



Dacogen™ (Decitabine) Injection Data Presented at American Society of Hematology (ASH) Annual Meeting

- Updated Data From Alternative Dosing Regimen Study And Initial Phase 2 AML Results Presented -

ATLANTA, Dec. 12 /PRNewswire-FirstCall/ -- MGI PHARMA, INC. (Nasdaq: MOGN) and SuperGen, Inc. (Nasdaq: SUPG) today provided a summary of the Dacogen™ (decitabine) injection presentations made during the American Society of Hematology (ASH) 47th Annual Meeting and Exposition. Dacogen injection was the subject of five oral presentations and 10 poster presentations. Updated results from an alternative dosing study of Dacogen injection in patients with myelodysplastic syndromes (MDS) and initial data from a phase 2 trial of Dacogen injection in elderly acute myeloid leukemia (AML) patients were among the data presented. In addition, MGI PHARMA sponsored a Corporate Friday symposium titled Modulation of Methylation Status: Innovation in the Treatment of Hematological Malignancies, which was chaired by Dr. Jean-Pierre Issa of The University of Texas M.D. Anderson Cancer Center in Houston, TX.

"The data presented at ASH continue to support that Dacogen injection may represent a potential new therapeutic option for patients suffering from MDS and we look forward to an FDA decision on Dacogen injection for this indication in early 2006," said Lonnie Moulder, president and CEO of MGI PHARMA. "Additionally, Dacogen injection has shown clinical activity in a broad range of other hematologic malignancies, as both a monotherapy and in combination with other anti-cancer agents. We will continue to investigate Dacogen injection in other indications, as we expand the development program of this important product."

Updated Results From Alternative Dosing Study In 96 MDS Patients

Interim results of a study designed to compare three dosing regimens for Dacogen injection were presented in a poster session on Sunday, December 11. In this study, patients with intermediate-1, intermediate-2, and high risk MDS were randomized to receive one of three Dacogen regimens every four weeks: 1) a 20 mg/m² intravenous one hour infusion once per day for five days; 2) a 10 mg/m² one hour intravenous infusion once per day for 10 days; or 3) a 10 mg/m² subcutaneous injection twice per day for five days. Randomization of patients to each of the three dosing regimens was equal for the first 50 patients enrolled in this study. After the 50th patient was enrolled, a Bayesian randomization was implemented based on complete response rates, and all additional study participants were treated using the 5-day 20 mg/m² intravenous infusion regimen.

For 96 evaluable patients, the overall response rate was 47 percent, including a 42 percent complete response rate and a 5 percent partial response rate. In the 65 patients treated with a 20 mg/m² intravenous Dacogen infusion once per day for five days, the complete response rate was 49 percent. The most frequently-observed adverse events were primarily a result of myelosuppression and included fever (4 percent) and infection (9 percent).

These data support the hypothesis that these alternative Dacogen regimens are active in treating MDS patients and may offer dose-scheduling flexibility. A multicenter phase 2 study evaluating the 20 mg/m² intravenous one hour infusion once per day for five days is currently ongoing, with an enrollment goal of 93 patients with MDS.

Initial Phase 2 AML Results Utilizing A 5-Day, One Hour Infusion Regimen

Results from a multicenter phase 2 study of Dacogen injection in previously-untreated elderly AML patients were presented in a poster session on Sunday, December 11. Patients in this trial received initial Dacogen injection therapy intravenously at a dose of 15 mg/m² every 8 hours for 3 days (total dose 135 mg/m²), repeated every six weeks in addition to all-trans retinoic acid. Following completion of four courses of initial therapy, patients may then receive maintenance therapy consisting of a one hour infusion of 20 mg/m² Dacogen injection daily for three days, repeated every eight weeks. The primary endpoint of this study is best response, and secondary endpoints include overall and progression free survival, toxicity and duration of hospitalization. Of the 29 fully evaluable patients, 14 percent experienced a complete response, 17 percent had a partial response, and 10 percent had stable disease. The median overall survival from the start of therapy was 7.5 months. Adverse events included neutropenia, fever, infection, and pancytopenia. These interim results suggest that Dacogen injection may be tolerated and may show activity in elderly patients with AML. This study is currently ongoing with an enrollment goal of at least 60 patients.

Analysis of Phase 2 & 3 Data Indicate That Prolonged Therapy Optimizes Efficacy

An analysis of response rates from four trials of Dacogen injection in MDS patients was presented in a poster session on Sunday, December 11. One pivotal phase 3 trial and three supportive phase 2 trials were conducted to assess the safety and efficacy of Dacogen injection plus supportive care compared to supportive care alone in patients with MDS. In the phase 2 studies, patients received a median of four cycles of Dacogen injection therapy, compared to the phase 3 study, in which patients received a median of three cycles of therapy. Across these four studies, responses were observed in MDS patients from all IPSS and FAB subgroups. In the two phase 2 studies, in which responses were centrally reviewed, overall response rate was 26 percent in each trial. The overall response rate (ORR) observed in the phase 3 study (D-0007) was 17 percent as assessed by IWG criteria, compared to 0 percent for patients that received supportive care alone. The primary toxicity associated with Dacogen injection treatment in these trials was myelosuppression, including neutropenia, thrombocytopenia, and anemia.

Because Dacogen injection impacts DNA methylation patterns, DNA synthesis and subsequent demethylation are required for its activity. Analysis of ORR results and median durations of therapy for these studies suggest that prolonged therapy with Dacogen injection may optimize response rates for MDS patients.

