



ABSTRACT #5005

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**UPDATED STUDY RESULTS REINFORCE SURVIVAL BENEFIT OF TAXOTERE[®]
(DOCETAXEL) FOR MEN WITH ADVANCED, HORMONE-RESISTANT
PROSTATE CANCER**

**ASCO Oral Presentation Reports Significantly More Patients Treated With Taxotere[®]-
Based Chemotherapy Regimen Survived At Least Three Years**

Chicago, Illinois - June 4 - Taxotere[®] (docetaxel) Injection Concentrate-based chemotherapy (Taxotere plus prednisone) maintained long-term efficacy as a treatment for advanced (metastatic) hormone-resistant prostate cancer patients, according to the three-year updated results of the landmark TAX 327 study. Results of the international multi-center phase III trial were reported in an oral presentation at the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO).

The TAX 327 data show that among patients with metastatic hormone-resistant prostate cancer, significantly more of those treated with Taxotere[®] 75mg/m² combined with prednisone 5 mg once every three weeks survived at least three years, than those treated with anti-cancer antibiotic mitoxantrone combined with prednisone. Patients treated with the Taxotere[®] regimen lived a median of three months longer (19.3 months versus 16.3 months, p=0.006) and had a 21% lower risk of dying (HR=17.6-21.3). These results are consistent with results published in 2004 in the *New England Journal of Medicine* and document the maintenance of the survival benefit previously reported in patients treated with the Taxotere-based therapy.

"The results confirm docetaxel's survival benefit in patients with metastatic hormone resistant prostate cancer," said study author Dominik R. Berthold, Department of Medical Oncology, Princess Margaret Hospital, Toronto, Canada. "Prolonged survival is extremely important for these patients and docetaxel is the only chemotherapeutic agent to demonstrate a survival benefit in this setting."

Original TAX 327 Analysis Showed Improved Survival

The TAX 327 study was initiated in 2000 to evaluate long-term survival among men with metastatic hormone refractory prostate cancer treated with regimens of Taxotere[®] plus prednisone (n=335) or mitoxantrone plus prednisone (n=337). The primary analysis published in the *New England Journal of Medicine* in 2004 demonstrated that Taxotere[®] given every three weeks with prednisone led to a superior survival advantage, versus mitoxantrone plus prednisone. The median survival was 18.9 months in the group given docetaxel every 3 weeks and 16.5 months in the mitoxantrone group (HR=0.76, 95% CI [0.62-0.94], p=0.0094).



Press Release

The primary endpoint was overall survival. Secondary endpoints measured pain and prostate-specific antigen (PSA) levels. PSA is a substance made by the prostate that may be found in an increased amount in the blood of men who have prostate cancer or other conditions such as enlarged prostate.

The most commonly observed adverse events in TAX 327 were alopecia, fatigue and nausea. Grade 3-4 neutropenia was reported more frequently in the Taxotere[®] group than the mitoxantrone group (32 percent vs. 21.7 percent, p=0.004).

The once every three weeks 75mg/m² Taxotere[®] (docetaxel) plus 5 mg prednisone regimen has been approved for use as a treatment for androgen independent (hormone-refractory) metastatic prostate cancer in the U.S. since May 2004 and October 2004 in Europe. It is the only standard of care first line chemotherapy option for patients with metastatic hormone refractory prostate cancer.

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. Although men of any age can get prostate cancer, it is found most often in men over age 50; more than 7 of 10 men with prostate cancer are over the age of 65.

Advanced prostate cancer means the cancer has spread to tissues next to the prostate, such as the muscles that help control urination, the rectum or the wall of the pelvis. The cancer may have also spread to lymph nodes near the prostate or, if it has metastasized, to other more distant places in the body. With early detection, the five-year survival rate of prostate cancer is almost 100%. But if it has spread, that rate goes down dramatically to 33%.

For full prescribing information, including boxed **WARNING**, call 800-633-1610 or visit www.taxotere.com.

About sanofi-aventis

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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