Dacogen(TM) NDA Accepted for Filing by FDA

DUBLIN, Calif., and MINNEAPOLIS, Jan. 3 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) and MGI PHARMA, INC. (Nasdaq: MOGN) today announced that the New Drug Application (NDA) for Dacogen™ (decitabine) for injection was accepted for filing by the United States Food and Drug Administration (FDA).

The NDA for Dacogen injection was submitted to the FDA on November 1, 2004. The acceptance for review of the NDA represents the FDA's determination that the application is sufficiently complete to permit a substantive review. The filing of the application by the FDA does not represent any opinion regarding the safety, efficacy or approvability of Dacogen injection. Under PDUFA (Prescription Drug User Fee Act) III, the FDA's goal is to review and act on the NDA by September 1, 2005. During October 2004 the Marketing Authorization Application (MAA) for Dacogen injection was submitted and is currently under review by the European Medicines Agency (EMEA).

As previously reported, the NDA included clinical data from one phase 3 clinical trial of Dacogen injection in MDS patients in addition to two phase 2 studies. The co-primary endpoints of the phase 3 study were response rate and time to AML transformation or death. The phase 3 trial achieved the co-primary endpoint of overall response rate. Patients in the Dacogen arm had a response rate of 17% as determined by intent to treat (ITT) analysis, compared to a 0% response rate for patients who received supportive care ($p<0.001$). Responses were durable and lasted a median of nine months, and all patients who responded to Dacogen therapy remained or became transfusion independent. Median time to progression to AML or death was 340 days for patients treated with Dacogen injection, compared to a median of 219 days for patients in the supportive care arm, which was not statistically significant.

"This NDA filing represents the achievement of another key regulatory milestone for both MGI PHARMA and SuperGen in our quest for marketing approval of Dacogen injection," said Lonnie Moulder, president and chief executive officer of MGI PHARMA. "We remain committed to bringing this important product to patients as quickly as possible and to exploring the breadth of its clinical potential. We look forward to initiating a phase 3 study of Dacogen injection in AML patients in early 2005."

"We are very pleased that the Dacogen NDA has been accepted for review," said Dr. James Manuso, president and chief executive officer of SuperGen. "We believe that Dacogen injection will become an important treatment option for hematologic cancer patients."

About Dacogen™ Injection

Dacogen injection is an investigational drug that belongs to a class of drugs called DNA methyltransferase inhibitors. DNA methylation is a process in which methyl (CH_3) groups are added to DNA to inactivate or "silence" genes. 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. In clinical trials, Dacogen injection has been shown to have a broad spectrum of activity in several hematological malignancies as well as solid tumors.

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 sulfate) 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 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 either Company's results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, whether Dacogen injection will be approved in a timely manner, if at all; 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 supply; 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 Form 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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