"Taxotere® Injection" (docetaxel hydrate) approved in Japan for the treatment of prostate cancer

-Taxotere® now approved in eight cancer types in Japan-


A New Drug Application (sNDA) was filed on February 28, 2007 and designated as a priority review on May 10, 2007 for the treatment of patients with prostate cancer having progressed or relapsed prostate cancer after surgical or medical castration.

Taxotere® is already approved in Japan for the treatment of breast cancer, non-small cell lung, gastric, head and neck, ovarian, esophageal and endometrial cancers.

This new approval is based on the results of an international large-scale Phase III clinical study TAX327 and on a Japanese Phase II clinical trial.

The TAX327 Study demonstrated that Taxotere® 75 mg/m² every 3 weeks + prednisone / prednisolone combination therapy significantly increases the overall survival versus mitoxantrone + prednisone (in median: 19.2 months vs. 16.3 months, p=0.004; resulting in a reduction of the risk of death by 21%) and improves quality of life (QOL) compared with mitoxantrone + prednisone. The most commonly observed adverse events were alopecia, fatigue and nausea. Grade 3-4 neutropenia was reported more frequently in the Taxotere® group than in the mitoxantrone group (32 percent versus 21.7 percent, p=0.004).

In the Japanese Phase II clinical trial, Taxotere® + prednisolone¹ combination therapy has demonstrated a safety and clinical benefit profile similar to the one observed in the TAX327 study. The overall tumor response rate was 44.2% and PSA marker response rate was 44.4%.

Since its approval in 2004 in Western countries, Taxotere® + prednisone combination has become a standard therapy for the treatment of metastatic Hormone-Resistant Prostate Cancer (mHRPC)

Currently, there are a limited number of drugs with health insurance coverage, which are effective against prostate cancer in Japan. Taxotere® has a unique mode of action different from the existing drugs and is the only chemotherapy which significantly shows the prolongation of overall survival in the patients with mHRPC.

¹ Prednisone and prednisolone are adrenocortical hormones. Prednisone is not approved in Japan.
**About TAX 327 study**

From March 2000 through June 2002, 1,006 men with mHRPC were enrolled in the TAX 327 international multicenter phase III randomized study.

Patients randomly assigned to Taxotere® groups received either 75 mg/m² of Taxotere® by intravenous infusion every three weeks, or 30 mg/m² of Taxotere® weekly for five of every six weeks. Patients randomly assigned to the standard treatment received 12 mg/m² of mitoxantrone every three weeks. All patients received 5 mg of prednisone or prednisolone given orally twice daily. On average, patients tended to receive the greater number of cycles in the Taxotere® arm (9.5 cycles for the 3 weekly scheme) than in the mitoxantrone arm (5 cycles for the 3 weekly scheme).

The primary end point was overall survival. Secondary end points were pain, Prostate Specific Antigen (PSA) levels, and quality of life. All statistical comparisons were against mitoxantrone.

The overall survival benefit for the patients with mHRPC, receiving 3-weekly 75 mg/m² Taxotere®-prednisone regimen compared to mitoxantrone-prednisone gives a median survival of 19.2 months vs. 16.3 months, \( p=0.004 \); resulting in a reduction of the risk of death by 21% for patients receiving the 3-weekly 75 mg/m² Taxotere®-prednisone regimen.

The most commonly observed adverse events in patients receiving Taxotere® 3-weekly were anemia, alopecia, fatigue and nausea and the incidence of grade 3 and 4 neutropenia was 32% vs. 22% (\( p \leq 0.05 \)) and febrile neutropenia occurring in 3% of the patients treated with the 3-weekly 75 mg/m² Taxotere®-prednisone / prednisolone regimen, compared to 2% with the mitoxantrone-prednisone regimen.

**About the Japanese Phase II clinical trial**

From August 2004 to January 2006, 44 Japanese men with mHRPC were enrolled in the Japanese Phase II single arm study. Among them, 43 patients received 70 mg/m² of Taxotere® as intravenous infusion every three weeks and 5 mg of prednisolone given orally twice daily. The median number of cycles was 7. The primary endpoint was overall tumor response. Secondary endpoints were PSA levels and the safety. The overall tumor response rate was 44.2% and the PSA response rate was 44.4%.

The most common grade 3/4 non-hematological event was infection without neutropenia (14.0%), and the most common grade 3/4 hematological event was neutropenia (93.0%); seven patients (16.3%) developed febrile neutropenia. Only one patient (2.3%) developed grade 3/4 anemia; Edema occurred in 9 (20.9%) patients.

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**About Prostate Cancer**

Prostate cancer ranks third worldwide in cancer incidence and sixth in cancer mortality among men. In Europe in 2004, according to the International Agency for Research on Cancer, 238,000 men were diagnosed with prostate cancer and 85,000 died from prostate cancer in the same year. Approximately 219,000 men in the U.S. are expected to be diagnosed with the disease in 2007 and over 27,000 men are expected to die from the disease. In the European Union, over 200,000 new cases are expected to be diagnosed, and over 60,000 patients are expected to die each year. Since the incidence of prostate cancer increases with age, the aging of the overall population is expected to further increase the number of prostate cancer patients. In Japanese males, the death rate is the sixth among all types of cancer for males.
About Taxotere®
Taxotere® is currently approved in 5 different cancer types in Europe and the US. In Japan, Taxotere® is indicated for the treatment of 7 types of cancer: Taxotere® has been approved for the treatment of breast cancer and non-small cell lung cancer as the first taxoid antitumor agent in 1996. Furthermore, it obtained the approval for gastric, head and neck, and ovarian cancers in 2000 followed by esophageal cancer in 2004 and endometrial cancer since 2005.

• In Breast Cancer
In the United States and in Europe Taxotere® is approved to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. It is also approved in Europe in combination with doxorubicin for patients who have not received prior cytotoxic therapy for this condition and in combination with capecitabine after failure of cytotoxic therapy which would have included anthracycline. In the adjuvant setting (post surgery) it is approved in the U.S. and in Europe in combination with doxorubicin and cyclophosphamide (TAC regimen) for the treatment of patients with operable, node-positive breast cancer. Finally, in Europe, Taxotere® is approved in combination with trastuzumab for the treatment of patients with metastatic breast cancer-overexpressing HER2 receptor.

• In Lung Cancer
In the U.S. and in Europe, Taxotere®, in combination with cisplatin, is approved for the treatment of patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not received prior chemotherapy, and it also is approved, as a single agent, for patients with unresectable locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.

• In Prostate Cancer
Taxotere® is approved for use in combination with prednisone as a treatment for androgen independent (hormone-refractory) metastatic prostate cancer in the U.S. and in Europe.

• In Gastric (Stomach) Cancer
In the US and in Europe the use of Taxotere® Injection Concentrate is approved in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastro esophageal (GE) junction, who have not received prior chemotherapy for advanced disease.

• In Head and Neck Cancer
In October 2006, the European Medicines Agency (EMEA) and the FDA approved Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN). In September 2007, the FDA extended this approval to include patients with locally advanced SCCHN prior to chemo radiotherapy and surgery. In November 2007, EMEA gave its approval for the use of Taxotere® for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

Sanofi-aventis in oncology - Target Cancer: commitment in action
At sanofi-aventis, we are committed to continuing the fight against cancer by attacking it on all fronts. From our innovative research strategy, to our diverse portfolio of therapies, to our patient awareness and support programs, we are committed to making a difference in the lives of cancer patients and their families.
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).

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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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 EMEA, 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 labeling 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 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, 2007. 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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