Phase 2 Data Demonstrate Activity in Combination with Imatinib in CML Patients

Data from a phase 2 study of Dacogen injection in combination with imatinib in patients with chronic myelogenous leukemia (CML) were presented in a poster session on Saturday, December 10. To be eligible for this study, patients who had previously been treated with imatinib must have clinical evidence of imatinib failure. Patients enrolled in this trial were treated with Dacogen injection 15 mg/m² intravenously for five days per week for two consecutive weeks, repeated every six weeks, plus 600 mg oral imatinib daily. A total of 20 patients received at least 2 cycles of treatment and were evaluated for response. For these 20 patients, the overall hematologic response rate was 44 percent, including a 33 percent complete hematologic response rate and an 11 percent partial hematologic response rate. The median duration of response was 13 weeks. The most frequently observed grade 3 and 4 toxicities associated with this study included neutropenia, infection, CNS bleed and GI bleed. These data demonstrate that the combination of Dacogen injection plus imatinib may be an active regimen for patients with CML, including those who have previously been treated with imatinib.

Below is the list of all Dacogen injection abstracts presented at the 2005 ASH annual meeting:

Oral Presentations

Abstract Number: 371

Hypomethylation Therapy of Decitabine in Patients with Myelodysplastic Syndromes (MDS) Induces Apoptosis and Reduces Proliferation. Session Type: Oral Session

Monday, December 12, 2005, 12:00 PM

Abstract Number: 495

Decitabine: Where Is the Target? Session Type: Oral Session

Monday, December 12, 2005, 2:00 PM

Abstract Number: 525

Subdomains of the Baboon (*P. anubis*) α -Globin Gene Cluster Are Differentially Sensitive to Dacogen Treatment. Session Type: Oral Session

Monday, December 12, 2005, 2:00 PM

Abstract Number: 408

Final Results of a Phase I/II Study of the Combination of the Hypomethylating Agent 5-aza-2'-Deoxycytidine (DAC) and the Histone Deacetylase Inhibitor Valproic Acid (VPA) in Patients with Leukemia. Session Type: Oral Session

Monday, December 12, 2005, 2:45 PM

Abstract Number: 790

CpG Island Methylation Is a Poor Prognostic Factors in Myelodysplastic Syndrome Patients and Is Reversed by Decitabine Therapy-Results of a Phase III Randomized Study. Session Type: Oral Session

Tuesday, December 13, 2005, 8:45 AM

Poster Presentations

Abstract Number: 1092

Outcome of Salvage Therapy in Patients (pts) with Chronic Myeloid Leukemia (CML) Who Failed Imatinib after Developing BCR-ABL Kinase Mutation. Session Type: Poster Session 250-I

Saturday, December 10, 2005, 9:15 AM

Abstract Number: 1099

Phase II Study of Decitabine in Combination with Imatinib Mesylate in Patients with Accelerated (AP) or Blastic Phase (BP) of Chronic Myeloid Leukemia (CML). Session Type: Poster Session 257-I

Saturday, December 10, 2005, 9:15 AM

Abstract Number: 1854

A Phase I Pharmacokinetic Trial of Decitabine Administered as a 3-Hour Infusion to Patients with Acute Myelogenous Leukemia (AML) or Myelodysplastic Syndrome (MDS).

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 2534

Myelodysplastic Syndromes (MDS): An International Practice and Treatment Survey. Session Type: Poster Session 738-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 1852

Continued Low-Dose Decitabine (DAC) Is an Active First-Line Treatment of Older AML Patients: First Results of a Multicenter Phase II Study. Session Type: Poster Session 56-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 2522

Decitabine Low-Dose Schedule (100 mg/m²/Course) in Myelodysplastic Syndrome (MDS). Comparison of 3 Different Dose Schedules. Session Type: Poster Session 726-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 2515

Response Rates of Phase 2 and Phase 3 Trials of Decitabine (DAC) in Patients with Myelodysplastic Syndromes (MDS). Session Type: Poster Session 719-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 1861

Phase I Study of Low Dose Decitabine in Patients with Acute Myeloid Leukemia (AML): Pharmacokinetics (PK), Pharmacodynamics (PD), and Clinical Activity. Session Type: Poster Session 65-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 2516

Decitabine, a Potential Targeted Therapeutic for Juvenile Myelomonocytic Leukemia. Session Type: Poster Session 720-II

Sunday, December 11, 2005, 9:15 AM

Abstract Number: 3440

Demethylation Profiling of CD34-Positive Hematopoietic Cells in Patients with Myelodysplastic Syndromes. Session Type: Poster Session 691-III

Monday, December 12, 2005, 10:30 AM

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, AML, 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. The Dacogen injection New Drug Application (NDA) is under review by the FDA for the MDS indication. A phase 3 EORTC-sponsored trial is currently ongoing in Europe to evaluate Dacogen injection in patients with MDS. MGI PHARMA is conducting a pivotal program to evaluate Dacogen injection in patients with AML. Additional clinical studies are also underway in patients with MDS to evaluate alternative dosing regimens for Dacogen injection.

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 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.

CONTACT:

For further information about MGI PHARMA, please contact:

Jennifer M. Davis

MGI PHARMA, INC.

Tel: (212) 332-4381

E-mail: IR@mgipharma.com

Robert Stanislaro

Noonan Russo

Tel: (212) 845-4268

E-mail: robert.stanislaro@eurorscg.com

For further information about SuperGen, please contact:

Timothy L. Enns
SuperGen, Inc.
Tel: (925) 560-0100 x111
E-mail: tenns@SuperGen.com

Sharon Weinstein
Noonan Russo
Tel: (212) 845-4271
E-mail: sharon.weinstein@eurorscg.com