



## **SuperGen Completes Submission of New Drug Application (NDA) for Orathecin(TM) As an Oral Treatment for Pancreatic Cancer**

DUBLIN, Calif., Jan. 27 /PRNewswire-FirstCall/ -- SuperGen Inc. (Nasdaq: SUPG - ) announced today that it has completed submission to the FDA of a rolling New Drug Application (NDA) for the investigational anticancer compound Orathecin™ (rubitecan) capsules. Orathecin is an oral chemotherapy agent that has been investigated as a treatment for pancreatic cancer patients who are refractory/resistant to the limited available therapies in this disease. Two other portions of the NDA, the Chemistry/Manufacturing/Controls and the Preclinical portions, were submitted earlier.

The Clinical Module of the NDA, which completed the submission, contains data on more than 1,000 pancreatic cancer patients, with over 600 of them treated with Orathecin and the remainder with control therapies. SuperGen's Phase III clinical program is believed to be the largest clinical development program in pancreatic cancer ever initiated worldwide.

"On the occasion of this important company milestone, I would like to acknowledge our team at SuperGen, whose considerable efforts were instrumental in the completion of this complex NDA process," said Dr. James Manuso, Chairman, President and Chief Executive Officer of SuperGen.

In November 2002, the company was granted a 'fast-track' designation for Orathecin for use in pancreatic cancer patients. "Fast-track" designation means that the FDA agrees to facilitate development and review of the application for new drugs that show promise in a serious or life-threatening condition where there is an unmet medical need. Pancreatic cancer patients who have failed the available therapies present a clear unmet medical need.

According to the Pancreatic Cancer Action Network (PanCAN), pancreatic cancer has the highest fatality rate of all cancers. Approximately 30,700 people will be diagnosed with pancreatic cancer this year in the United States and 30,000 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.

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. The company's website can be reached at [www.supergen.com](http://www.supergen.com).

This press release contains 'forward-looking' statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbors created thereby. Such forward-looking statements include statements regarding expectations about Orathecin™ and its completed FDA submission. The success of Orathecin could differ materially from those projected in the forward-looking statements as a result of known and unknown risk factors and uncertainties associated with drug development. Such factors include, but are not limited to: risks and uncertainties related to the Orathecin NDA submission, whether the NDA will be filed by the FDA for substantive review, how long the FDA review process will take, and if Orathecin will ever be approved by the FDA and reach the market. References made to the discussion of the risk factors are detailed in the company's filing with the Securities and Exchange Commission including the report on Form 10-Q for the quarter ended September 30, 2003. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.