MGI PHARMA and SuperGen Provide Regulatory Status Updates for Dacogen™ (decitabine) Injection for MDS

- Approvable Letter Response Submitted to FDA; Confirms Phase 3 Results -

- European Regulatory Strategy Revised -

MINNEAPOLIS and DUBLIN, Calif., Nov. 15 /PRNewswire-FirstCall/ -- MGI PHARMA, INC. (Nasdaq: MOGN) and SuperGen, Inc. (Nasdaq: SUPG) today provided an update on the regulatory status for Dacogen™ (decitabine) injection in both the United States and Europe.

Approvable Letter Response Submitted To FDA

MGI PHARMA and SuperGen have submitted their response to the Approvable Letter received for Dacogen injection to the U.S. Food and Drug Administration (FDA). The Approvable Letter for Dacogen injection, which was received on September 1, 2005, provided that Dacogen injection is approvable pending the FDA's review of a requested analysis of the transfusion requirements of patients enrolled in the completed phase 3 trial, submission of certain other information, and completion of labeling discussions. The Companies believe that their response addresses all items noted in the Approvable Letter.

The response provided to the FDA by MGI PHARMA and SuperGen confirms that the phase 3 trial of Dacogen injection met its co-primary endpoint of overall response rate (ORR) in patients with myelodysplastic syndromes (MDS). MGI PHARMA and SuperGen intend to provide an update to investors regarding the review timeline for Dacogen injection following receipt of feedback from the FDA.

European Regulatory Strategy Revised

MGI PHARMA and SuperGen have determined that additional clinical data will be required to continue the review of Dacogen injection in Europe. Therefore, the Companies have withdrawn the Marketing Authorization Application for Dacogen injection. This revision in the European regulatory strategy for Dacogen injection does not affect regulatory strategies being pursued in the U.S.

MGI PHARMA and SuperGen will continue to work with European regulatory authorities to determine the information required to support a resubmission of the application, and anticipate resubmitting the application at a later date. MGI PHARMA anticipates that next steps in the European regulatory strategy may be finalized in collaboration with a partner.

About MDS

Myelodysplastic syndromes, or MDS, are a group of diseases that affects the bone marrow with the majority of cases seen in patients over 60 years of age. Depending on the stage of the disease, the life expectancy for patients diagnosed with MDS is 6 months to 5 years. In MDS, the bone marrow stops making healthy blood cells and instead produces poorly functioning and immature blood cells. People with MDS may experience a variety of symptoms and complications, including anemia, bleeding, infection, fatigue and weakness. Over time, MDS can progress to acute leukemia. The Aplastic Anemia and MDS International Foundation currently estimates that 20,000 to 30,000 new cases of MDS are diagnosed annually in the U.S. Those patients with high-risk MDS may experience bone marrow failure, which may lead to death from bleeding and infection.

About Dacogen™ (Decitabine) Injection

Dacogen injection is a product candidate that belongs to a class of drugs called hypomethylating agents that is currently being evaluated in a broad clinical development program in patients with MDS, acute myeloid leukemia (AML), chronic myelogenous leukemia, or CML, and solid tumors. Dacogen injection is not approved for marketing in the U.S. or by other regulatory agencies in their respective countries; therefore, safety and efficacy have not yet been established in any patient population. A phase 3 EORTC-sponsored trial is currently ongoing in Europe to evaluate Dacogen injection in patients with MDS. In addition, MGI PHARMA is currently conducting a pivotal program to evaluate Dacogen injection in patients with AML. The New Drug Application (NDA) is currently under review by the FDA in the U.S.

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 Orathecin™ (rubitecan) capsules, an investigational drug being evaluated for the treatment of pancreatic cancer; Nipent® (pentostatin for injection), approved for the treatment of hairy-cell leukemia; Mitomycin, for use in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as a palliative treatment when other modalities have failed; and SurfaceSafe® cleaner. For more information about SuperGen, please visit http://www.supergen.com.

About MGI PHARMA

MGI PHARMA, INC. is an oncology and acute care focused biopharmaceutical company that acquires, researches, develops and commercializes proprietary products that address the unmet needs of patients. MGI PHARMA markets Aloxi® (palonosetron hydrochloride) injection and Gliadel® Wafer (polifeprosan 20 with carmustine implant) in the United States. The company directly markets its products in the U.S. and collaborates with partners to reach international markets. For more information about MGI PHARMA, please visit http://www.mgipharma.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. These forward-looking statements are not guarantees of MGI PHARMA's or 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. Factors that might cause the Companies' results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, the ability of MGI PHARMA's and SuperGen's product candidates to be proven safe and effective in humans, to receive marketing authorization from regulatory authorities, and to ultimately compete successfully with other therapies; continued sales of MGI PHARMA's and SuperGen's marketed products; development or acquisition of additional products; reliance on contract manufacturing; changes in strategic alliances; continued access to capital; and other risks and uncertainties detailed from time to time in the Companies' filings with the Securities and Exchange Commission including their most recently filed Forms 10-Q or 10-K. MGI PHARMA and SuperGen undertake no duty to update any of these forward-looking statements to conform them to actual results.

SOURCE SuperGen, Inc.
CONTACT:
Jennifer M. Davis, of MGI PHARMA, INC.,
+1-212-332-4381, IR@mgipharma.com;
or
Robert Stanislaro, of Noonan Russo, for MGI PHARMA, INC.,
+1-212-845-4268, robert.stanislaro@eurorscg.com;
or
Timothy L. Enns, of SuperGen, Inc.,
+1-925-560-0100 x111, tenns@SuperGen.com;
or
Sharon Weinstein, of Noonan Russo, for SuperGen, Inc.,
+1-212-845-4271. sharon.weinstein@eurorscg.com

Web site: http://www.supergen.com
http://www.mgipharma.com
(MOGN SUPG)