



## **SuperGen Reports Results of Phase III Rescue Study With Orathecin(TM) (Rubitecan Capsules) Versus 5-FU in Pancreatic Cancer Patients**

DUBLIN, Calif., May 16 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) announced that results from a Phase III study of Orathecin™ (rubitecan capsules) versus 5-FU in pancreatic cancer patients with progressive disease following treatment with gemcitabine were reported this week during the General Poster Session at the annual meeting of the American Society of Clinical Oncology in Orlando.

The randomized multinational open-label study enrolled 224 patients. Key patient eligibility criteria included pathologic diagnosis of pancreatic cancer, progressive disease on gemcitabine, Karnofsky Performance Status of >50, and life expectancy of >2 months. The primary endpoint was overall survival. Rubitecan was administered at 1.5 mg/m<sup>2</sup> orally 5 days/week. 5-FU was administered at 600 mg/m<sup>2</sup> intravenously once weekly. Patients who progressed or experienced intolerable toxicity could crossover to the alternate treatment arm.

In the study, 93 of 224 (41%) 5-FU patients crossed over to rubitecan rescue. The main reasons for rescue with rubitecan were radiologic (75%) and symptomatic (12%) progression on 5-FU. Median survival was longer for patients who crossed over from 5-FU to rubitecan rescue compared to patients who did not crossover from 5-FU (184 versus 66 days). Of the 93 patients who crossed over to rubitecan 35 (38%) were evaluable for tumor response assessment and had follow-up scans after the initiation of rubitecan rescue. In the evaluable group, 14 of 35 patients (40%) achieved tumor growth control (4 showed objective tumor responses and 10 had disease stabilization.) The most common Grade 3/4 adverse events with rubitecan were myelotoxicity (16%) and gastrointestinal (14%). All deaths on study were primarily related to disease progression.

The results demonstrate that patients with refractory/resistant pancreatic cancer, who have progressed on gemcitabine and 5-FU, can derive benefit from rubitecan, an oral medication that can be taken at home with manageable toxicity.

### 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>.

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