U.S. FDA Approves Dacogen™ (Decitabine) For Injection

- Dacogen™ Approved for Patients with all FAB Classifications of MDS - - Commercial Launch Planned For Late May -

MINNEAPOLIS and DUBLIN, Calif., May 3 /PRNewswire-FirstCall/ -- MGI PHARMA, INC. (Nasdaq: MOGN) and SuperGen, Inc. (Nasdaq: SUPG) today announced that the U.S. Food and Drug Administration (FDA) has approved Dacogen™ (decitabine) for Injection. Dacogen is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo, and secondary MDS of all French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia), and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System (IPSS) groups. MGI PHARMA plans to make Dacogen commercially available during the second quarter of 2006.

"The FDA approval of Dacogen marks an important advancement for patients who suffer from MDS," said John M. Bennett, M.D., Chair of The Myelodysplastic Syndromes Foundation. "Patients with this serious condition are often anemic, experience fatigue and weakness and, in certain cases with an increase in leukemic blast cells, MDS can result in bone marrow failure."

Results from a phase 3 clinical trial demonstrated an overall response rate of 21% in Dacogen-treated patients considered evaluable for response, defined as those patients with pathologically confirmed MDS at baseline who received at least 2 cycles of treatment, compared to 0% in the supportive care arm. All patients who responded to Dacogen treatment became or remained transfusion independent during the time of the response. The most commonly occurring adverse reactions with Dacogen include neutropenia, thrombocytopenia, anemia, pyrexia, fatigue, nausea, cough, petechiae, constipation, and diarrhea. It is recommended that patients be treated with Dacogen for a minimum of four cycles, and treatment may continue as long as the patient continues to benefit.

"The approval of Dacogen demonstrates MGI PHARMA's ability to identify, acquire, develop, and register promising products," said Lonnie Moulder, president and chief executive officer of MGI PHARMA. "We look forward to providing clinicians with an effective therapy to offer their MDS patients. MGI PHARMA is committed to continuing the development of Dacogen for patients with acute myeloid leukemia, chronic myelogenous leukemia, and solid tumors, in addition to developing alternative dosing regimens for patients with MDS."

"This approval is a significant milestone for SuperGen. Over the course of more than seven years, SuperGen developed Dacogen by working with scientists, clinicians, patient advocacy groups, and regulatory agencies to get this product approved for patients with MDS," said James S. Manuso, Ph.D., President and CEO of SuperGen. "The approval of Dacogen is a significant benefit for patients because of the drug's ability to address the underlying disease and, potentially, to improve patient outcomes."

Summary of Clinical Results

SuperGen conducted a randomized open-label, multicenter, controlled trial that evaluated 170 adult patients with myelodysplastic syndromes meeting FAB classification criteria and IPSS High-Risk, Intermediate-2 and Intermediate-1 prognostic scores. Eighty-nine patients were randomized to Dacogen therapy plus supportive care, 83 of whom received Dacogen, and 81 were randomized to supportive care alone. Dacogen was intravenously infused at a dose of 15 mg/m2 over a 3-hour period, every eight hours, for three consecutive days. Dacogen therapy was repeated every 6 weeks, depending on the patient's clinical response and toxicity. Supportive care consisted of blood and blood product transfusions, prophylactic antibiotics, and hematopoietic growth factors. Co-primary endpoints of the study were overall response rate (complete responses plus partial responses) and time to acute myeloid leukemia (AML) or death. Secondary endpoints included hematologic improvement, duration of response, cytogenetic response rate, transfusion requirements, quality of life, survival, and safety.

The overall response rate in the Dacogen study arm was 17% with a median response duration of 288 days, compared to 0% in the supportive care arm ($p<0.001$). A complete response rate of 9% and a partial response rate of 8% were observed in the Dacogen arm. The overall response rate was 21% in Dacogen-treated patients considered evaluable for response, defined as those patients with pathologically confirmed MDS at baseline who received at least 2 cycles of treatment. In addition, 13% of patients in the Dacogen arm had hematologic improvement, compared to 7% of patients in the supportive care arm.

Two additional open label, single arm, multicenter studies were conducted to evaluate the safety and efficacy of Dacogen in patients with MDS of any FAB subtype. The results of the phase 2 studies were consistent with the results of the phase 3 trial with overall response rates of 26% (N=66) and 24% (N=98).

