

## **OSI Pharmaceuticals Announces Tarceva to Be Reviewed by the FDA's Oncologic Drugs Advisory Committee for Use as a First-Line Maintenance Therapy in Advanced Non-Small Cell Lung Cancer**

MELVILLE, N.Y., Nov 16, 2009 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the Oncologic Drugs Advisory Committee (ODAC) will review the use of Tarceva<sup>(R)</sup> (erlotinib) as a first-line maintenance therapy for patients with advanced non-small cell lung cancer (NSCLC) who have not progressed following first-line treatment with platinum-based chemotherapy at its December 16, 2009 meeting. The ODAC panel is a committee of external experts, formed by the U.S. Food and Drug Administration (FDA), to advise the FDA in the evaluation of marketed and investigational drugs for use in the treatment of cancer.

In June 2009, the FDA accepted for filing and review the supplemental New Drug Application (sNDA) for the use of Tarceva as a first-line maintenance treatment for patients with advanced NSCLC who have not progressed following first-line treatment with platinum-based chemotherapy. In addition, the overall survival data was included in an update to the U.S. sNDA. The FDA Prescription Drug Fee Act (PDUFA) review date for the Tarceva application is on or about January 18, 2010.

Tarceva is the only oral, non-chemotherapy agent shown to provide a statistically significant improvement in both progression-free survival (PFS) and overall survival (OS) in the NSCLC maintenance setting.

### **About Lung Cancer**

According to the American Cancer Society, lung cancer is the leading cause of cancer death in the United States. In 2009, approximately 159,000 Americans will die from the disease. Most people are diagnosed with advanced stage disease and only 15 percent survive five years. NSCLC is the most common type of lung cancer.

### **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. Tarceva is not intended to be used at the same time as chemotherapy for NSCLC.

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 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.

**OSI Pharmaceuticals, Inc.**

Kathy Galante (investors/media)

*Senior Director*

or

Kim Wittig (media)

*Director*

631-962-2000

or

**Burns McClellan, Inc. (representing OSI)**

Justin Jackson/Kathy Nugent (media)

212-213-0006

Copyright Business Wire 2009