

OSI Pharmaceuticals Announces That Tarceva(R) Received a Positive Opinion from Health Authorities in the European Union for First-Line Maintenance Use in Advanced Non-Small Cell Lung Cancer

MELVILLE, N.Y., Mar 19, 2010 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that its international partner for Tarceva^(R) (erlotinib), Roche, informed OSI that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending approval of Tarceva as monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with stable disease following four cycles of standard platinum-based first-line chemotherapy. A final decision is expected from the European Commission within 45 days.

"Advanced lung cancer is an aggressive disease and when the cancer grows or spreads the health of patients deteriorates rapidly. By giving Tarceva earlier after chemotherapy, instead of waiting for the disease to progress, we could help more people live longer without their disease getting worse," said Professor Federico Cappuzzo, M.D., Head of Oncology Unit, Livorno Hospital, Italy and principal investigator of the SATURN trial.

The CHMP positive opinion is based on a review of data from the pivotal Phase III SATURN study which showed a statistically significant improvement in both progression-free survival (PFS) and overall survival (OS)- the study's primary and secondary endpoints, respectively- with Tarceva compared to placebo across a broad range of patients with advanced NSCLC in the maintenance setting. The magnitude of the benefit was greater in patients with stable disease following first-line chemotherapy compared to patients achieving a complete or partial response. Data for patients with stable disease will be presented at a forthcoming scientific meeting.

The U.S. Food and Drug Administration (FDA) recently extended the review period for the supplemental New Drug Application (sNDA) for Tarceva as a first-line maintenance therapy in advanced NSCLC by 90 days, and the agency is now expected to make a decision by April 18, 2010.

Sales of Tarceva outside the U.S. represent an important component of the Company's revenues. In 2009, \$146 million (or 41%) of the Company's \$359 million in Tarceva-related revenues were derived from royalty payments received from Roche for sales outside the U.S. market.

About SATURN

SATURN was an international, placebo-controlled, randomized, double-blinded, 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. The co-primary endpoints were progression-free survival (PFS) in all patients and PFS in patients whose tumors over-expressed the epidermal growth factor receptor (EGFR) as assessed by Immunohistochemistry (IHC). PFS was defined as the length of time from randomization to disease progression or death from any cause. Secondary endpoints included overall survival, safety and an evaluation of exploratory biomarkers.

About Lung Cancer

Lung cancer is the most common cancer worldwide with 1.5 million new cases annually and NSCLC accounts for almost 85% of all lung cancers. NSCLC progresses rapidly; less than 5% of advanced NSCLC patients survive for five years.

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. Tarceva is prescribed for patients with advanced-stage NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen. Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC.

In pancreatic cancer, Tarceva in combination with gemcitabine is prescribed 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 infrequent 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. 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 study. 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.

SOURCE: OSI Pharmaceuticals, Inc.

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