



FDA Accepts DACOGEN(R) (Decitabine) sNDA Submission in Acute Myeloid Leukemia

DUBLIN, Calif., Jul 13, 2011 (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 that the U.S. Food and Drug Administration (FDA) has accepted for review its supplemental New Drug Application (sNDA) seeking approval of DACOGEN[®] (decitabine) for injection in the treatment of acute myeloid leukemia. Acute myeloid leukemia (AML) is a life-threatening cancer of the blood for which there are few treatment options.

Acceptance of the sNDA indicates that the FDA has found Eisai's submission to be sufficiently complete to review. The sNDA was submitted to FDA on May 6, 2011.

The application is based on the Phase III randomized open-label, multi-center trial (DACO-016) comparing DACOGEN versus patient's choice with physician's advice of either supportive care or low-dose cytarabine in patients 65 years and older with newly diagnosed *de novo* or secondary AML and with poor- or intermediate-risk cytogenetics. It is the largest randomized controlled study in older patients with AML conducted to date.

About DACOGEN

DACOGEN is currently approved 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.

Important Safety Information

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. After administration of the recommended dosage for the first cycle, treatment for subsequent cycles should be adjusted if indicated by dose adjustment guidelines. 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. Women of childbearing potential should be counseled to use effective contraception during this time. Men should be advised not to father a child while receiving treatment with DACOGEN and for 2 months following completion of treatment. DACOGEN may cause fetal harm. Men with female partners of childbearing potential should use effective contraception during this time.

In the phase 3 clinical trial, the highest incidence of Grade 3 or Grade 4 adverse events in the DACOGEN arm was 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 single-arm study, the highest incidence of Grade 3 or Grade 4 adverse events was neutropenia (37%), thrombocytopenia (24%), and anemia (22%). Seventy-eight percent of patients had dose delays, the median duration of this delay was 7 days. 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 hematologic recovery from a previous DACOGEN treatment cycle requires more than 6 weeks when administering the 3-day dosing, then the next DACOGEN cycle should be delayed and dosing temporarily reduced. When administering the 5-day dosing, the DACOGEN cycle should be delayed until there is hematologic recovery. If the following nonhematologic 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.

Because there are no data on use of DACOGEN in patients with renal or hepatic dysfunction, DACOGEN should be used with caution in these patients.

For DACOGEN full prescribing information, please click [here](#).

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. SuperGen developed *DACOGEN*[®] and receives significant royalties on global sales.

On April 6, 2011, SuperGen entered into a definitive merger agreement to acquire Astex Therapeutics Limited, a UK based biotechnology company. The transaction was approved by SuperGen stockholders on June 16, 2011 and by Astex Therapeutics shareholders on June 13, 2011. The transaction is subject to customary regulatory and legal approvals and is targeted to close in July 2011.

Further information about this transaction is available at <http://www.astex-supergen.com>. For more information about SuperGen, please visit <http://www.supergen.com>.

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