OSI Pharmaceuticals Seeks to Strengthen Tarceva Patent by Filing Re-Issue Application with the U.S. Patent and Trademark Office

MELVILLE, N.Y.--(BUSINESS WIRE)--Feb. 27, 2008--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that it has filed with the U.S. Patent and Trademark Office an application to reissue its composition of matter patent for Tarceva® (erlotinib), U.S. Patent No. 5,747,498 (the '498 patent), 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 seeks 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. While the reissue application is pending, the '498 patent remains listed in the Orange Book with the FDA and enforceable against any infringer.

"The generic industry is employing increasingly aggressive tactics toward innovator intellectual property rights, with challenges to IP around the world becoming increasingly common," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "We view eliminating these errors as soon as possible as the best approach to defending against any challenge to our Tarceva intellectual property position and have settled on a strategy to reissue the core '498 patent. We remain confident in the ultimate core composition of matter protection of Tarceva and view the reissue filing as a prudent step, given the current environment, in order to manage any prospective generic challenge to the patent estate and to address concerns associated with any possible future litigation."

OSI - together with Genentech, Inc. and Roche - has continually assessed the Tarceva intellectual property estate around the world, with particular attention to the United States, where the five year data exclusivity under Hatch-Waxman expires on November 18, 2009. Under U.S. law, a generic manufacturer can file an Abbreviated New Drug Application (ANDA) with the FDA on the fourth anniversary of the original approval (November 18, 2008 for Tarceva), provided it asserts that it does not infringe the innovator IP or that IP is invalid or unenforceable.

"Should any ANDA filing occur we would, of course, file suit and aggressively assert our rights. We believe we have a strong case for the inventiveness of Tarceva and are confident that a favorable outcome will be achieved," added Dr. Goddard.

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, a rejection of the reissue application, challenges to OSI's intellectual property, any adverse litigation decisions, competition from other pharmaceutical companies, the ability to effectively market products, OSI's and its collaborators' abilities to successfully develop and commercialize drug candidates, the completion of clinical trials, the FDA review process and other governmental regulation, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission.

CONTACT: 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 (media)

Kathy Nugent (media)
212-213-0006

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