SuperGen Reports Promising Results from Phase I Study of Dacogen(TM) and Carboplatin for Treatment of Advanced Solid Tumors

DUBLIN, Calif., June 9 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) today announced that a Phase I study of Dacogen™ (decitabine) for injection, the company's investigational cancer treatment for myelodysplastic syndromes (MDS), demonstrated positive clinical results in patients with advanced solid tumors. Chooi P. Lee, M.B.B.S., a medical oncologist from the University of Glasgow, summarized the clinical data from the study in an oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO). Abstract # 2005.

The phase I open label, dose-escalation study enrolled 21 patients with a variety of chemo-resistant tumors and was conducted at three sites in the U.K. The purpose of the study was to establish the feasibility and safety of delivering decitabine in combination with carboplatin without causing prohibitive myelosuppression. The primary objectives were to determine the optimal therapeutic dosage for evaluation in a Phase II study. Patients received decitabine intravenously at a starting dose on Day 1 of 45 mg/m2, with the dose escalated in steps of 45 mg/m2 to a maximum of 135mg/m2. Carboplatin was administered at a fixed dose on Day 8. The interval between decitabine and carboplatin was 8 days. Treatment was repeated every four weeks.

Preliminary results indicate that, with the exception of the dose limiting toxicity, decitabine was well-tolerated, with mild, manageable side effects all under grade 2. Pharmacodynamic studies at all dose levels of decitabine showed that demethylation in peripheral mononuclear cells was greater than that achieved in animal models. The effect was maximal between days 8 and 12, following decitabine infusion. The maximum tolerated dose of decitabine in combination with carboplatin was identified as decitabine 135mg/m2 with the dose limiting toxicity of grade 4 febrile neutropenia.

The study confirmed the feasibility of using decitabine in combination with carboplatin, and additional patients will be accrued to further assess the pharmacodynamic effects in tumors. A Phase II study of platinum-resistant ovarian cancer patients is planned.

"We are seeing increasing evidence that DNA hypermethylation plays a key role in resistance to chemotherapy regimens," stated Karl Mettinger, M.D., Ph.D., Senior Vice President and Chief Medical Officer of SuperGen. "While this is a small preliminary study, the results demonstrate that decitabine is an active demethylating agent that is well-tolerated in combination with standard chemotherapy to treat advanced solid tumors, and we look forward to commencing additional larger studies that will potentially improve treatment outcomes for these cancer patients."

About Decitabine

Decitabine is an investigational drug. It has not yet been approved for marketing in the U.S. by the FDA or by other regulatory agencies in their respective countries; therefore, safety and efficacy have not yet been established in any patient population. Decitabine is a chemotherapeutic agent that has been shown to have a broad spectrum of activity in several hematological malignancies as well as solid tumors. Decitabine belongs to a new class of drugs called hypomethylating agents, with a unique mechanism of action. Methylation is a process in which methyl (CH3) groups are added to DNA to inactivate or "silence" genes.

About SuperGen

Based in Dublin, Calif., 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 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 is subject to the safe harbor created thereby. Such forward-looking statements include statements related to our expectations regarding Dacogen in the treatment of a variety of chemotherapy resistant tumors. The success of such product could differ materially from those discussed in the forward-looking statements as a result of known and unknown risk factors and uncertainties. Such factors include, but are not limited to: risks and uncertainties related to whether the Company will commence or complete additional clinical trials or submit a complete NDA application to the FDA for the treatment of chemotherapy resistant tumors or any other indication, or whether Dacogen will receive regulatory approval for any indication. 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

March 31, 2004. 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.

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