Dacogen® (Decitabine) for Injection Phase III AML Results Announced

sNDA Submission to FDA by Eisai Planned Based on Preliminary Results

DUBLIN, Calif., Jun 30, 2010 (BUSINESS WIRE) --

SuperGen, Inc. (Nasdaq: SUPG), a pharmaceutical company dedicated to the discovery and development of novel cancer therapies, announced that Eisai Inc. today released information regarding a randomized Phase III clinical trial of Dacogen® (decitabine) for Injection in elderly patients with acute myeloid leukemia (AML). The comparator in this trial was low-dose cytarabine, a chemotherapy agent, or supportive care.

Overall survival was the primary endpoint of this study. While Dacogen did not achieve statistically significant superiority over the control arm, a trend was evident.

Based on the primary analysis and supporting data from secondary endpoints in this Phase III trial, SuperGen's partner, Eisai, has announced its plan to submit to the U.S. Food and Drug Administration (FDA) a supplemental New Drug Application (sNDA) for Dacogen in the treatment of elderly patients with AML and poor- or intermediate-risk cytogenetics. Eisai has stated that the sNDA will be submitted to FDA by March 31, 2011.

Eisai and Cilag GmbH International are further examining the data to better understand the full implications of the study. Eisai will present to the medical community at future major meetings and in peer-reviewed publications the comprehensive data sets from the Phase III trial.

"SuperGen is encouraged by Eisai's intent to file an sNDA for Dacogen in a new indication," said James S.J. Manuso, Ph.D., President and Chief Executive Officer. "Analysis of the study results is ongoing, and Eisai will submit the results for presentation at major medical meetings and peer-reviewed publications."

The most frequently reported adverse events observed during the Phase III trial include neutropenia, anemia, thrombocytopenia, fever and pneumonia. Sepsis and febrile neutropenia were reported as serious adverse events.

About AML

Acute myeloid leukemia (AML) is an aggressive, fast-growing cancer that starts inside the bone marrow with production of abnormal blood cells. It is generally a disease of older adults, with an average patient age of 67, and is slightly more common among men than women. The most common symptoms of AML include weight loss, tiredness, fever, night sweats, and loss of appetite. AML can sometimes spread to other parts of the body including the lymph nodes, liver and spleen. In 2008, there were slightly more than 13,000 new cases of AML reported and nearly 9,000 deaths in the United States.

About Dacogen

Dacogen (decitabine) for Injection 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, chronic myelomonocytic leukemia), and Intermediate-1, Intermediate-2 and High-Risk International Prognostic Scoring System (IPSS) groups.

Recently, a five-day dosing regimen for Dacogen was approved by the FDA for the treatment of MDS. Dacogen was first approved by the FDA as a three-day dosing regimen for the treatment of patients with MDS on May 2, 2006.

Dacogen is currently approved for the treatment of MDS in more than 20 countries outside of the United States, where it is being developed and marketed by Janssen-Cilag International NV and other affiliates of Cilag GmbH International, the licensing partner of Eisai.

Important Safety Information for MDS Patients

Treatment with Dacogen is associated with neutropenia and thrombocytopenia. Complete blood and platelet counts should be performed as needed to monitor response and toxicity, but at a minimum prior to each dosing cycle. Clinicians should consider the need for early institution of growth factors and/or antimicrobial agents for the prevention or treatment of infections in patients with MDS.

Dacogen may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with Dacogen and for 1 month following completion of treatment. Men should be advised not to father a child while receiving treatment with Dacogen, and for 2 months following completion of treatment.

In the MDS Phase 3 controlled clinical trial, the highest incidence of Grade 3 or Grade 4 adverse events in the Dacogen arm were neutropenia (87%), thrombocytopenia (85%), febrile neutropenia (23%), and leukopenia (22%). Bone marrow suppression was the most frequent cause of dose reduction, delay, and discontinuation. Six patients had fatal events associated with their underlying disease and myelosuppression (anemia, neutropenia, and thrombocytopenia) that were considered at least possibly related to drug treatment. Of the 83 Dacogen-treated patients, 8 permanently discontinued therapy for adverse events; compared to 1 of 81 patients in the supportive care arm.

In the MDS single-arm study, the highest incidence of Grade 3 or Grade 4 adverse events were neutropenia (37%), thrombocytopenia (24%), and anemia (22%). Seventy-eight percent of patients had dose delays. Hematologic toxicities and infections were the most frequent causes of dose delays and discontinuation. Eight patients had fatal events due to infection and/or bleeding that were considered at least possibly related to drug treatment. Nineteen of 99 patients permanently discontinued therapy for adverse events.

Other commonly occurring reactions include fatigue, pyrexia, nausea, cough, petechiae, constipation, diarrhea, and hyperglycemia.

If hematological recovery from a previous Dacogen treatment cycle requires more than 6 weeks, then the next Dacogen cycle should be delayed and dosing temporarily reduced. If the following non-hematologic toxicities are present, Dacogen treatment should not be restarted until the toxicity is resolved 1) serum creatinine greater than or equal to 2 mg/dL; 2) SGPT, total bilirubin greater than or equal to 2 X ULN; and 3) active or uncontrolled infection.

There are no data on the use of Dacogen in patients with renal or hepatic dysfunction; therefore, Dacogen should be used with caution in these patients.

The full prescribing information for Dacogen is available on the Eisai website at www.eisai.com.

About SuperGen

SuperGen is a pharmaceutical company dedicated to the discovery and development of novel cancer therapeutics in epigenetic and cell signaling modulation. The Company develops products through biochemical and clinical proof of concept to partner for further development and commercialization. For more information about SuperGen, please visit http://www.supergen.com.

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