SuperGen Announces Withdrawal of Orathecin(TM) NDA

BULLETIN! BULLETIN! BULLETIN!

SuperGen will hold a telephone conference call today, Monday, January 3, 2005 at 12:00 Noon (EST) / 9:00 a.m. (PST). Dr. James Manuso, Chairman and Chief Executive Officer; Edward Jacobs, Chief Operating Officer; Dr. Karl Mettinger, Senior Vice President and Chief Medical Officer; Dr. Audrey Jakubowski, Chief Regulatory and Quality Officer; and Mr. Michael Molkentin, Chief Financial Officer, will discuss issues relating to this news release.

Those wishing to participate in the call should dial 800-706-7749 (international callers dial 617-614-3474) at approximately 11:50 a.m. (EST). The passcode for the call is 49581788. An audio recording of today's conference call will be available from January 3, 2005 at 2: 00 p.m. (EST) until February 2, 2005 at 5:00 p.m. Those wishing to access the replay of this conference call should dial 888-286-8010 (international callers dial 617-801-6888). The passcode for the replay is 56192474.

A live web cast of the call can be accessed by visiting http://www.supergen.com. Upon conclusion, an audio recording of the call will be available on SuperGen's web site for 90 days.

DUBLIN, Calif., Jan. 3 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) today announced that it has withdrawn its New Drug Application (NDA) for Orathecin™ (rubitecan) Capsules based on feedback indicating that the current data package would not be sufficient to gain approval for Orathecin at this time in the United States. Orathecin is SuperGen's investigational drug for the treatment of pancreatic cancer patients who have failed at least one prior chemotherapy regimen.

SuperGen's decision to withdraw the filing was based on discussions with both the FDA and consultants helping the company dialog with the Agency regarding the Orathecin NDA.

Dr. James Manuso, Chairman, President and Chief Executive Officer of SuperGen, stated, "Based on the feedback we received, we decided it was best for the long-term development of Orathecin to withdraw the application. After we review the FDA's complete findings, we will determine the most appropriate course of action for Orathecin in the U.S."

Dr. Manuso added, "SuperGen's European filing remains on track, and our planned U.S. non-randomized portion of the Phase III trial of Orathecin and gemcitabine as a combination first-line therapy for advanced pancreatic cancer patients continues to move forward."

SuperGen originally submitted the NDA for Orathecin on January 26, 2004, with a target Prescription Drug User Fee Act (PDUFA) date of November 26, 2004. At the request of the FDA, the company recently submitted additional clinical data from a trial of Orathecin as a first-line treatment for pancreatic cancer as well as new analyses of data from the pivotal study in 2nd and 3rd line patients. The FDA classified these data as a Major Amendment, which triggered an extension of the review period by 90 days. The revised target PDUFA date was February 26, 2005.

About Orathecin

Orathecin™ (rubitecan) Capsules, an orally active camptothecin, is a topoisomerase I inhibitor.

Orathecin has Orphan Drug status in both the U.S. and EU for the treatment of pancreatic cancer. 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 has also been evaluated in numerous other cancers and blood disorders.

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 action on the Orathecin NDA, the progress of SuperGen's European filing and the planned U.S. non-randomized portion of the Phase III trial of Orathecin and gemcitabine as a combination first-line therapy. 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. For example, actions by European regulators or numerous other factors could delay or halt progress on the European filing. Other 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 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 the 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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