



SuperGen and MGI PHARMA Announce Submission of Dacogen(TM) NDA to U.S. FDA

DUBLIN, Calif. and MINNEAPOLIS, Nov 1, 2004 /PRNewswire-FirstCall via COMTEX/ -- SuperGen, Inc. (Nasdaq: SUPG) and MGI PHARMA, INC. (Nasdaq: MOGN), today announced that the full New Drug Application (NDA) seeking approval of Dacogen™ (decitabine) for injection has been submitted to the U.S. Food and Drug Administration (FDA) for its review. Dacogen is an investigational anti-cancer therapeutic for the treatment of patients with myelodysplastic syndromes or MDS. MGI PHARMA has exclusive worldwide rights to the development, manufacture, commercialization and distribution of Dacogen.

"SuperGen is delighted to achieve this key U.S. regulatory milestone for Dacogen," said Dr. James Manuso, President and Chief Executive Officer of SuperGen. "Thanks to the valuable assistance from our partner MGI PHARMA and the diligent efforts of the entire SuperGen team, we completed our submission of the Dacogen NDA early in the fourth quarter. We look forward to FDA's response, and we remain committed to bringing Dacogen to patients as quickly as possible."

"Given today's announcement and the recently announced acceptance for review of the Marketing Authorization Application (MAA) for Dacogen by the European Medicines Agency (EMA), we look forward to working closely with SuperGen and the regulatory authorities in both the U.S. and Europe throughout the review processes," said Lonnie Moulder, President and Chief Executive Officer of MGI PHARMA.

SuperGen completed Phase III clinical trials of Dacogen in patients with MDS in March 2004. SuperGen and MGI PHARMA are collaborating on the regulatory development process for Dacogen in MDS. MGI PHARMA plans to initiate a Phase III trial of Dacogen for the treatment of acute myelogenous leukemia (AML) in early 2005 and plans to evaluate Dacogen for further development in other hematologic malignancies. Alternative dosing schedules for Dacogen, including subcutaneous administration and other intravenous infusion regimens, are currently being evaluated in clinical studies.

About Dacogen

Dacogen is an investigational drug. It has not yet been 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. In clinical trials, Dacogen has been shown to have a broad spectrum of activity in several hematological malignancies as well as solid tumors. Dacogen belongs to a 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, which may inactivate or "silence" tumor suppressor genes.

About MDS

MDS is a cancer of the bone marrow that is often fatal. Some cases of MDS progress to leukemia. According to the Aplastic Anemia and MDS International Foundation (<http://aamds.org/>), 20,000 to 30,000 new cases of MDS are diagnosed annually in the United States. The number of new cases diagnosed each year is increasing. The average life expectancy for patients diagnosed with MDS is 6 months to 5 years, depending on the severity of the disease.

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 intended for the treatment of pancreatic cancer; Nipent® (pentostatin for injection); Mitomycin; and SurfaceSafe® cleaner. For more information about SuperGen, please visit <http://www.supergen.com>.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of cancer patients. MGI PHARMA has a portfolio of proprietary pharmaceuticals, and intends to become a leader in oncology. MGI PHARMA markets Aloxi® (palonosetron hydrochloride) injection, KADIAN® (sustained release morphine capsules), Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules in the United States. The Company directly markets its products in the U.S. and collaborates with

partners in 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, and include statements regarding the timing of the submission of an NDA for Dacogen to the U.S. Food and Drug Administration. 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 either company's results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, whether acceptance of the NDA submission for regulatory approval for Dacogen will be made in the U.S. in a timely fashion, if at all; whether the drug will be timely approved, if at all in any country where a submission is made; whether the drug, if approved will be successfully commercialized; continued sales of MGI PHARMA's or SuperGen's other marketed products; development or acquisition of additional products; reliance on contract manufacturing and third party suppliers; changes in strategic alliances; and other risks and uncertainties detailed from time to time in either company's 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.

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