SuperGen Announces 90 Day Extension of FDA Review Date for Orathecin(TM) New Drug Application

DUBLIN, Calif., Nov. 29 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) today announced that it received notification from the U.S. Food & Drug Administration (FDA) that the Agency extended the Pharmaceutical Drug User Fee Act (PDUFA) date for completing its review of the Orathecin™ (rubitecan) capsules New Drug Application (NDA) to February 26, 2005. Orathecin is SuperGen's investigational drug for the treatment of pancreatic cancer patients who have failed at least one prior chemotherapy regimen.

SuperGen submitted additional data from the Company's trial of Orathecin for use as a first-line pancreatic cancer treatment that had been requested by the FDA. The Company also included several new sets of data analysis to further evaluate Orathecin in second and third line patients. Submission of this additional data was classified as a major amendment by the FDA, which allowed the Agency to extend its review by three months.

The first-line Phase III pancreatic cancer study enrolled 996 patients who were randomized to receive either Orathecin or gemcitabine. While the trial failed to reach its endpoint of improving survival over gemcitabine, the chemo-naive pancreatic cancer patients that were the subjects of this study fall outside of the proposed use of Orathecin as a second and/or third line therapy in the current NDA SuperGen submitted on January 27, 2004. The treatment of chemo-naive pancreatic cancer patients with Orathecin will be further explored in a proposed, post-marketing, confirmatory study of gemcitabine with or without Orathecin. The completed single agent, chemo- naive study, along with other completed Orathecin trial data, will be presented in a future scientific forum.

"The additional clinical data submitted to the FDA provides additional support for the Orathecin NDA," stated Dr. James Manuso, Chairman, President and Chief Executive Officer of SuperGen. "We wanted the Agency to have access to the most complete body of clinical data in order to clearly understand the utility of Orathecin."

About Orathecin

Orathecin™ (rubitecan) Capsules, an orally active camptothecin, is a topoisomerase I inhibitor that was developed for the treatment of pancreatic cancer.

Orathecin has Orphan Drug status in both the US and EU. The Orathecin European filing or Marketing Authorization Application contains data from a Phase III clinical program believed to be the largest program in pancreatic cancer ever initiated worldwide, with more than 1,000 patients. Orathecin is also in clinical trials for numerous other cancers and blood disorders.

SuperGen's Orathecin NDA was submitted to the FDA on January 26, 2004. It was accepted for filing and assigned a PDUFA goal date of November 26, 2004. The entire NDA now includes data on the treatment of over 1,900 advanced pancreatic cancer patients.

About Pancreatic Cancer

According to American Cancer Society Cancer Facts and Figures 2004, 31,860 people will be diagnosed with pancreatic cancer this year in the United States and 31,270 people will die. Pancreatic cancer is the fourth highest cancer killer in the United States amongst both men and women. The 99 percent mortality rate for pancreatic cancer is the highest of any cancer.

About SuperGen

Based in Dublin, California, SuperGen is a pharmaceutical company dedicated to the acquisition, rapid development and commercialization of therapies for solid tumors, hematological malignancies and blood disorders. SuperGen's product portfolio includes Nipent® (pentostatin for injection); Mitomycin (generic brand of Mutamycin®); and SurfaceSafe® cleaner. For more information about SuperGen, please visit http://www.supergen.com.

This news release contains certain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will,"

"may," "should," or similar expressions, and include statements regarding the timing of the U.S. Food and Drug Administration's review and action on the Orathecin NDA. These forward- looking statements are not guarantees of SuperGen's future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Factors that might cause results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, whether review of the NDA filing for regulatory approval of Orathecin will be made in a timely fashion, whether the drug will be timely approved, if at all in any country where a filing has been made; whether the drug, if approved will be successfully commercialized; and other risks and uncertainties detailed from time to time in either company's filings with the Securities and Exchange Commission, including their most recently filed Forms 10-Q or 10-K. SuperGen undertakes no duty to update any of these forward- looking statements to conform them to actual results.

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