OSI Pharmaceuticals Announces Notification of ANDA Filing for Tarceva

MELVILLE, N.Y.--(BUSINESS WIRE)--Feb. 10, 2009-- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today receipt of a Paragraph IV Certification Notice Letter advising that Teva Pharmaceuticals USA, Inc. submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of Tarceva® (erlotinib).

OSI is currently reviewing the Notice Letter and has 45 days from the date of receipt to commence a patent infringement lawsuit against Teva and expects to file suit in that time frame. Tarceva is currently protected by three patents that are listed in the FDA's Approved Drugs Products List (Orange Book). A lawsuit brought with respect to one or more of those patents would restrict the FDA from approving Teva's ANDA until May 18, 2012 (the statutory stay period), unless an adverse court ruling occurs prior to such time.

About the Paragraph IV / ANDA Process

Under the Hatch-Waxman Act of 1984, generic companies have the opportunity to file an ANDA after the fourth anniversary of the FDA approval of an innovator's New Drug Application (NDA) of a drug with a new chemical entity, provided they allege (through a Paragraph IV certification) that the Orange Book-listed innovator patents are invalid and/or unenforceable or will not be infringed. Recent examples of this include Teva's ANDA filings for a generic form of Lilly's Alimta and Gilead's Truvada. An ANDA filing often causes the filing and commencement of patent infringement litigation by the innovator company, which results in a prohibition of FDA approval of that ANDA before the statutory stay period has expired.

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.

Source: OSI Pharmaceuticals, Inc.

OSI Pharmaceuticals, Inc.
Investors/Media:
Kathy Galante, Senior Director
or
Media:
Kim Wittig, Director
631-962-2000
or
Burns McClellan, Inc. (representing OSI)
Media:
Justin Jackson/Kathy Nugent, 212-213-0006