

FDA Approves Tarceva as a Maintenance Therapy for Advanced Non-Small Cell Lung Cancer

- First Maintenance Therapy Approved For a Broad Patient Population Including Squamous and Non-Squamous Histology -

MELVILLE, N.Y., Apr 16, 2010 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the U.S. Food and Drug Administration (FDA) approved the daily pill Tarceva^(R) (erlotinib) as a maintenance treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

"We are delighted that lung cancer patients and their physicians will have the option of beginning Tarceva therapy in the first-line maintenance setting. We believe that Tarceva, as the only medicine approved in the maintenance setting for the squamous and non-squamous forms of NSCLC, offers a valuable treatment option for these patients," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We remain committed to a strategy of maximizing the value of Tarceva as an important therapy for cancer patients and are pursuing the study of additional uses for Tarceva, including as a first-line treatment for lung cancer patients with an activating EGFR mutation, as an adjuvant therapy in NSCLC, and in other tumor types such as ovarian cancer and hepatocellular carcinoma."

The new approval for Tarceva was based on data from the pivotal Phase III SATURN study. SATURN showed that Tarceva given as a maintenance therapy immediately after first-line chemotherapy significantly extended overall survival (OS) and significantly improved the time people with advanced NSCLC lived without the disease getting worse (progression-free survival, PFS) in a broad patient population, including squamous and non-squamous histology, compared with placebo. The goal of maintenance therapy, a new approach in lung cancer, is to provide an active treatment for patients whose disease either responded to, or was stable, following initial chemotherapy before their cancer worsens. Many people are unable to receive further treatment after their cancer grows or spreads because of rapid cancer growth and worsening symptoms.

Tarceva is already FDA-approved for people with advanced NSCLC whose cancer has grown or spread after receiving at least one course of chemotherapy. Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC.

According to the American Cancer Society, lung cancer is the leading cause of cancer death in the United States and approximately 159,000 Americans died from the disease in 2009. NSCLC is the most common type of lung cancer. Most people are diagnosed with advanced stage disease and only one to five percent of people with advanced stage (IIIB/IV) NSCLC survive five years.

About SATURN

SATURN was an international, placebo-controlled, randomized, double-blind, Phase III study that enrolled 889 patients with advanced NSCLC at approximately 160 sites worldwide. Patients were treated with four cycles of standard first-line platinum-based chemotherapy and then randomized to Tarceva or placebo if the cancer did not progress. PFS was defined as the length of time from randomization to disease progression or death from any cause.

- OS was significantly improved by 23 percent with Tarceva compared to placebo (hazard ratio=0.81, 19 percent reduction in the risk of death, p=0.0088).
- People who received Tarceva had a 41 percent improvement in the likelihood of living without the disease getting worse (PFS, the primary endpoint) compared to placebo (hazard ratio=0.71, 29 percent reduction in the risk of cancer progression or death, p<0.0001).
- The most commonly reported adverse events in patients who received Tarceva as maintenance therapy were rash (49 percent) and diarrhea (20 percent). Grade 3 rash and diarrhea were experienced by six percent and two percent of patients, respectively. There were no cases of Grade 4 rash or diarrhea.

About Tarceva

Tarceva is a once-a-day pill that targets the EGFR pathway. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cancer cell, one of the critical growth factors in NSCLC and pancreatic cancer. The way Tarceva works to treat cancer is not fully known.

In addition to its indications in advanced NSCLC, Tarceva is also prescribed in combination with gemcitabine for patients with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed, and who have not received previous chemotherapy.

Tarceva Safety

There have been reports of serious Interstitial Lung Disease (ILD)-like events including deaths in patients taking Tarceva. Serious side effects (including deaths) in patients taking Tarceva include liver and/or kidney problems; gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); and severe blistering skin reactions including cases similar to Stevens-Johnson syndrome. Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke. Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Difficulty with blood clotting, and bleeding events, including gastrointestinal and non-gastrointestinal bleeding, have been reported in clinical studies. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients should call their doctor right away if they have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, vomiting or stomach pain; new or worsening shortness of breath or cough; fever; eye irritation. Rash and diarrhea were the most common side effects associated with Tarceva in the NSCLC clinical studies. Fatigue, rash, nausea, loss of appetite and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in the pancreatic cancer clinical study.

For full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality, novel and differentiated targeted medicines designed to extend life and improve the quality of life for patients with cancer and diabetes/obesity. For additional information about OSI, please visit <http://www.osip.com>.

This news release contains forward-looking statements. These statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, OSI's and its collaborators' abilities to effectively market and sell Tarceva and to expand the approved indications for Tarceva, OSI's ability to protect its intellectual property rights, safety concerns regarding Tarceva, competition to Tarceva and OSI's drug candidates from other biotechnology and pharmaceutical companies, the completion of clinical trials, the effects of FDA and other governmental regulation, including pricing controls, OSI's ability to successfully develop and commercialize drug candidates, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

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