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. Latest figures show that an estimated 300,000 new cases of prostate cancer appear in the European Union every year<sup>2</sup>. 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 the TROPIC Trial**

Results from the TROPIC trial demonstrated a 30 percent [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 or prednisolone, compared with a chemotherapy regimen consisting of a standard dose of mitoxantrone and prednisone or prednisolone. In addition, the median survival of patients receiving JEVTANA was 15.1 months, 2.4 months higher than patients receiving mitoxantrone.<sup>2</sup>

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

#### About JEVTANA® (cabazitaxel Injection)

JEVTANA is a semi-synthetic taxane and works differently than docetaxel and paclitaxel. An antineoplastic agent, it acts by disrupting the microtubular network in cells. It binds to tubulin and promotes the assembly of tubulin into microtubules while simultaneously inhibiting their disassembly. This leads to the stabilization of microtubules. JEVTANA demonstrated a broad spectrum of antitumor activity against advanced solid tumours xenografted in mice. JEVTANA is active in docetaxel sensitive tumours. In addition, JEVTANA demonstrated activity in tumor models insensitive to chemotherapy, including docetaxel.

#### About sanofi-aventis Oncology

Based in Cambridge, Massachusetts, and Vitry, France, sanofi-aventis Oncology, a division of sanofi-aventis, is translating science into effective cancer therapeutics to address unmet medical needs for patients with cancer. Starting with a deep understanding of the mechanisms by which cancer develops, grows and spreads, the company employs innovative approaches in drug discovery, clinical development and partnerships to bring the right medicines to the right patients with the goal of helping cancer patients live healthier and longer lives.

Sanofi-aventis Oncology is committed to the pursuit of science and innovative cancer therapies. We believe in partnership with leading experts, and combining that expertise with our own internal scientific strength and heritage. There are currently more than 10 compounds in clinical development including small molecules and biological agents.

#### 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).

#### References

1. De Bono et al. Lancet 2010; 376:1147-54
2. European Cancer Patient Coalition Accessed at <http://www.ecpc-online.org/cancer-facts-a-figures.html> on 18 March 2011

#### 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, 2010. 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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