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OSI Pharmaceuticals Announces Tarceva International Phase III Refractory / Advanced Non-Small Cell Lung Cancer Clinical Trial Has Reached Its Target Enrollment Goal

MELVILLE, N.Y.--(BUSINESS WIRE)--Jan. 30, 2003--OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) announced today that the Phase III clinical trial evaluating the investigational therapy, Tarceva™ (erlotinib HCl), as monotherapy for the treatment of second or third-line patients with incurable stage IIIB/IV non-small cell lung cancer (NSCLC) for whom the standard chemotherapy has failed has reached its target enrollment of 700 patients. Tarceva™ is a small molecule HER1/EGFR inhibitor being developed through a tripartite alliance with OSI, Genentech, and Roche. With today's announcement the alliance has now completed target enrollment for all four major Phase III trials for Tarceva™ involving approximately 3,500 patients.

In September, the U.S. Food and Drug Administration designated Tarceva™ a Fast Track Product for second or third-line treatment of patients with incurable stage IIIB/IV NSCLC. The sample size of the second/third-line NSCLC trial, which is being conducted in collaboration with the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), was increased from 330 to approximately 700 patients to provide a more robust data set with which to examine improvement in patient survival and other potential clinical benefits of Tarceva™.

"As the only ongoing single-agent, randomized placebo-controlled study of an HER1/EGFR targeted agent designed to detect a survival advantage in advanced NSCLC, we believe this study to be of fundamental importance to the development of agents targeting HER1/EGFR. The management of this study remains OSI's highest clinical priority," stated Colin Goddard, Ph.D., Chief Executive Officer of the Company.

The FDA also designated Tarceva™ a Fast Track Product for the treatment of chemotherapy-naive stage III/IV NSCLC patients in May 2002. Completion of patient enrollment in both the U.S. and worldwide (ex U.S.) randomized, Phase III clinical trials evaluating Tarceva™ in combination with standard chemotherapy for patients with chemotherapy-naive stage IIIB/IV NSCLC was announced in the fourth quarter of OSI's fiscal year 2002. Both of these ongoing studies were enrolled within a year of study initiation. Approximately 1,050 patients were enrolled in the Genentech sponsored U.S. trial and approximately 1,200 patients were enrolled in the international (ex U.S.) Roche sponsored trial.

Tarceva™ is a small molecule designed to target the human epidermal growth factor receptor (HER1) pathway, which is critical for cell growth in many cancers. HER1/EGFR is a key component of the HER signaling pathway, which is often involved in the formation and growth of numerous cancers. Tarceva™ is designed to inhibit specifically the tyrosine kinase activity of HER1/EGFR, thereby blocking the signaling pathway with the intent of potentially inhibiting tumor cell growth.

OSI Pharmaceuticals, Inc. 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. The Company has a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic agents and novel mechanism-based, gene-targeted therapeutics.

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, pharmaceutical collaborators' ability 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™ (erlotinib HCl) is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

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