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OSI Summarizes Key Clinical Data for Tarceva - erlotinib HCl - Presented at ASCO

CHICAGO, Jun 3, 2003 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) provided a summary of key results from a series of studies on the Company's leading investigational anti-cancer drug, Tarceva™ (erlotinib HCl), that were presented at the 2003 Annual Meeting of the American Society of Clinical Oncology (ASCO). Data presented included promising evidence of anti-tumor activity for monotherapy Tarceva™ in two disease settings generally considered to be resistant or unresponsive to chemotherapy, Bronchioloalveolar Cell Carcinoma (BAC) and Glioblastoma Multiforme (GBM). A retrospective analysis of Phase II study data was also presented in support of the Company's previous observations that dosing Tarceva™ at levels producing rash may correlate with survival. In addition, early data were presented studying the use of Tarceva™ in combination with Avastin™ (bevacizumab, rhuMAb-VEGF), another investigational novel targeted therapy. Tarceva™ is designed to inhibit the tyrosine kinase activity of the HER1/EGFR signaling pathway inside the cell, which may block tumor cell growth. Tarceva™ is being developed by a global alliance between OSI, Genentech, Inc. and Roche.

Encouraging Indications of Activity Seen for Tarceva™ in Patients with Bronchioloalveolar Cell Carcinoma and Glioblastoma Multiforme

In the BAC Phase II study, patients were enrolled following pathological confirmation that their tumor was either pure BAC, adenocarcinoma with a BAC component or BAC with focal invasion. Dr. Miller, of Memorial Sloan-Kettering Cancer Center, reported that as many as 20 percent of all NSCLC patients are estimated to fall into this category.

Of the 50 patients who were treated with Tarceva™, 13 patients (26 percent) achieved a partial response. Of the 13 responders, 6 patients (46 percent) never smoked. The study is ongoing and has been expanded to 100 patients. The median duration of response has not yet been reached. Dr. Miller reported that the activity of Tarceva™ in non-smokers is particularly encouraging. Side effects have been similar to those observed in previous Phase II studies of Tarceva™, with all but one patient developing rash and one patient experiencing grade 3 diarrhea.

In GBM, Dr. Michael Prados of the University of California San Francisco had earlier reported that, in a total of 49 evaluable patients, 8 partial responses (16 percent), 3 minor responses (6 percent) and 11 stable disease (22 percent) were observed in a Phase I dose escalation study of Tarceva™. Rash and occasional diarrhea were also reported in this study. Based on these results, OSI and Genentech have already committed to initiate a Phase II program in GBM.

"We are pleased with these encouraging indications of anti-tumor activity in these two disease settings which have historically been so challenging to treat," stated Colin Goddard, Ph.D., Chief Executive Officer of the Company. "These results further suggest that Tarceva™ will have utility in the treatment of multiple forms of cancer."

Rash Severity May Correlate with Increased Survival (Abstract #786)

Dr. Gary Clark et al presented results from a retrospective analysis that evaluated the correlation between the occurrence and severity of rash and survival for patients who received Tarceva™ in previous Phase II studies. Three single-agent Phase II trials using 150mg per day of Tarceva™ in patients with refractory NSCLC (n=57), head and neck (n=115), and ovarian (n=34) cancers were analyzed. The incidence of rash in each study was 75 percent, 79 percent, and 82 percent respectively.

In all three trials, patients with rash had longer survival than those without rash and the duration of survival was correlated with the severity of rash. However, the study authors reported little or no correlation between the incidence or grade of rash and HER1/EGFR levels measured in pretreated tumor samples. This analysis supports the Company's belief that this higher dose strategy may translate into an improved survival benefit in larger, randomized and controlled Phase III studies.

Median Survival in Days (# patients)

Rash Grade	NSCLC (n=57)	H&N (n=115)	Ovarian (n=34)
0	46 days (n=14)	120 days (n=24)	109 days (n=6)
1	257 days (n=26)	153 days (n=29)	224 days (n=12)

(Greater Than or Equal To) 2	597 days (n=17)	224 days (n=62)	352 days (n=16)

Based on this analysis, the alliance of OSI, Genentech and Roche is moving forward with a Phase II dose-to-rash study in NSCLC to explore if all patients can be safely dosed to rash and to further study the association of dose with rash and activity.

Early Study of Tarceva™ and Avastin™ in Non-Small Cell Lung Cancer

An interim report was also presented at ASCO for a study evaluating the combination of Tarceva™ with another targeted therapy--Genentech's Avastin™ (bevacizumab, rhuMAb-VEGF)--in patients with recurrent NSCLC. The combination of two drugs with novel mechanism of action in Tarceva™, which targets the HER1/EGFR signaling pathway and Avastin™, an anti-angiogenic agent, is considered particularly promising. Early data reported from twelve patients showed three (25%) partial responses, five (42%) stable disease and four (33%) progressive disease. The most common side effects were mild to moderate instances of rash, diarrhea and nausea. This Phase I/II study continues to enroll patients.

Global Clinical Development Program

More than 3,500 patients currently are enrolled in the overall Phase III clinical trial program for Tarceva™. The Tarceva™ Phase III program in NSCLC consists of three Phase III randomized studies: an OSI trial, conducted in collaboration with the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG), assesses Tarceva™ as a single agent versus placebo in a refractory (second/third-line) setting, and two trials-- one conducted by Genentech and the other by Roche-- are designed to assess Tarceva™ as a first-line agent in combination with approved chemotherapy regimens. All Phase III NSCLC trials have completed enrollment and are progressing as planned. Data from the second/third-line NSCLC study are anticipated in late 2003 or early 2004.

OSI also is sponsoring a Phase III trial evaluating Tarceva™ in patients with previously untreated advanced pancreatic cancer. This Phase III study also is being conducted in collaboration with the NCIC CTG and is a randomized, placebo-controlled study assessing the use of Tarceva™ in combination with gemcitabine, the only approved first-line chemotherapy treatment for pancreatic cancer. Improvement in patient survival is the primary endpoint in this study.

Safety Information

Analysis to date of more than 2,000 patients in the overall Tarceva™ safety database from all ongoing and completed alliance studies with Tarceva™ has continued to show an adverse event profile consistant with previous observations including rash and diarrhea. The alliance has seen a few cases of pneumonitis in Tarceva™ trials, which also have been reported for other HER1/EGFR targeted agents. Incidence observed to date, however, is at a level well within expectations for this patient population.

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 a once-a-day oral tablet.

The alliance of OSI, Genentech and Roche provides all of the essential elements for the rapid, comprehensive and competitive development of Tarceva™, including extensive experience with targeted therapy research, demonstrated comprehensive development, and marketing expertise of next-generation cancer therapies in the United States and globally.

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.

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.

SOURCE: OSI Pharmaceuticals, Inc.

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