

OSI Pharmaceuticals Announces Completion Of Initial Cohort In Phase III Pancreatic Cancer Trial For Tarceva

MELVILLE, N.Y., May 2, 2002 (BW HealthWire) -- OSI Pharmaceuticals announced today that it has completed the initial stage of the on-going Phase III trial for Tarceva™ (erlotinib HCl, OSI-774), in pancreatic cancer. The Phase III study is being conducted by OSI in collaboration with the National Cancer Institute of Canada Clinical Trials Group and is an 800 patient randomized, controlled study assessing the use of Tarceva™ in combination with gemcitabine (Gemzar®), the only approved front-line chemotherapy treatment for pancreatic cancer. Improvement in patient survival is the primary end-point in this study.

The initial cohort was used to assess the safety of daily doses of Tarceva™ when combined with the approved dose and schedule of gemcitabine used in the treatment of pancreatic cancer. This initial phase of the study was conducted in selected centers because patients with pancreatic cancer are typically seriously ill and often less tolerant to combinations of anti-cancer drugs. Results to date indicate the combination of 100mg/day of Tarceva™ with gemcitabine appears to be the appropriate dose for this patient population. The trial is now entering an expanded phase that includes opening all international sites as soon as possible with safety monitoring continuing throughout the study as is customary in these types of trials. Over 200 sites will be activated in this study which will encompass more than 20 countries. OSI intends to provide investors with clear guidance on the timeline for likely completion of this study when the majority of sites are activated and sufficient patient accrual data is available for the expanded program. OSI anticipates this will occur by late summer.

"We are pleased to have completed this first phase of the pancreatic cancer program and with the overall progress of the comprehensive global development plan that we are carrying out together with our alliance partners Genentech and Roche," stated Colin Goddard, Ph.D., Chairman and Chief Executive Officer.

The American Cancer Society estimates that 29,200 Americans were diagnosed with cancer of the pancreas during 2001. Studies indicate that between 60% and 90% of these patients have tumors that either over-express the EGFR gene or contain a mutant form of the gene. The treatment of pancreatic cancer remains a major unmet need; an estimated 28,900 Americans were expected to die of the disease in 2001, making this type of cancer the fourth leading cause of cancer death in the United States. Only approximately 19% of patients with cancer of the pancreas survive at least one year after diagnosis and the five-year survival rate is only 4%.

Non-Small Cell Lung Cancer Program

The Company also noted that all three Phase III trials in non-small cell lung cancer (NSCLC) are proceeding according to plan. The NSCLC program is the main initial indication targeted for registration by the alliance. OSI's U.S. partner, Genentech, Inc., is conducting an approximately 1,000 patient, randomized, controlled study assessing the use of Tarceva™ in combination with carboplatin (Paraplatin®) and paclitaxel (Taxol®), the most commonly used front-line combination chemotherapy regimen in the U.S. OSI's partner outside of the U.S., Roche, is conducting an approximately 1,000 patient, randomized controlled study assessing the use of Tarceva™ in combination with gemcitabine (Gemzar®) and cisplatin (Platinol®), the most commonly used front-line combination chemotherapy regimen in Europe. In addition to the front-line program, OSI is conducting a 330 patient, randomized controlled study assessing the use of Tarceva™ as a single agent in patients who are refractory to first and second line chemotherapy treatment of NSCLC. The study is also being conducted in collaboration with the National Cancer Institute of Canada Clinical Trials Group and is the only randomized Phase III study comparing the potential benefits of monotherapy use of an EGFR inhibitor (Tarceva™) to best supportive care in refractory lung cancer patients. The primary end-point in all three studies is improvement in patient survival with secondary end-points including improvement in patient quality-of-life. Daily (150mg) doses of Tarceva™ are being used in all three studies.

OSI Pharmaceuticals is a leading biopharmaceutical company primarily focused on the discovery, development and commercialization of innovative products for the treatment of cancer. OSI has built a pipeline of discovery programs and drug candidates addressing major, unmet medical needs in cancer and selected opportunities, including diabetes, arising from its extensive drug discovery research programs that represent significant commercial opportunities outside of cancer. OSI's most advanced drug candidate, Tarceva™ (erlotinib HCl, OSI-774), a small molecule inhibitor of the EGFR gene, is currently in Phase III clinical trials for lung and pancreatic cancers.

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, uncertainties related to the identification of lead compounds, the successful pre-clinical development thereof, 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, product pricing and third party reimbursement, and other factors described on OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ (erlotinib HCl, OSI-774) is an investigational compound and has not yet been determined safe or efficacious in humans for its ultimate intended use.

Additional information on OSI Pharmaceuticals is available at www.osip.com

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