(osi) pharmaceuticals

OSI Reiterates Confidence in Tarceva

MELVILLE, N.Y.--(BUSINESS WIRE)--Oct. 12, 2005--OSI Pharmaceuticals, Inc. (NASDAQ:OSIP) today reiterated its confidence in the launch year performance and long-term prospects of its flagship anti-cancer drug Tarceva® (erlotinib). The announcement follows the release of third quarter Tarceva U.S. sales data by Genentech, Inc., the company's U.S. partner for Tarceva, in their third quarter press release and conference call.

"Tarceva continues on-track for an impressive launch year performance and is en route to become one of the top four oncology launches in the U.S.," stated Colin Goddard, Chief Executive Officer of OSI. "We estimate that third quarter performance of Tarceva reflects a solid 12-15 percent quarter-on-quarter growth in the overall market share for the brand."

Genentech reported third quarter U.S. net sales of Tarceva of $73.2 million, up from $70.2 million in the second quarter and $47.6 million in the first quarter. However, Genentech also commented that average inventory levels at the wholesaler level have been varied with $10 million in the first quarter, $17.5 million in the second quarter and $16.5 million in the third quarter. The impact of this is to imply stronger than actual performance in the second quarter and weaker than actual performance in the third quarter. The growth in Tarceva use is supported by prescription and market research tracking data. The market research tracking data show that Tarceva's share of the second-line NSCLC market increased from 24 to 29 percent in the third quarter and that of the third-line NSCLC market from 42 to 47 percent.

The third quarter also saw continued progress in the joint OSI/Genentech/Roche development program for Tarceva. The FDA's Oncologic Drugs Advisory Committee (ODAC) voted 10-3 in favor of approving Tarceva for front-line use in pancreatic cancer in combination with gemcitabine at its meeting on September 13th. The PDUFA date for this supplemental NDA is November 2, 2005. In addition, Phase III label expansion studies are either close to initiation or have been initiated in front-line NSCLC, ovarian cancer and colorectal cancer, and an OSI-managed Phase III trial in the adjuvant setting in NSCLC is in the advanced stages of planning.

"Successful oncology drugs are built on the back of strong science and extensive clinical development programs. In addition to the Phase III trial program there are over 130 ongoing or pending clinical trials for Tarceva exploring its use as a single agent or in combination with both other targeted therapies and conventional chemotherapy agents in a wide range of different cancers," stated Gabe Leung, President of (OSI) Oncology. "The widespread importance of the EGFR signaling pathway in human cancer is well-documented, and we have also embarked upon a strong biomarker research program aimed at better identifying patients who can most benefit from Tarceva use. We remain very confident in the long-term prospects for Tarceva to emerge as a major therapeutic option in the treatment of human cancer."

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to "shaping medicines and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products that extend life or improve the quality of life for cancer and diabetes patients worldwide. The company operates through two business teams, (OSI) Oncology and (OSI) Prosidion. (OSI) Oncology is focused on developing molecular targeted therapies designed to change the paradigm of cancer care. (OSI) Prosidion is 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. OSI markets Tarceva through partnerships with Genentech, Inc. in the U.S. and with Roche throughout the rest of the world. For additional information about OSI, please visit http://www.osip.com.

In addition to Tarceva, (OSI) Oncology exclusively markets Novantrone® (mitoxantrone concentrate for injection) for its approved oncology indications and markets Gelclair® Bioadherent Oral Gel for the relief of pain associated with oral mucositis. The research and development pipeline consists of novel molecularly targeted anti-cancer agents focused on signal transduction pathways involved in cell proliferation, apoptosis and angiogenesis. The most advanced of these programs, targeting the co-inhibition of c-kit and VEGFR, has two candidates in development.

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.

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