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# OSI Pharmaceuticals Announces Patent Term Extension for Tarceva(R) (erlotinib)

MELVILLE, N.Y.--(BUSINESS WIRE)--Sept. 18, 2007--OSI Pharmaceuticals, Inc. (Nasdaq: OSIP) announced today that the Company has received Notice of Final Determination from the US Patent and Trademark Office that the patent for Tarceva® (erlotinib), US Patent No. 5,747,498, covering composition of matter, processes for its preparation, methods of treating cancer, and pharmaceutical compositions containing Tarceva has been extended through November 8, 2018. In addition to the composition of matter patent, OSI also has a crystalline polymorph patent (US Patent No. 6,900,221) for Tarceva which expires in 2020.

"A strong intellectual property estate has significant implications for the commercial potential of Tarceva and this extension protects our exclusivity in the U.S. for an additional three years," said Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals, Inc. "We are pleased with the performance of Tarceva since its launch in the U.S. market as well as globally, and continue to believe in the future of Tarceva as we seek to expand its use to earlier in the course of lung cancer treatment and to other disease settings."

Supplementary Protection Certificates (SPCs) have also been granted for Tarceva, extending exclusivity to March 2020 in 14 countries including France, Germany, Italy, Switzerland and the United Kingdom. Other granted patent term extensions include Australia (expires in January 2021), Russia (expires in March 2021) and South Korea (expires in October 2016).

Additional Tarceva Information

Tarceva was approved by the FDA in November 2004 for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one chemotherapy regimen. Results from two earlier large, randomized, placebo-controlled Phase III clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, one of the factors critical to cell growth in NSCLC and other solid tumors. HER1, also known as EGFR, is a component of the HER signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the HER1 signaling pathway inside the cell, which may block tumor cell growth. Tarceva is the only HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single agent.

In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. Tarceva is the first drug in a Phase III trial to have shown a significant improvement in overall survival when added to gemcitabine chemotherapy as an initial treatment for pancreatic cancer.

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

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. In the pancreatic cancer trial, other serious adverse events 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 side effects in patients with NSCLC receiving Tarceva monotherapy 150 mg were rash and diarrhea. The most common side effects in patients with pancreatic cancer receiving Tarceva 100 mg plus gemcitabine were fatigue, rash, nausea, anorexia and diarrhea.

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 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, 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.

CONTACT: OSI Pharmaceuticals, Inc.
Kathy Galante - investors/media, 631-962-2043
or
Kim Wittig - media, 631-962-2135
or
Burns McClellan, Inc. (representing OSI)
Justin Jackson - media
Carney Noensie - investors
212-213-0006

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