OSI Pharmaceuticals Updates Investors on Status of Tarceva Development Program

Protocol Modifications Announced for Front-line Non-Small Cell Lung Cancer Study

MELVILLE, N.Y., Apr 10, 2003 (BUSINESS WIRE) -- OSI Pharmaceuticals, Inc. (NASDAQ: OSIP) today updated investors on the status of the Tarceva™ development program. The broad-based global development plan for Tarceva™, being conducted in a global alliance between Genentech, OSI and Roche, continues to make steady progress in all three main disease indications: non-small cell lung cancer (NSCLC), pancreatic cancer and glioblastoma (brain cancer). TRIBUTE, the U.S. Phase III front-line NSCLC Tarceva™ combination study being conducted by Genentech, is fully enrolled and has survival as its primary endpoint (statistical analysis will be event driven). This trial's independent Data Monitoring Committee (DMC) conducted a planned review of safety and efficacy data in the Tarceva™ front-line NSCLC study and the DMC concluded that there was no safety or efficacy reason to warrant stopping the study.

In addition to concluding that the trial should continue, the DMC recommended that study treatment be discontinued at the time of disease progression or the start of second-line chemotherapy or radiation due to a safety signal. No specific details were given by the DMC, but they did not recommend any additional safety monitoring guidelines for the ongoing clinical program. Treatment beyond progression is a novel approach in oncology and had been attempted in this setting in an effort to maximize benefit.

The TRIBUTE trial was the only study in the Tarceva™ program where treatment beyond progression has been implemented to a significant extent, so this change does not impact other programs and is not expected to impact the timeline for top-line data results for either the TRIBUTE study or the other front-line Tarceva™ combination chemotherapy study, TALENT, being conducted by Roche. Data is anticipated in the second half of 2003.

The OSI second/third-line NSCLC trial and pancreatic study have both completed enrollment. The second/third-line NSCLC trial is the only large-scale Phase III randomized monotherapy study of an HER1 targeted drug with survival as the primary endpoint. If this study meets its primary endpoint, OSI believes it is well positioned to gain full FDA approval for this indication. Data from the OSI second/third-line NSCLC study is anticipated in late 2003 or early 2004. OSI also announced that the Phase I study in glioblastoma completed enrollment and that based on the data, a decision to continue with a Phase II study has been made. The data from the Phase I glioblastoma study have been submitted to ASCO. Multiple additional Tarceva™ abstracts have been submitted to ASCO, including data on the correlation of rash with survival.

Tarceva™ Safety Update

Analysis to date of the overall Tarceva™ safety database from all ongoing and completed alliance studies with Tarceva™ have shown no significant adverse event signals beyond the previously reported incidence of rash and diarrhea. It should be noted that we have seen a few cases of pneumonitis-related lung adverse events in global Tarceva™ trials (which have also been reported for other HER1 targeted agents). Incidence observed to date is at a level within expectations for this patient population. Also previously reported Phase Ib data have indicated some safety concerns when combining certain chemotherapy agents including Taxotere® with Tarceva™ at full doses in heavily pre-treated and advanced cancer patients.

OSI Pharmaceuticals, Inc. 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. 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's oncology product portfolio includes Novantrone® (mitoxantrone concentrate for injection), a U.S. FDA-approved treatment of acute nonlymphocytic leukemia and the relief of pain associated with advanced hormone-refractory prostate cancer.

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.

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