OSI Pharmaceuticals Initiates Phase II 'Dose-to-Rash' Dose Escalation Study for Tarceva--erlotinib HCl--

MELVILLE, N.Y.--(BUSINESS WIRE)--Nov. 10, 2003--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) today announced that it has initiated a Phase II dose-escalation study of Tarceva™ (erlotinib HCl) in patients with advanced non-small cell lung cancer (NSCLC) who have failed prior chemotherapy. Tarceva™, OSI's leading drug candidate, is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR receptor thereby blocking the HER1/EGFR signaling pathway inside the cell. Tarceva™ is being developed in a global alliance between OSI, Genentech and Roche.

This open-label study is designed to evaluate the feasibility of dose escalation of Tarceva™ to induce tolerable rash with no other undue toxicities and to assess whether there is evidence of enhanced activity in patients who have developed rash. The study is designed to explore the previously reported observation that survival of patients who developed rash in the completed Phase II studies of Tarceva™ was longer than in those without rash, generating the hypothesis that rash might be a surrogate for patient's benefit.

"The observed correlation between rash and survival previously reported with Tarceva™ and some other agents targeting the HER1/EGFR pathway is intriguing and of particular interest to the oncology community," stated Dr. Eric Rowinsky, Principal Investigator and Director of Clinical Research, Institute for Drug Development. "More importantly, this potential opportunity to maximize the clinical benefit of Tarceva™ to cancer patients warrants further exploration."

About Tarceva™

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is critical to cell growth in many cancers. HER1, also known as EGFR, is a key component of the HER signaling pathway, which often is involved 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 blocks tumor cell growth. Tarceva™ currently is being studied as an oral dosage tablet.

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company focused on the discovery, development and commercialization of high-quality, next-generation oncology products that both extend and improve the quality-of-life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic agents and novel mechanism-based, gene-targeted therapeutics focused in the areas of signal transduction and apoptosis. OSI's most advanced drug candidate, Tarceva™ (erlotinib HCl), a small-molecule inhibitor of the HER1 gene, is currently in Phase III clinical trials for lung and pancreatic cancers. OSI has a commercial presence in the U.S. oncology market where it exclusively markets Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications and Gelclair™ for the relief of pain associated with oral mucositis.

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, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

CONTACT: OSI Pharmaceuticals, Inc.
Kathy Galante, 631-962-2000
or:
Burns McClellan (representing OSI)
Media:
Kathy Jones
Investors:
E. Blair Schoeb
212-213-0006