# Approvable Letter Received from the FDA for Dacogen(TM) (Decitabine) Injection for the Treatment of MDS

MINNEAPOLIS & DUBLIN, Calif.--(BUSINESS WIRE)--Sept. 1, 2005--MGI PHARMA, INC. (Nasdaq:MOGN) and SuperGen, Inc. (Nasdaq:SUPG) today announced they have received an approvable letter from the U.S. Food and Drug Administration (FDA) for Dacogen™ (decitabine) injection for the treatment of myelodysplastic syndromes (MDS). The letter provides 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.

"We are working diligently to complete the requested analysis of data and provide this information to the FDA as early as possible during the fourth quarter," stated Lonnie Moulder, president and CEO of MGI PHARMA. "The MGI PHARMA commercial organization is prepared to launch Dacogen injection upon final FDA approval."

"The approvable letter from the FDA brings Dacogen injection one step closer to patients suffering from MDS," stated Jim Manuso, president and CEO of SuperGen. "I am confident that MGI PHARMA and SuperGen can promptly provide the information that the FDA has requested."

Conference Call & Webcast Information

MGI PHARMA and SuperGen will host a conference call at 5:15 p.m. ET on Thursday, September 1, 2005, to discuss the approvable letter and related matters. Lonnie Moulder, president and CEO of MGI PHARMA, and Jim Manuso, president and CEO of SuperGen, will host the call. The live webcast can be accessed by visiting the Investor Relations section of MGI PHARMA's or SuperGen's website, www.mgipharma.com or www.supergen.com. An archived version of the call will be available via the MGI PHARMA website for seven days following the call.

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 Injection

Dacogen injection belongs to a class of drugs called hypomethylating agents and is the subject of more than 40 ongoing clinical trials. In clinical trials, Dacogen injection has demonstrated activity in several hematological malignancies as well as solid tumors. MGI PHARMA is currently conducting a pivotal program to evaluate Dacogen injection in patients with acute myeloid leukemia (AML). Additional studies are also underway to evaluate alternative dosing regimens for Dacogen injection. The New Drug Application (NDA) and Marketing Authorization Application (MAA) for Dacogen injection for MDS are currently under review by the United States Food and Drug Administration (FDA) and European Medicines Agency (EMEA), respectively.

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); Mitomycin; 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, develops and commercializes proprietary products that address the unmet needs of patients. MGI PHARMA has a portfolio of proprietary pharmaceuticals, and intends to become a leading biopharmaceutical company. 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. MGI PHARMA signed a definitive merger agreement, dated July 20, 2005, that provides for the acquisition of Guilford Pharmaceuticals by MGI PHARMA; this transaction is expected to close during the fourth quarter of 2005. 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.

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