

## **Tarceva® (erlotinib) Endorsed by the U.K.'s National Institute for Health and Clinical Excellence for Use in Patients with Advanced Non-Small Cell Lung Cancer**

MELVILLE, N.Y., Nov 26, 2008 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) welcomes today's announcement by the U.K.'s National Institute for Health and Clinical Excellence (NICE) issuing Final Guidance recommending funding by the National Health Service (NHS) for Tarceva® (erlotinib) as an alternative treatment to the IV chemotherapy agent docetaxel for the second-line treatment of advanced non-small cell lung cancer (NSCLC). Tarceva is the first EGFR targeted agent for advanced NSCLC recommended for use by NICE.

With this action, lung cancer patients in England, Wales and Northern Ireland will now have access to an oral targeted therapy that has been approved throughout Europe for advanced NSCLC.

Tarceva is approved in 92 countries including the United States and the European Union as a monotherapy for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Tarceva is also approved in combination with gemcitabine chemotherapy for the first-line treatment of locally advanced, unresectable or metastatic pancreatic cancer in 68 countries worldwide.

### About Tarceva

Tarceva is a small molecule designed to target the EGFR pathway, which is one of the factors critical to cell growth in NSCLC and pancreatic cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cell.

Tarceva is FDA-approved for use as a monotherapy in patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy (at a recommended dose of 150 mg/day). 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.

Tarceva is also approved in combination with gemcitabine for the treatment of locally advanced or metastatic pancreatic cancer in patients who have not received previous chemotherapy (at a recommended dose of 100 mg/day).

### Tarceva Safety Profile

There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving Tarceva for treatment of NSCLC, pancreatic cancer or other advanced solid tumors. Cases of hepatic failure, hepatorenal syndrome, acute renal failure (all including fatalities) and renal insufficiency have been reported during use of Tarceva. In the pancreatic cancer trial, other serious adverse reactions associated with Tarceva plus gemcitabine, and which may have included fatalities, were myocardial infarction/ischemia, cerebrovascular accident and microangiopathic hemolytic anemia with thrombocytopenia. When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. Tarceva is pregnancy category D. The most common adverse reactions in patients with NSCLC receiving Tarceva monotherapy 150 mg were rash and diarrhea. The most common adverse reactions in patients with pancreatic cancer receiving Tarceva 100 mg plus gemcitabine were fatigue, rash, nausea, anorexia and diarrhea.

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 and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are committed to the generation of novel, targeted therapies for the treatment of type 2 diabetes and obesity. OSI's flagship product, Tarceva® (erlotinib), is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in both non-small cell lung cancer and pancreatic cancer patients in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. For additional information about OSI, please visit .

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, the completion of clinical trials, the FDA review process and other governmental regulation, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

SOURCE: OSI Pharmaceuticals, Inc.

OSI Pharmaceuticals, Inc. Investors/Media Kathy Galante, 631-962-2043 Senior Director, Investor/Public Relations or Media Kim Wittig, 631-962-2135 Director, Public Relations or Burns McClellan (Representing OSI) Media Justin Jackson/Kathy Nugent 212-213-0006