

## **Patients with advanced prostate cancer in Newfoundland can access new treatment option: Province now funds coverage for JEVTANA® (cabazitaxel) Therapy provides statistically significant survival benefit in second-line metastatic hormone-refractory prostate cancer in combination with prednisone**

**Laval, Canada, August 20, 2014** - Sanofi Canada is pleased to announce that patients suffering with prostate cancer in the province of Newfoundland can now access JEVTANA® (Cabazitaxel for injection) through the provincial formulary. JEVTANA® (cabazitaxel) in combination with prednisone or prednisolone is indicated for the treatment of patients with castration resistant (hormone refractory) metastatic prostate cancer (mCRPC) previously treated with a docetaxel containing regimen.

"Being able to access JEVTANA® and knowing that Newfoundland understands the value of the treatment is reassuring for patients with advanced prostate cancer and their loved ones," said Richard Gregoire, Vice President of Evidence, Value and Access. "Sanofi is deeply committed to bringing new innovative therapies to the cancer community and to working in cooperation with the reimbursement regimes to demonstrate the value of new therapies."

The combination of JEVTANA® and prednisone has shown a statistically significant survival benefit for patients with mCRPC previously treated with a docetaxel-containing regimen. "JEVTANA® meets a critical treatment gap for patients with this advanced stage of metastatic hormone-refractory prostate cancer. It is an important therapy option for patients living with mCRPC as well as for health professionals in their efforts to treat patients," said Victoria Vertesi, Vice President, Hospital Patient-Centered Unit.

JEVTANA® (cabazitaxel) is also currently covered on provincial formularies in British Columbia, Alberta, Manitoba, Ontario, New Brunswick and Nova Scotia.

### **About JEVTANA®**

JEVTANA® (cabazitaxel) is an approved treatment option for metastatic castration resistant (hormone-refractory) prostate cancer (mCRPC).(1) 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.(2)

Results of the TROPIC study showed that the combination of JEVTANA® and prednisone significantly reduced the relative risk of death by 30% [HR=0.70 (95 % CI: 0.59-0.83); P<0.0001], with an 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 statistically 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].(3) The PSA response was 39.2% in patients on JEVTANA (95% CI: 33.9-44.5) versus 17.8% in patients on mitoxantrone (95% CI: 13.7-22.0), p=0.0002.(4)

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.(5) The most common (≥5%) grade 3-4 adverse reactions in patients who received JEVTANA® were neutropenia, leukopenia, anemia, febrile neutropenia and diarrhea. Potential serious risks include severe hypersensitivity reactions, neutropenic deaths, and fatal gastrointestinal hemorrhage and perforation.(6)

Please see full prescribing information for JEVTANA®, including Serious Warnings and Precautions box, at <http://products.sanofi.ca/en/jevtana.pdf>

### **About Prostate Cancer**

In Canada, prostate cancer is the most commonly diagnosed cancer of all new cancer cases with almost one in four men (24%) being diagnosed with the disease annually. It is the third leading cause of death from cancer in men in Canada.(7) Despite being the most frequently diagnosed cancer in men, the death rate has declined significantly by almost 4% per year between 2001 and 2009, likely due to detecting prostate cancer earlier and better treatment options.(8)

### **About Sanofi**

Sanofi, a global 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, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi entities in Canada include Sanofi Canada (pharmaceuticals), Sanofi Pasteur (vaccines), Sanofi Consumer Health (cosmeceuticals, over-the-counter products and specialty care), Genzyme (rare diseases) and Merial (animal health). Together they employ close to 1,700 people across the country. In 2013 Sanofi companies invested \$129.1 million in R&D in Canada, creating jobs, business and opportunity throughout the country.  
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(2) 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.

(3) 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.

(4) <http://products.sanofi.ca/en/jevtana.pdf>

(5) <http://products.sanofi.ca/en/jevtana.pdf>

(6) Jevtana (cabazitaxel for injection) Canadian Product Monograph, April 22, 2014

(7) <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=on>

(8) <http://www.prostatecancer.ca/Prostate-Cancer/About-Prostate-Cancer/Statistics>

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