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Data from Tarceva Clinical Trial Program Presented at American Society of Clinical Oncology Annual Meeting

ORLANDO, Fla., May 17, 2005 (BUSINESS WIRE) -- OSI Pharmaceuticals (Nasdaq: OSIP)

-- First-Line, Monotherapy Non-Small Cell Lung Cancer Data Presented

-- Symptom Response / Quality of Life Analysis from the Registration BR.21 Trial Presented

-- Updates from Ongoing Phase II Program in Additional Indications

OSI Pharmaceuticals (Nasdaq: OSIP) provided a second informational update summarizing highlights from presentations on Tarceva™ (erlotinib) made at the 41st Annual Meeting of the American Society of Clinical Oncology (ASCO) being held from May 14-17 in Orlando, Fla. The presentations included data from two separate single-arm Phase II studies of monotherapy Tarceva in chemotherapy-naive or front-line NSCLC patients. Both studies indicated encouraging indications of anti-tumor activity for monotherapy Tarceva in this setting. Another presentation based on data from the BR.21 study concluded that patients on Tarceva had slower deterioration of their disease-related symptoms of cough, dyspnea and pain and that these differences were clinically and statistically significant. Encouraging indications of anti-tumor activity were also reported in several Phase II studies outside of NSCLC including combination therapy data for Tarceva with Avastin in renal cell carcinoma, Tarceva with chemotherapy in head and neck cancer and monotherapy use of Tarceva in colorectal and hepatocellular cancer.

A Phase II Trial of Erlotinib in First-line Treatment for Advanced Non-small Cell Lung Cancer - Giuseppe Giaconne, M.D. et al (Abstract #7073)

Results from a Phase II, multi-center trial evaluating the efficacy and safety of Tarceva monotherapy as a first-line treatment in unselected patients with advanced NSCLC were presented.

Fifty-three patients were enrolled between January and July of 2004, treated with Tarceva at 150mg / day and evaluable for tumor response. Complete response (CR) was reported in 1 patient (2 percent), partial response (PR) was reported in 11 patients (21 percent) and 17 patients (32 percent) had stable disease. Responses were observed in both males (1CR, 3PR) and females (8 PR). Median time to progression was 94 days, however the median survival had not been reached at the time of the analysis. Thirty-six of 53 patients were still alive at the time of the analysis and to date 12 patients have been treated for over 6 months. Tarceva demonstrated encouraging activity in this unselected, front-line setting for patients with advanced NSCLC.

As expected, the most common treatment-related adverse events were rash (87 percent) and diarrhea (60 percent) which were primarily grades 1 and 2.

Phase II Study of the EGFR Tyrosine Kinase Inhibitor Erlotinib (Tarceva) In Patients Greater Than or Equal to 70 Years of Age with Previously Untreated Advanced Non-small Cell Lung Carcinoma - David M Jackman, M.D. et al (Abstract # 7148)

Results from a Phase II study of patients 70 years of age or older with previously untreated advanced NSCLC were presented.

Seventy-six patients were evaluated at time of data presentation and treated with Tarceva at 150mg / day. Partial response was noted in 8 patients (12 percent) and 32 patients (48 percent) had stable disease of the 66 patients evaluable for response. Median survival was 11 months and median duration of partial response has not been reached. Median survival for patients with stable disease was 12 months. Tarceva demonstrates encouraging activity as a front-line treatment in patients 70 years of age and older with previously untreated advanced NSCLC.

As expected, rash (75 percent) and diarrhea (61 percent) were the most common side effects seen in the study and 3 cases of interstitial pneumonitis were reported. Nine patients were discontinued from the study due to toxicity and there was one treatment-related death (due to pneumonitis) in this population of patients aged 70 years or older.

Symptom Response in Non-small Cell Lung Cancer (NSCLC) Patients Treated with Erlotinib: Quality of Life Analysis of the NCIC CTG BR.21 Trial - A. Bezjak, M.D. (Abstract #7018)

The presentation summarized results of an analysis of the BR.21 data set on the self-assessment surveys patients were asked to complete in order to assess any changes in the key lung cancer-related symptoms of cough, dyspnea and pain. The

protocol employed the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire and the QLQ-LC13 lung cancer module for this purpose. Tarceva was shown to significantly delay the deterioration in symptoms for cough (median for Tarceva = 4.9 months versus 3.7 months for placebo; p=0.04), dyspnea (median for Tarceva = 4.7 months versus 2.9 months for placebo; p=0.01) and pain (median for Tarceva = 2.8 months versus 1.9 months for placebo; p=0.02) and 35% of patients in the study reported an improvement in their overall quality of life.

