Published Data Suggests SuperGen's Nipent®, as Part of a Combination Preparative Regimen, is Active in Allogeneic Bone Marrow Transplant Patients with Myelodysplastic Syndrome

Results appear in current issue of Biology of Blood and Marrow Transplantation

DUBLIN, Calif., Jan. 23 /PRNewswire/ -- SuperGen, Inc. (Nasdaq: SUPG -) today announced the publication of data from a clinical study demonstrating the activity of a combination preparative regimen - which included its anticancer compound Nipent® (pentostatin for injection) - in "reduced intensity" allogeneic bone marrow transplant patients with myelodysplastic syndrome (MDS). Results from this study were peer-reviewed and published in the current issue of the journal Biology of Blood and Marrow Transplantation (vol. 9, pp. 753-759). Nipent is currently approved as a single-agent treatment for patients with hairy cell leukemia and is not approved as either a single agent or as part of a combination preparative regimen treatment for reduced-intensity bone marrow transplants.

The Phase II clinical study, conducted by principal investigator Geoffrey W. Chan, M.D., at the Tufts-New England Medical Center in Boston, enrolled 18 patients who underwent a regimen of photopheresis, radiation and Nipent beginning one week prior to the allogeneic (from a donor, rather than from oneself) transplant. The results are as follows:

- 89 percent of patients (16/18) experienced full bone marrow engraftment within 100 days;

- 88 percent of patients (14/16) who demonstrated durable donor engraftment achieved clinically complete remission with the absence of circulating or bone marrow blasts and normal trilineage hematopoiesis;

- Grade II-IV acute graft-versus-host disease (GVHD), an often-fatal syndrome wherein immune cells from the transplant donor reject the recipient's normal tissue following an allogeneic transplant, was observed in 19 percent of patients (3 /16);

- Extensive chronic GVHD was observed in 20 percent of patients (3 /16);

- After a median follow-up period of 14 months, the 1-year failure-free survival was 64 percent and the 1-year overall survival was 65 percent. Ten patients were alive and free from clinical disease at the time of analysis.

According to the Bearman toxicity score, no patients experienced grade 3 or 4 mucositis, liver or renal toxicity. Grade 1 mucositis was seen in 9 patients and grade 2 mucositis was seen in 2 patients. Ten patients had grade 1 liver toxicity and 1 patient had grade 2 liver toxicity. Grade 1 renal toxicity was seen in 10 patients and grade 2 renal toxicity was seen in 1 patient. No patient experienced veno-occlusive disease. CMV reactivation was seen in only 3 patients, and all were successfully treated with valganciclovir therapy. There were no deaths due to treatment-related complications before day 100. The 1-year treatment-related mortality rate was 14 percent. There were 8 deaths in this study: 3 patients died from complications related to extensive chronic GVHD while in complete remission; 1 patient in complete remission died of idiopathic pulmonary syndrome 19 months after transplantation; both patients whose donor engraftment failed died of disease progression; and, 2 patients who had donor engraftment died of disease relapse.

According to Dr. Chan's published study, conventional allogeneic stem cell transplantation, although sometimes curative for MDS patients, is associated with a high incidence of treatment-related mortality (37 percent), grade II-IV acute GVHD (36 percent) and chronic GVHD (39 percent), resulting in a 3-year disease-free and overall survival of 23 percent and 40 percent, respectively. In addition, other studies utilizing fludarabine-based reduced-intensity preparative regimens for allogeneic transplantation of MDS patients have been complicated by high incidences of treatment-related mortality (27-48 percent), Grade II-IV acute GVHD (38 percent), and disease relapse (25-33 percent), resulting in low disease-free survival (12-38 percent) and overall survival (26-39 percent).

Based in Dublin, California, SuperGen is a pharmaceutical company dedicated to the acquisition, rapid development and commercialization of therapeutic anticancer products. The company's website can be reached at 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 Nipent as a single agent and in combination with other chemotherapeutic drugs in the treatment of various hematological conditions. 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 initiating, conducting and completing larger clinical trials in patients, reduced intensity of allogeneic bone marrow transplant patients with MDS, whether Nipent will demonstrate any clinical benefit in any future study of these patients and whether the company will submit or receive regulatory approval for Nipent for this 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 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.

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