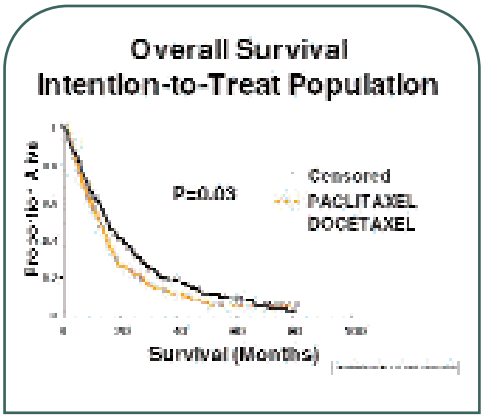
A RANDOMIZED PHASE III STUDY DEMONSTRATES IMPROVED SURVIVAL IN WOMEN WITH METASTATIC BREAST CANCER TREATED WITH TAXOTERE® (docetaxel) COMPARED TO PACLITAXEL

Overall survival and time to disease progression improved with Taxotere®

COPENHAGEN, DENMARK – SEPTEMBER 24, 2003 – Today at the European Cancer Conference (ECCO) annual meeting, results from a randomized, Phase III study were presented which demonstrated that women with metastatic breast cancer who were treated with Taxotere® (docetaxel) Injection Concentrate had a statistically significant improvement in overall survival and time to disease progression compared to those who were treated with paclitaxel. Both these agents are in a class of drugs knows as taxanes that are used extensively to treat women with metastatic breast cancer.

The multi-center study included 449 women who were randomized to either Taxotere® 100mg/m2 (1 hour infusion) or paclitaxel 175 mg/m2 (3 hour infusion) every three weeks. Treatment was continued until progression of disease, unmanageable toxicity or intercurrent illness occurred, or until the patient decided to terminate treatment for any other reason. Eligibility criteria included: bi-dimensionally measurable metastatic breast cancer, having failed either one prior anthracycline-based regimen as first-line therapy for metastatic breast cancer or disease progression during or within 12 months of completing anthracycline-based adjuvant or neoadjuvant chemotherapy.



"While Taxotere® is already the most widely used chemotherapy agent in the treatment of women with metastatic breast cancer, this trial offers more hope to women with breast cancer and has significance in treatment decisions," said Peter Ravdin, M.D., PhD., an Associate Professor of Oncology at the University of Texas Health Science Center at San Antonio and Principal Investigator of the study. "Taxanes have been proven to be a leading class of agents across a wide range of cancers. This trial is an important comparison of the taxanes that may influence future research and treatment strategies."

The primary endpoint of this study was the rate of overall response (tumor shrinkage). The secondary endpoints included time to disease progression (time without the cancer growing) and overall survival. In the "intent to treat" population, results are as follows:

- Median survival was 15.4 months for Taxotere® and 12.7 months for paclitaxel (P-value = 0.03).
- Median time to disease progression for patients treated with Taxotere® was 5.7 months compared to 3.6 months for those treated with paclitaxel (P-value = <0.001).
- Response rates were numerically higher for Taxotere® (32.0%) compared to paclitaxel (25.0%), with P-value=0.10. (The overall response rate was statistically significant for Taxotere® (37.4%) compared to paclitaxel (26.4%) in the "eligible and evaluable" population (P-value=0.02).

Taxotere® was associated with increased incidence of grade 3/4 toxicities, including neutropenia (decrease in white blood cells which help fight infection), fever, diarrhea and edema (fluid retention).

"The study builds upon our base of research and provides additional support that Taxotere® is one of the most active chemotherapy agents in the treatment of metastatic breast cancer after the failure of prior chemotherapy," said Michael L. Meyers, Senior Director, Medical Affairs, Aventis Pharmaceuticals.

Full prescribing information is available by visiting the Aventis Pharmaceuticals U.S. Web site at http://www.aventis-us.com.