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OSI Pharmaceuticals and Genentech Enter into Co-Promotion and Manufacturing Agreements For Tarceva

MELVILLE, N.Y. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--June 16, 2004--OSI Pharmaceuticals, Inc. (Nasdaq:OSIP) and Genentech, Inc. (NYSE:DNA) today announced the companies have entered into two agreements detailing the roles of the two parties with respect to promotion, marketing and manufacturing responsibilities for the investigational drug Tarceva™ (erlotinib HCl) once it is approved for distribution in the United States. A Phase III clinical trial of Tarceva™ in relapsed non-small cell lung cancer was successfully completed and an New Drug Application (NDA) rolling submission to the U.S. Food and Drug Administration (FDA) is ongoing.

In January 2001, the companies signed an agreement for the co-development and commercialization of Tarceva™ in the United States. The agreements announced today include an amendment of the 2001 contract in order to further clarify the roles and responsibilities of OSI and Genentech around general principles outlined in 2001. As stated in the original agreement, Genentech will continue to be responsible for the marketing, launch and promotion of Tarceva™. OSI will assist with the promotion of Tarceva™ by providing at least 25 percent of the combined U.S. sales force. The companies will continue to share responsibility for the ongoing development of Tarceva™ post-launch. OSI is responsible for obtaining the current approval by the FDA and is working to complete the NDA for Tarceva™ during the summer of 2004.

The second agreement signed today is a manufacturing agreement covering OSI's responsibilities in this regard. OSI is responsible for commercial manufacturing and supply of Tarceva™ in the U.S. market.

"We have worked closely together with our colleagues at Genentech to detail the working relationship and responsibilities of each company in the post-launch environment," stated Colin Goddard, Ph.D., Chief Executive Officer of OSI Pharmaceuticals. "With the signing of these agreements we are even more confident that Tarceva™ will be positioned to compete effectively in the growing EGFR market in the U.S. once it is approved."

About OSI Pharmaceuticals

OSI Pharmaceuticals is a leading biotechnology company focused on the discovery, development and commercialization of high-quality, next-generation oncology products that both extend life and improve the quality-of-life for cancer patients worldwide. OSI has a balanced pipeline of oncology drug candidates that includes both novel mechanism-based, gene-targeted therapies focused in the areas of signal transduction and apoptosis and next-generation cytotoxic chemotherapy agents. OSI's most advanced drug candidate, Tarceva™, a small-molecule inhibitor of the HER1 gene, has successfully completed Phase III clinical trials for lung cancer and is subject to an ongoing rolling submission of an NDA. OSI has a commercial presence in the U.S. oncology market where it exclusively markets Novantrone® (mitoxantrone concentrate for injection) for approved oncology indications and Gelclair® for the relief of pain associated with oral mucositis. For additional information about the company, please visit http://www.osip.com.

About Genentech

Genentech is committed to changing the way cancer is treated by establishing a broad oncology portfolio of innovative, targeted therapies with the goal of improving patients' lives. The company is the leading provider of anti-tumor therapeutics in the United States. Genentech is leading clinical development programs for Rituxan® (Rituximab), Herceptin® (Trastuzumab), and Avastin™ (bevacizumab) and markets all three products in the United States either alone (Avastin, which it recently launched in the United States, and Herceptin) or with Biogen Idec Inc. (Rituxan). Genentech has licensed Rituxan, Herceptin and Avastin to Roche for sale by the Roche Group outside of the United States.

The company has a robust pipeline of potential oncology therapies with a focus on four key areas: angiogenesis, apoptosis (i.e. programmed cell death), the HER pathway and B-cell biology. Potential oncology therapies directed at the HER pathway include Tarceva™ (erlotinib) and a therapeutic antibody currently in Phase II trials. Also in early development are a small molecule directed at the hedgehog pathway, a therapy targeting apoptosis and a humanized anti-CD20 antibody for hematology/oncology indications.

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Eighteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 12 biotechnology products 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. For additional information about the company and complete prescribing information for marketed products, please visit http://www.gene.com.

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 successful marketing of products, product pricing and third-party reimbursement, 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, and other factors described in OSI Pharmaceuticals' filings with the Securities and Exchange Commission. Tarceva™ is an investigational compound and has not yet been approved as safe of efficacious in humans for its ultimate intended use.

The statement made in this press release relating to the expected timeframe for the NDA filing is forward-looking and actual results could differ materially. Among other things, the timeframe could be affected by manufacturing issues, additional time requirements for NDA preparation, discussions with the FDA, or FDA actions or delays.

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