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OSI Pharmaceuticals and Genentech Provide Update On Status of Tarceva Program

MELVILLE, N.Y. & SAN FRANCISCO--(BW HealthWire)--Aug. 19, 2002--OSI Pharmaceuticals (NASDAQ: OSIP) and Genentech (NYSE: DNA) announced an update and commentary on the progress of the Companies' clinical trial candidate, Tarceva™ (erlotinib HCl). The announcement followed the release of top-line results on a competitor's drug candidate which belongs to the same class of HER1/EGFR targeted therapies as Tarceva™.

"Overall we continue to be pleased with the progress of our comprehensive Tarceva™ development program," stated Dr. Colin Goddard, Chairman and CEO of OSI. "Despite today's events, we also continue to believe that Tarceva™ and HER1/EGFR inhibitors in general, represent a potentially important new class of agents for the treatment of human cancer."

Although both drug candidates block the EGFR pathway, there are important differences between the agents and clinical programs including structure, formulation, pharmacokinetics and Phase III design and dosing. These may all play a role in the results of the Phase III trials. The Phase III program for Tarceva™ was built on previously disclosed Phase II data for the drug candidate which demonstrated encouraging indications of clinical activity in three separate single agent Phase II trials in refractory or advanced cancer patients with non-small cell lung, ovarian or squamous cell carcinoma of the head and neck.

The Tarceva™ Phase III program in non-small cell lung cancer (NSCLC) is being conducted as a global alliance between OSI, Genentech and Roche and consists of three Phase III randomized studies; one trial assesses Tarceva™ as a single agent in a refractory setting and two trials are designed to assess Tarceva™ as first-line agent in combination trials with approved chemotherapy regimens. The design of the study in refractory NSCLC is investigating the potential survival benefit of single agent Tarceva™ at 150mg/day. This is the only single agent controlled Phase III study of an EGFR targeted agent designed to detect a survival advantage in refractory non-small cell lung cancer.

The alliance's two front-line studies in non-small cell lung cancer are designed to assess the potential of survival benefit of Tarceva™ with standard chemotherapy. These trials contain noteworthy differences in study design versus those of the competitor trial results released today. The dose employed in the alliance's Phase III program of 150 mg/day is the apparent maximum tolerated dose (MTD) for this agent as determined in earlier Phase I studies. The choice of dose for the Phase III studies is based on the belief that this dosing strategy may be clinically important in the use of this agent. These studies are powered to demonstrate a 25% improvement in survival and are two-armed studies comparing Tarceva™'s MTD with combination chemotherapy versus combination chemotherapy alone.

All three NSCLC Phase III trials are progressing as planned. Accrual was recently completed for the first of the two front-line combination studies for Tarceva™ in non-small cell lung cancer (an approximately 1000 patient Genentech sponsored study combining Tarceva™ with carboplatin and Taxol®). Accrual to the other front-line combination study (an approximately 1000 patient Roche sponsored study combining Tarceva™ with gemcitabine and cisplatin) is currently on track. The single agent, refractory study (an approximate 330 patient OSI sponsored study in refractory NSCLC patients) is also progressing as planned.

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 the Company's extensive drug discovery research programs that represent significant commercial opportunities outside of cancer.

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Fifteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes ten biotechnology products directly in the United States. The company has headquarters in South San Francisco, California, and is traded on the New York Stock Exchange under the symbol DNA.

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 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.

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

CONTACT: Genentech, Inc.
Media: Neil Cohen 650/225-8681
Investors: Kathee Littrell 650/225-1034
or
OSI Pharmaceuticals
Kathy Galante, 631/962-2000