

**Taxotere[®]-Based Chemotherapy Significantly Improved
Overall Survival Compared With Standard Anthracycline-Based Chemotherapy In Early
Stage Breast Cancer**

***– Oral Presentation of the US Oncology Adjuvant Trial 9735 at 2007 San Antonio Breast
Cancer Symposium Showed Taxotere[®] and Cyclophosphamide Improved Overall Survival
Versus An Anthracycline Combination –***

Paris, France, December 13, 2007 – Results presented at the 30th annual San Antonio Breast Cancer Symposium (SABCS) showed that for women with early stage breast cancer who have had surgery, treatment with the investigational chemotherapy combination of Taxotere[®] (docetaxel) Injection Concentrate and cyclophosphamide significantly improved overall survival compared to standard chemotherapy. The presentation reports results with a median follow-up of 7 years and has been updated since the last report was published with 5.5 years median follow-up [Jones S et al. J Clin Oncol, 2006, 24:5381–7]. This latest report has also been updated from the abstract submitted to SABCS 2007.

In the updated analysis, overall survival at 7 years was statistically higher among women treated with Taxotere[®] and cyclophosphamide (TC) versus those treated with doxorubicin and cyclophosphamide (AC): 87% versus 82% (HR: 0.69, [95% CI, 0.50, 0.97]). The 31% reduction in the risk of death was statistically significant (p=0.032). At 7 years, the disease-free survival (DFS) was also statistically greater among women treated with TC than those treated with AC: 81% versus 75% (HR: 0.74, [95% CI, 0.56, 0.98]). The 26% reduction in the risk of cancer recurrence among women treated with TC was statistically significant (p=0.033). The disease-free survival benefit seen in the elderly patients (aged 65 years or older; 31% risk reduction of recurrence) is consistent with that in the overall patient population.

Principal study investigator Dr. Stephen Jones, medical director and co-chair, breast cancer research committee of US Oncology, helped develop the regimen combining the anthracycline doxorubicin with cyclophosphamide, which became a foundation of breast cancer chemotherapy for more than 30 years.

“The investigational Taxotere[®] combination significantly increased the percentage of women living with no signs of cancer at 7 years, as compared to the anthracycline combination,” said Dr. Jones.

USO Adjuvant Trial 9735 was designed primarily to evaluate disease-free survival among women with node-positive and node-negative early breast cancer. Node-positive indicates that the cancer has spread to the lymph nodes under the arm, while node-negative breast cancer means that the lymph nodes are clear of cancer. Secondary endpoints included overall survival and safety. The investigators also explored the efficacy and safety of the treatments based on the age of patients and the biologic characteristics of their tumors.

All patients taking part in the study had received surgery for Stage I–III invasive breast cancer, meaning that the cancer was either localized to the breast or had spread to the lymph nodes under the adjacent arm.

A total of 1016 patients were randomized between June 1997 and December 1999; 48% of patients had node-negative disease and 16% were age 65 years or older. After surgery, patients were randomized to receive four cycles of either standard-dose of anthracycline doxorubicin 60 mg/m² and cyclophosphamide 600 mg/m² (n=510) or Taxotere® 75 mg/m² and cyclophosphamide 600 mg/m² (n=506), administered by intravenous infusion every three weeks. After chemotherapy was completed, patients were treated with radiation therapy if indicated. Patients with hormone receptor positive disease also received hormonal therapy (tamoxifen).

In the TC group, there were 88 DFS events (17%) and 58 deaths (12%). The AC group had 118 DFS events (23%) and 84 deaths (17%). Exploratory analyses showed benefit of TC irrespective of age, hormonal status or Her2 status. Grade 3–4 neutropenia occurred in 60% of younger (<65 years) and 52% of older (≥65 years) women in the TC group, and in 54% and 59% of younger and older women, respectively, in the AC group. Among younger patients, the frequencies of Grade 3–4 febrile neutropenia were 4.4% with TC and 2.3% with AC, while in older patients the frequencies were 7.7% and 3.7% for TC and AC, respectively. Grade 3–4 nausea was less common among women in both age groups treated with TC (<65 years: 2%, ≥65 years: 3%) than those given AC (<65 years: 7%, ≥65 years: 5%). In the TC group, additional Grade 3–4 adverse events reported among women <65 and ≥65 were Grade 3–4 fever in 4% and 6% and Grade 3–4 infection in 7% and 6%, respectively, while in the AC arm the rates of Grade 3–4 fever were 3% and 4 % and Grade 3–4 infections were 10% and 2 % for younger and older women, respectively.

Breast Cancer, the Most Common Cancer in Women

Breast cancer is the most frequently diagnosed cancer in women throughout the world. By the end of 2007, more than 178,000 American women will have learned they have invasive breast cancer. In the European Union (EU), more than 429,900 new cases were diagnosed in 2006. Age is the biggest risk factor, and one in 26 women over 70 will have breast cancer in her lifetime.

In the U.S., breast cancer is the third-leading cause of cancer death in women. More than 40,000 women in the U.S. will die of breast cancer this year; more than half are 65 or older. In the EU, breast cancer is the leading cause of cancer death among women; an estimated 132,000 died from breast cancer in 2006.

About US Oncology, Inc.

US Oncology, headquartered in Houston, Texas, supports one of the nation's largest cancer treatment and research networks. US Oncology provides extensive services and support to its affiliated cancer care sites nationwide to help them expand their offering of the most advanced treatments and technologies, build integrated community-based cancer care centers, improve their therapeutic drug management programs, and participate in many of the new cancer-related clinical research studies. US Oncology also provides a broad range of services to pharmaceutical manufacturers, including product distribution and informational services such as data reporting and analysis.

According to the company's last quarterly earnings report, US Oncology is affiliated with 1,164 physicians operating in 443 locations, including 91 radiation oncology facilities in 39 states.

About US Oncology Research Network

The US Oncology Research Network is an established community-based research operation specializing in all phases of cancer clinical trials. The research network currently has 500 physicians actively enrolling patients, 77 research sites, and is currently involved in more than 60 open research trials. The network has contributed to the development of 24 of 30 of the latest cancer-fighting drugs approved by the Food and Drug Administration for use. Since 1993, more than 32,000 patients have participated in clinical trials managed by US Oncology network practices. For more information, visit the "Research" section under "Our Services" on the company's Web site, www.usoncology.com.

About Taxotere®

Taxotere® is currently approved in 5 different cancer types in Europe and the US:

• 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 the 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 Europe, Taxotere® in combination with cisplatin and 5-fluorouracil is approved 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**

The European Medicines Agency (EMA) and the FDA approved Taxotere® 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 chemoradiotherapy and surgery.

In November 2007 EMA 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.

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 PARIS: SAN) and in New York (NYSE: SNY).