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FDA Approves Five-Day Dosing Regimen for Dacogen® (decitabine) for Injection, Offering a New Outpatient Dosing Option for Myelodysplastic Syndromes (MDS)

Woodcliff Lake, NJ, March 11, 2010 – Eisai Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved a five-day dosing regimen for Dacogen® (decitabine) for Injection to treat patients with myelodysplastic syndromes (MDS), a group of bone marrow diseases that alter the production of functional blood cells.

The new outpatient dosing option provides physicians and patients with the flexibility of a dosing regimen with a reduced infusion time. Dacogen is the only hypomethylating agent approved for a five-day dosing regimen. The new regimen will be administered at a dose of 20 mg/m^2 continuous intravenous (IV) infusion over one hour repeated daily for five days per cycle. The cycle is repeated every four weeks.

The previously approved Dacogen three-day regimen is administered in an in-patient setting at a dose of 15 mg/m^2 continuous IV infusion over three hours repeated every eight hours for three days per cycle and repeated every six weeks.

Three open-label, single-arm, multicenter studies were conducted to evaluate the safety and efficacy of Dacogen in MDS patients with any of the French-American-British (FAB) subtypes. In one study, 99 patients with International Prognostic Scoring System (IPSS) Intermediate-1, Intermediate-2, or high-risk prognostic scores received Dacogen by IV infusion at a dose of 20 mg/m^2 continuous IV infusion over one hour repeated daily for five days per cycle. The cycle is repeated every four weeks.

If myelosuppression is present, subsequent treatment cycles of Dacogen should be delayed until there is a hematologic recovery.

The Dacogen study results, based on International Working Group 2000 Response Criteria, showed that patients experienced an overall response rate (ORR) of 16 percent (complete remission [CR] of 15 percent and a partial response [PR] of 1 percent). In addition, the median time to (CR+PR) response was 162 days and the median duration of (CR+PR) response was 443 days. These results were consistent with the results of the Phase III controlled trial. The highest incidences of Grade 3 or Grade 4 adverse events in the Dacogen arm were neutropenia (37%), thrombocytopenia (24%), and anemia (22%).

"The approval of Dacogen offers doctors and patients the flexibility of choosing the most appropriate dosing regimen for an individual patient," said Steven C. Sembler, Senior Vice President of Commercial U.S. Pharmaceuticals at Eisai Inc. "This important milestone demonstrates our commitment to furthering Eisai's *human health care* mission of increasing benefits for patients and their families."

About MDS

Myelodysplastic syndromes, or MDS, are a potentially life-threatening group of bone marrow diseases that alter the production of functional blood cells. MDS affects mostly people over the age of 60 and is more commonly found in men. People with MDS may experience anemia, neutropenia, and/or thrombocytopenia which can lead to a variety of symptoms including fatigue, shortness of breath, infections, bruising and bleeding. In the United States, between 10,000 and 15,000 new cases of MDS are diagnosed each year.

About Dacogen

Dacogen was first approved by the FDA for treatment of patients with MDS on May 2, 2006. 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.

Dacogen is currently approved in the treatment of MDS in more than 20 countries outside of the United States.

Important Safety Information

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. Men should be advised to not to father a child while receiving treatment with Dacogen, and for two months afterwards.

In the previous Dacogen Phase III studies, the highest incidences 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.

In the single-arm study (N=99) when Dacogen was dosed at 20mg/m^2 intravenous, infused over one hour daily for five consecutive days, 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, the median duration of this delay was seven days and the largest percentage of delays were due to hematologic toxicities. 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 (seven of which occurred in the clinical setting of myelosuppression) that were considered at least possibly related to drug treatment.

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.

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

Dacogen treatment cycles should be delayed until there is a hematological recovery. If the following non-hematologic toxicities are present, Dacogen treatment should not be restarted until the toxicity is resolved 1) serum creatinine ≥ 2 mg/dL; 2) SGPT, total bilirubin ≥ 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.

Please visit www.eisai.com for full prescribing information.

About Eisai Inc.
Eisai Inc. was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). The company began marketing its first product in the United States in 1997 and has rapidly grown to become a fully integrated pharmaceutical business with fiscal year 2008 (year ended March 31, 2009) sales of approximately $3.7 billion. Eisai Inc.'s areas of commercial focus include neurology, gastrointestinal disorders and oncology/critical care. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based *human health care* (*hhc*) company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Maryland, Massachusetts, New Jersey, North Carolina and Pennsylvania as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com.

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ADDITIONAL SUGGESTED QUOTE
"We are very pleased that the FDA has granted approval of the alternate five-day dosing regimen for Dacogen (decitabine) for Injection," said Kathy Heptinstall, operating director, The MDS Foundation, Inc. "This increases dosing options and provides alternatives for our MDS patients, particularly those who are being treated in the outpatient setting."

For media inquiries, contact Kathy Heptinstall, operating director, The MDS Foundation, Inc. at 1-800-MDS-0839, outside the U.S. only (609) 298-6746; fax (609) 298-0590.