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Taxotere® (docetaxel) granted FDA approval to treat Locally Advanced Head and Neck Cancer prior to chemoradiotherapy and surgery

Sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) has approved Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and 5-fluorouracil (TPF regimen), for induction therapy of locally advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN) before patients undergo chemoradiotherapy and surgery.

The FDA based its approval on the results of the phase III randomized, open-label, international trial, TAX 324, which established the efficacy and safety of the Taxotere-based regimen in significantly improving survival.

Approval Based on Clinical Trial TAX 324

Among patients treated with Taxotere-based therapy (TPF, n=255) overall survival was significantly improved compared to patients receiving just cisplatin and 5-fluorouracil (PF, n=246); the relative risk of death was 30% lower (HR 0.70; p=0.0058). Patients treated with TPF had a longer median Overall Survival of 70.6 months vs. 30.1 months for patients receiving PF only, representing a more than three year improvement in median OS for patients treated with TPF. The probability to survive 3 years was 62% in the TPF arm compared to 48% in the PF arm.

"The TAX 324 trial found that the addition of Taxotere to standard induction chemotherapy significantly improved patient survival, adding years to patients' lives," noted clinical investigator Marshall Posner, MD, Medical Director of the Head and Neck Oncology Program at Dana-Farber Cancer Institute in Boston. *"The approval of Taxotere to be given in combination with other standard chemotherapy as the first step in a therapeutic sequence followed by chemoradiotherapy and surgery is a significant advancement in treatment for patients with locally advanced head and neck cancer."*

All patients entering TAX 324 had tumors of the oropharynx, larynx, hypopharynx or oral cavity that either could not be removed, were considered potentially operable but unlikely to be cured with surgery, or could not be removed in order to preserve organ function. Participants in the trial had either stage III or IV SCCHN with no distant metastases.

Patients were treated every three weeks for three cycles with either TPF (Taxotere 75 mg/m² plus cisplatin 100 mg/m² and 5-fluorouracil 1000 mg/m² a day for four days) or PF (intravenous cisplatin 100 mg/m² followed by 5-fluorouracil 1000 mg/m² a day for five days), the standard therapy. Both groups of patients were then given weekly chemotherapy (carboplatin) together with radiation therapy

for seven weeks, followed by surgery for those patients identified as candidates. The study was designed primarily to evaluate Overall Survival. Secondary endpoint included Progression-Free Survival, response rates, toxicity, quality of life and clinical benefits.

Overall, the incidence of grade 3/4 toxicity was 65% in the Taxotere arm (TPF) compared to 62% in the group receiving cisplatin and fluorouracil (PF). Patients treated with TPF had more febrile neutropenia (12% vs 7%), neutropenic infection (12% vs 8%), and grade 3/4 neutropenia (84% vs. 56%), dizziness (4% vs. 2%), alopecia (4% vs 1%) and diarrhea (7% vs. 3%) than those in the PF group. Patients in the PF group had more grade 3/4 thrombocytopenia (11% vs. 4%), stomatitis (27% vs. 21%), lethargy (10% vs. 5%) and vomiting (10% vs. 8%). The incidence of other grade 3/4 events was similar between the two groups, such as nausea, anorexia and constipation.

Head and Neck Cancer, a Deadly Disease

More than 640,000 people worldwide are diagnosed with head and neck cancer each year, and more than 350,000 die from the disease annually. Head and neck cancer is a group of many related diseases that mostly begin in the cells that line the mucosal surfaces in the head and neck area such as the mouth, tongue, tonsils, throat and voicebox. The term encompasses cancers of the oral cavity, salivary glands, paranasal sinuses and nasal cavity, pharynx, larynx, and lymph nodes in the upper part of the neck.

“Head and neck cancer is particularly hard to treat and if not detected early has low survival rates,” commented Nancy Leupold, survivor, President and Founder of Support for People with Oral and Head and Neck Cancer (SPOHNC). *“The availability of effective therapies that advance treatment and help patients live longer is very welcome news for the cancer community.”*

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 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

The FDA and the Committee for Medicinal Products for Human Use (CHMP) of the European Agency for the Evaluation of Medicinal Products (EMA) approved in March 2006, the use of Taxotere® Injection Concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastro oesophageal (GE) junction, who have not received prior chemotherapy for advanced disease.

In Head and Neck Cancer

In October 2006, the European Medicines Agency (EMA) 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).

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).