Bevacizumab and Erlotinib in the Treatment of Patients with Metastatic Renal Carcinoma (RCC): Update of a Phase II Multi-center Trial - D.R. Spigel, et al (Abstract #4540)

This single-arm Phase II study, presented by David Spigel, M.D., of the Sarah Cannon Cancer Center in Nashville, provided interim results from 63 patients, 59 of which were evaluable for analysis, with metastatic renal cell carcinoma treated with a combination of Avastin and Tarceva. All patients received Avastin 10 mg/kg every two weeks and 150mg Tarceva daily. After median follow-up of 21 months, the study found that 25 percent (15/59) of patients demonstrated an objective response to the treatment combination while 61 percent (36/59) had either stable disease or a minor response. Median progression-free survival was 11 months. Median survival has not yet been reached, however one and two year survival were estimated at 76 and 44 percent, respectively.

A preliminary assessment of safety showed that two patients discontinued treatment because of skin toxicity and one patient experienced a serious (Grade 4) gastrointestinal bleed. Grade 3/4 adverse events included diarrhea (13 percent, 8/63), rash (13 percent, 8/63), nausea/vomiting (10 percent, 6/63), hypertension (10 percent, 6/63), bleeding (8 percent, 5/63), proteinuria (8 percent, 5/63) and pruritus (3 percent, 2/63).

Phase II Study of Combination Cisplatin, Docetaxel and Erlotinib in Patients with Metastatic/Recurrent Head and Neck Squamous Cell Carcinoma (HNSCC) - E.S. Kim (Abstract #5546)

Encouraging preliminary data was presented from an ongoing Phase II trial combining Tarceva with cisplatinum and docetaxel in HNSCC. Results were reported for the 22 patients evaluable for response. Complete response was reported in 3 patients (13 percent), partial response was reported in 14 patients (64 percent) and 4 patients (18 percent) were reported having stable disease. Responses were documented using RECIST. No unanticipated toxicities were evident from the combination. One patient experienced grade 4 febrile neutropenia and 6 patients had grade 3 neutropenia and 15 patients had rash grade 1/2 rash and grade 3 rash was reported for 1 patient. The trial continues to accrue patients.

Phase II Study of Erlotinib as 2nd and 3rd line Monotherapy in Patients with Metastatic Colorectal Cancer. Results of a Multi-center Two Cohort Phase II Trial - U. Keilholz (Abstract #3575)

Data were presented for 51 patients who were treated with Tarceva after either one (cohort 1) or two (cohort 2) prior 5-FU based chemotherapy regimens containing either irinotecan and /or oxaliplatin. Two partial responses were seen in cohort 1 and overall 15 patients had either a partial response or disease stabilization. The authors noted that this was the first time objective tumor responses had been observed in colorectal cancer using an oral EGFR inhibitor. As expected, the principal toxicities for Tarceva in this setting were rash and diarrhea.

A Phase II Open Label Study of OSI-774 (NSC 718781) in Unresectable Hepatocellular Carcinoma - M.B. Thomas (Abstract #4038)

Preliminary results were presented for an ongoing Phase II study enrolling patients to two sub-groups based on a determination of high or low EGFR expression, measured by immunohistochemistry (IHC). The primary endpoint in the study is progression-free survival at 16 weeks. Data presented to date showed that 8 out of 32 patients (or 25 percent) had met the endpoint overall including 2 minor responses in the first 22 evaluable patients. No apparent differences were evident between high and low EGFR expressors. One patient remained on Tarceva for 16 months. The median survival for patients in the study was 25 weeks. Rash was the primary drug-related toxicity (84 percent) and no patients to date were reported to require dose reduction or removal from the trial due to drug-related toxicity.

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 EGFR 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 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.

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