

## **SANOFI-AVENTIS RECEIVES MARKET AUTHORIZATION FOR NEW PROSTATE CANCER TREATMENT**

### ***Jevtana™ demonstrates higher survival rate among advanced stage prostate cancer patients***

MONTREAL, June 23, 2011 /CNW/ - Sanofi-aventis announced today that Health Canada has granted market authorization for Jevtana™ (cabazitaxel) injection in combination with prednisone for the treatment of patients with metastatic castration resistant (hormone refractory) prostate cancer (mCRPC), previously treated with a docetaxel-containing treatment regimen.

"Jevtana™ is an effective chemotherapy treatment. It has been approved for patients who have received prior chemotherapy, and provides a significant survival benefit to individuals diagnosed with metastatic castration resistant (hormone-refractory) prostate cancer according to a study published in the *Lancet* in 2010," said Dr. Fred Saad, Professor and Chair of Urology and Director of G-U Oncology at the University of Montreal Hospital Centre. "The impact of this approval will mean a new line of treatment for advanced stage Canadian prostate cancer patients, offering them a treatment option where there was previously none before."

mCRPC is an advanced form of prostate cancer in which the cancer has continued to grow despite the suppression of male hormones, called androgens, which often fuel the growth of prostate cancer cells. Jevtana™ has been shown to work by causing the intracellular microtubules, which help separate chromosomes into daughter cells during cell division, to stabilize so that the cells can no longer grow or divide.<sup>i, ii</sup>

"Through our continued dedication to research and innovation, sanofi-aventis is committed to working with the oncology community to improve the lives of Canadians affected by prostate cancer," said Stan Glezer, VP Medical, sanofi-aventis Canada Inc. "This approval announcement brings Jevtana™ one step closer to becoming available to advanced stage prostate cancer patients diagnosed with mCRPC, one of the most difficult types of prostate cancer to treat."

Jevtana™ was approved based on results from the Phase III TROPIC (Treatment of Metastatic Hormone-Refractory Prostate Cancer Previously Treated with Taxotere-Containing Regimen) clinical study involving 755 patients with mCRPC previously treated with a docetaxel-containing treatment regimen, the results of which were published in the *Lancet*.<sup>iii, iv</sup>

"Access to a greater range of effective treatment options at all stages of prostate cancer is of great importance to prostate cancer patients," said Steve Jones, President and CEO, Prostate Cancer Canada. "We welcome all advances that will improve the lives of men and their families who are living with this disease."

Recent statistics indicate that 1 in 7 Canadian men will develop prostate cancer during his lifetime<sup>v</sup>. Metastatic hormone-refractory prostate cancer<sup>1</sup> accounts for about 30 percent of prostate cancer cases, which means more than 300,000 men worldwide will develop this extensive disease every year.<sup>vi</sup>

### **About Jevtana™**

Jevtana™ (cabazitaxel) is a newly approved second-line treatment option for metastatic castration resistant (hormone-refractory) prostate cancer (mCRPC).<sup>vii</sup> Jevtana™ is a chemotherapy compound used with the steroid medicine prednisone or prednisolone to treat people with mCRPC previously treated with a docetaxel-containing treatment regimen.<sup>viii</sup>

Results of the TROPIC study showed that the combination of Jevtana™ and prednisone significantly reduced the relative risk of death by 30 percent [HR=0.70 (95 percent CI: 0.59-0.83); P<0.0001], with a 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 percent CI: 0.64-0.86); P<0.0001].<sup>ix</sup>

Jevtana™ has a safety profile consistent with other chemotherapies of the same class. The most common (≥10 %) adverse reactions (any grade) in patients who received Jevtana™ were neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia.<sup>x</sup> The most common (≥5 %) grade 3-4 adverse reactions in patients who received Jevtana™ were neutropenia, leukopenia, anemia, febrile neutropenia and diarrhea.<sup>xi</sup>

## About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi is represented in Canada by the pharmaceutical company sanofi-aventis Canada Inc., based in Laval, Quebec, and by the vaccines company Sanofi Pasteur Limited, based in Toronto, Ontario. Together they employ more than 2,000 people across the country. With combined R&D investments of \$159.2 million in 2010, they are leaders in Canada's biopharmaceutical sector, a critical knowledge-based industry that generates jobs, business and opportunity throughout the country.

For more information, please visit: <http://sanofi-aventis.ca>.

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<sup>1</sup> Hormone-resistant prostate cancer (HRPC) is prostate cancer that continues to progress after androgen deprivation, orchidectomy, or total androgen blockade. It may also be called castration-resistant prostate cancer (CRPC).

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<sup>i</sup> "Jevtana Mechanism of Action." Sanofi-aventis Oncology. Available online: <https://www.sanofi-aventisoncology.com/wps/portal/oncology/products/jevtana/mechanismofaction>. Accessed 2/23/2011.

<sup>ii</sup> Jevtana (cabazitaxel for injection) Canadian Product Monograph, June 15, 2011.

<sup>iii</sup> de Bono JS, Oudard S, Ozguroglu M, et al; for the TROPIC Investigators. *Lancet*. 2010; 376(9747):1147-1154.

<sup>iv</sup> "Jevtana Improves Survival in Advanced Prostate Cancer Patients." Sanofi-aventis. Available online: [http://en.sanofi-aventis.com/binaries/20101001\\_JEVTANA\\_en\\_tcm28-29299.pdf](http://en.sanofi-aventis.com/binaries/20101001_JEVTANA_en_tcm28-29299.pdf). Accessed: 3/15/2011.

<sup>v</sup> Prostate Cancer Canada - [www.prostatecancer.ca](http://www.prostatecancer.ca)

<sup>vi</sup> Bellmunt J, et al. *Clinical Transl Oncol*. 2009;11(2):82-85.

<sup>vii</sup> "About Jevtana." Sanofi-aventis Oncology. Available online: <https://www.sanofi-aventisoncology.com/wps/portal/oncology/products/jevtana>. Accessed 2/23/2011.

<sup>viii</sup> "About Jevtana." Sanofi-aventis Oncology. Available online: <https://www.sanofi-aventisoncology.com/wps/portal/oncology/products/jevtana>. Accessed 2/23/2011.

<sup>ix</sup> "Jevtana Improves Survival in Advanced Prostate Cancer Patients." Sanofi-aventis. Available online: [http://en.sanofi-aventis.com/binaries/20101001\\_JEVTANA\\_en\\_tcm28-29299.pdf](http://en.sanofi-aventis.com/binaries/20101001_JEVTANA_en_tcm28-29299.pdf). Accessed: 3/15/2011.

<sup>x</sup> de Bono JS, Oudard S, Ozguroglu M, et al; for the TROPIC Investigators. *Lancet*. 2010; 376(9747):1147-1154.

<sup>xi</sup> Jevtana (cabazitaxel for injection) Canadian Product Monograph, June 15, 2011.

For further information:

**or to coordinate an interview with Dr. Fred Saad or with Mr. Stan Glezer, please contact:**

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