"Dacogen represents a new treatment option that can reduce or eliminate the need for patients with MDS to receive frequent blood transfusions, which is an important clinical benefit," said Hagop Kantarjian, M.D., Professor and Chairman, Department of Leukemia, at the University of Texas MD Anderson Cancer Center and clinical investigator of the ongoing Dacogen clinical development program for MDS and AML. "This approval is a major advance in our fight against myelodysplastic syndromes."

Important Safety Information

Dacogen may cause fetal harm when administered to a pregnant woman. Women of childbearing potential would be advised to avoid becoming pregnant while using Dacogen. Men should be advised not to father a child while receiving treatment with Dacogen and for 2 months afterwards.

The most commonly occurring adverse reactions with Dacogen include neutropenia (90%), thrombocytopenia (89%), anemia (82%), pyrexia (53%), fatigue (48%), nausea (42%), cough (40%), petechiae (39%), constipation (35%), and diarrhea (34%). Please visit http://www.mgipharma.com for full prescribing information.

Ongoing Clinical Studies

MGI PHARMA is currently conducting a phase 3 pivotal trial to evaluate Dacogen in patients with AML. Additional phase 2 studies are also underway to evaluate alternative dosing regimens for Dacogen in patients with MDS and in patients with AML and chronic myelogenous leukemia, or CML. A phase 3 European Organization for Research and Treatment of Cancer-(EORTC-) sponsored study of Dacogen in patients with MDS is ongoing in Europe.

About MDS

Myelodysplastic syndromes, or MDS, are a group of diseases of the bone marrow characterized by the production of poorly functioning and immature blood cells. People with MDS may experience a variety of symptoms and complications, including anemia, bleeding, infection, fatigue and weakness. Those patients with high-risk MDS may experience bone marrow failure, which may lead to death from bleeding and infection. Over time, MDS can progress to acute leukemia, or AML. The Aplastic Anemia and MDS International Foundation currently estimates that up to 30,000 new cases of MDS are diagnosed annually in the United States.

About Dacogen™ (Decitabine) For Injection

Dacogen is a hypomethylating agent that is believed to exert its antineoplastic effects by incorporation into DNA and inhibition of an enzyme called DNA methyltransferase. Methylation is a process in which methyl (CH3) groups are added to DNA, resulting in the inactivation of genes that are critical for control of cellular differentiation and proliferation. Abnormal methylation, which silences certain genes, is associated with the development of many types of tumors. Dacogen-induced hypomethylation in neoplastic cells may restore normal function to genes that are critical for the control of cellular differentiation and proliferation. In rapidly dividing cells, the cytotoxicity of Dacogen may also be attributed to the formation of covalent adducts between DNA methyltransferase and decitabine incorporated into DNA. Non-proliferating cells are relatively insensitive to Dacogen. Please visit http://www.mgipharma.com for full prescribing information.

Conference Call & Webcast Information

MGI PHARMA will host a conference call at 9:00 a.m. ET on Wednesday, May 3, 2006, to discuss the FDA approval of Dacogen. Lonnie Moulder, President and CEO of MGI PHARMA, will host the call. The live webcast can be accessed by visiting the Investor Relations section of MGI PHARMA's website, http://www.mgipharma.com . An archived version of the call will be available via the MGI PHARMA website for seven days following the call.

About SuperGen

Based in Dublin, California, SuperGen is a pharmaceutical company dedicated to the discovery, acquisition, rapid development and commercialization of therapies for solid tumors, hematological malignancies and blood disorders. SuperGen's portfolio includes Orathecin™ (rubitecan) capsules, an investigational drug intended for the treatment of pancreatic cancer, Nipent® (pentostatin for injection), Mitomycin, SurfaceSafe® cleaner, and a number of preclinical products being developed as inhibitors of aurora-A, tyrosine kinase and DNA methyltransferase. 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 has a portfolio of proprietary pharmaceuticals, and intends to become a leading biopharmaceutical company. MGI PHARMA markets Aloxi® (palonosetron hydrochloride) Injection and Gliadel® Wafer (polifeprosan 20 with carmustine implant) in the United States, and intends to make Dacogen™ (decitabine) for Injection commercially available during the second quarter of 2006. The Company directly markets its products in the U.S. and collaborates with partners to reach international markets.

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 to successfully introduce Dacogen for Injection into the marketplace; acceptance by physicians and patients of the product; and Dacogen for Injection competing successfully with other therapies for MDS; and other risks and uncertainties detailed from time to time in the Companies' filings with the Securities and Exchange Commission including its 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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