U.S. Patent and Trademark Office Issues a Notice of Allowance in OSI Pharmaceuticals' Reissue Application on Tarceva(R) Composition of Matter Patent

MELVILLE, N.Y., Sep 17, 2009 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the U.S. Patent & Trademark Office has issued a "Notice of Allowance" in OSI's reissue application for U.S. Patent No.5,747,498 (the '498) composition of matter patent for Tarceva(R) (erlotinib). The reissued patent will replace the original '498 patent and have the same November 2018 expiration date.

"This decision by the PTO is encouraging as OSI, along with the biopharmaceutical industry, recognizes that patent rights are an important asset in protecting the extensive R&D investment necessary to bring new drugs and therapeutics to patients. Today's action by the PTO is significant as we view this reissue grant as a positive step in managing generic challenges to the Tarceva patent estate," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "With a potential approval on the horizon based on the SATURN data in the first-line maintenance setting for non-small cell lung cancer; additional ongoing Phase III studies in NSCLC for first-line EGFR mutation patients and in the stage I-IIIa adjuvant setting; and, further Phase III studies in ovarian cancer and hepatocellular carcinoma, we believe Tarceva will remain a growing, anchoring asset for the Company over the next decade."

Background

In February 2008, OSI filed with the U.S. Patent and Trademark Office an application to reissue its composition of matter patent for Tarceva in order to correct certain errors relating to the claiming of compounds, other than Tarceva, which fall outside of the scope of the main claim in the patent. OSI's reissue application looked to correct these errors by deleting surplus compounds from the claims. Like most composition of matter patents, the '498 patent claims many compounds in addition to Tarceva. Tarceva itself is accurately described in the '498 patent.

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 cell, one of the critical growth factors in NSCLC and pancreatic cancers. Tarceva is indicated as a monotherapy for patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy. Results from two multicenter, placebo-controlled, randomized Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

In pancreatic cancer, Tarceva is indicated in combination with gemcitabine for the first-line treatment of patients with locally advanced pancreatic cancer, pancreatic cancer that cannot be surgically removed or pancreatic cancer that has spread to distant body organs.

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 non-small cell lung cancer 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 andpharmaceutical 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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