

Data from Tarceva-TM- Clinical Trial Program Presented at American Society of Clinical Oncology Annual Meeting; EGFR Amplification / Mutation Analysis from the Registration BR.21 Trial Presented

ORLANDO, Fla., May 16, 2005 (BUSINESS WIRE) -- OSI Pharmaceuticals (Nasdaq:OSIP) provided an informational update summarizing highlights from presentations on the analysis of EGFR mutation and gene amplification from the Tarceva™ registration study (Trial BR.21) in non-small cell lung cancer (NSCLC) made at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO) being held from May 14-17 in Orlando, Fla. The presentation included analyses of EGFR protein status, gene amplification and mutations from the pivotal BR.21 study in NSCLC. These results represent the first detailed assessment of the characteristics of EGFR expression in a large randomized, placebo-controlled, Phase III trial and have provided additional insights into the role EGFR plays in NSCLC. The authors concluded that the survival benefit from Tarceva therapy that was seen for essentially all sub-sets of patients in the BR.21 study was greater, although not significantly, for patients whose tumors expressed EGFR protein and for those patients whose tumors possessed an abnormally high copy number of the EGFR gene. Importantly, the study showed that patients whose tumors had mutations in their EGFR genes experienced no greater survival benefit than patients whose tumors expressed the non-mutated - or "wild-type" - form of the gene. The authors concluded that mutation analysis is not necessary to select patients for treatment with EGFR inhibitors. Tarceva is the only EGFR inhibitor to have demonstrated a survival benefit in NSCLC, Tarceva's label does not limit prescribing to sub-set populations and it does not require testing for EGFR expression or mutation prior to use.

"We believe the molecular analysis of samples from the BR.21 study will be of great interest to investigators in NSCLC and we believe the affirmation of a survival benefit in patients whose tumors have wild-type EGFR is of particular importance," stated Gabe Leung, President of (OSI) Oncology. "We are committed to continuing to work toward gaining a better understanding, through prospectively planned clinical studies, of how EGFR and other gene markers might help in identifying cancer patients most likely to benefit from Tarceva therapy. However, we also believe that the currently available data are inconclusive and do not support making treatment decisions that could exclude patients who may benefit from Tarceva therapy."

Molecular Analysis of Epidermal Growth Factor Receptor (EGFR) Gene and Protein Expression in Non-small Cell Lung Cancer Patients Treated with Erlotinib in National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) Trial BR.21 - Ming-Sound Tsao, M.D. et al (Abstract # 7007)

The presentation both updated previous analyses of EGFR protein expression by immunohistochemistry (IHC) that were reported in the Tarceva label and reported new results based on an analysis of available tissue samples for abnormal gene copy number, using a technique called fluorescence in-situ hybridization (FISH), and for EGFR mutations. Analyses were carried out on sub-sets of patient tumor samples that were available for each technique.

Some researchers have speculated that only patients harboring EGFR mutations in their tumors would derive significant benefit from Tarceva therapy. Samples from 177 of the 731 patients in the study were successfully analyzed for possible mutations in the EGFR gene. The results confirmed previous observations that the tumor response rate was higher in the sub-set of patients with mutations, however, when survival was assessed, there was no apparent difference in survival benefit between those patients with wild-type or mutated EGFR in their tumors ("wild-type" EGFR: Hazard Ratio = 0.73; "Mutated" EGFR: Hazard Ratio = 0.77). A statistically significant improvement in survival (Hazard Ratio of 0.73) was reported for the overall population of patients in the BR.21 study.

Samples from 125 patients were available for FISH analysis of EGFR copy number. Analysis of the data showed that patients found to have a high copy number also had a more robust survival benefit (Hazard Ratio = 0.44) than those with low copy number (Hazard Ratio = 0.86). Updated analyses including additional samples were presented for EGFR expression measured by IHC. Forty-four percent (235 / 731) of the patient tumor samples were available for analysis. Fifty-seven percent of the patients were determined to be EGFR positive by IHC using the criteria applied by the investigators and these patients had a significant survival benefit (Hazard Ratio = 0.68). A non-statistically significant Hazard Ratio of 0.93 was reported for the EGFR negative group.

About Tarceva

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, which is one of the factors critical to cell growth in non-small cell lung cancer (NSCLC) and other solid tumors. HER1, also known as EGFR, is a component of the HER signaling pathway, which plays a role 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 may block tumor cell growth. Tarceva is the only HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single-agent.

Tarceva was approved by the FDA in November 2004 and is an oral tablet indicated for daily administration for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Results from two earlier large, randomized, placebo-controlled clinical trials in first-line advanced NSCLC patients showed no clinical benefit with concurrent administration of Tarceva with doublet platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

Additional early-stage trials of Tarceva are being conducted in other solid tumors. In April 2005, OSI submitted a supplemental New Drug Application (sNDA) with the FDA for use of Tarceva plus gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received any previous treatment. Tarceva is the only HER1/EGFR-targeted therapy proven to significantly prolong survival in first-line locally advanced or metastatic pancreatic cancer in combination with gemcitabine.

For Tarceva full prescribing information, please call 1-877-Tarceva or visit <http://www.Tarceva.com>.

Tarceva Safety Profile

In the pivotal NSCLC trial, the most common adverse reactions in patients receiving Tarceva were rash and diarrhea. Grade 3/4 rash and diarrhea occurred in 9 and 6 percent of Tarceva-treated patients, respectively. Rash and diarrhea each resulted in discontinuation of 1 percent of Tarceva-treated patients. Dose reduction for rash and diarrhea was needed for 6 and 1 percent of patients, respectively. Historically, there have been infrequent reports of serious interstitial lung disease (ILD), including fatalities, in patients receiving Tarceva for treatment of NSCLC or other advanced solid tumors. In the pivotal trial in NSCLC, severe pulmonary reactions, including potential cases of interstitial lung disease, were infrequent (0.8 percent) and were equally distributed between treatment arms. The overall incidence of ILD in Tarceva-treated patients from all NSCLC studies was approximately 0.7 percent.

About OSI Pharmaceuticals

OSI Pharmaceuticals is committed to shaping medicines and changing patients' 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 II 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 the company, please visit <http://www.osip.com>.

About (OSI) Oncology

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.

Regarding OSI

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.

SOURCE: OSI Pharmaceuticals

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