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**FDA Accepts sNDA for Alternative Dosing Regimen for Dacogen®  
(decitabine for injection) to Treat Patients with Myelodysplastic Syndromes (MDS)**

Woodcliff Lake, NJ, July 8, 2009 – Eisai Corporation of North America today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's supplemental new drug application (sNDA) for an alternative five-day dosing regimen for Dacogen® (decitabine for injection) to treat patients with myelodysplastic syndromes (MDS). MDS is a potentially life-threatening group of bone marrow diseases that limit the production of functional blood cells.

Currently, Dacogen is approved for use as a three-day regimen, administered at a dose of 15 mg/m<sup>2</sup> via continuous IV infusion over three hours repeated every eight hours for three consecutive days per cycle. The cycle is repeated every six weeks. The alternative five-day dosing regimen of Dacogen® submitted to the U.S. FDA is a single daily dose with a significantly reduced administration time. If approved, patients with MDS may experience increased convenience with the new dosing regimen.

“We're pleased that the FDA has agreed to review our application for the alternative dosing regimen, and we look forward to working with the agency throughout the review process,” said Cynthia Schwalm, President of Eisai Inc. “This application is one part of a full complement of clinical development programs we have committed for Dacogen and is a vital part of our *human health care* mission of increasing patient benefits and fulfilling unmet medical needs.”

Acceptance of the sNDA means that FDA has found the company's submission to be sufficiently complete to review.

**About Dacogen**

The safety profile of decitabine for injection is well characterized. Dacogen (decitabine for injection) was approved by the FDA on May 2, 2006, and 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 may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should 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 two months afterwards. The most commonly occurring adverse reactions with Dacogen include neutropenia (90 percent), thrombocytopenia (89 percent), anemia (82 percent), pyrexia (53 percent), fatigue (48 percent), nausea (42 percent), cough (40 percent), petechiae (39 percent), constipation (35 percent), and diarrhea (34 percent).

Please visit [www.dacogen.com](http://www.dacogen.com) for full prescribing information.

### **About Eisai Corporation of North America**

Eisai Corporation of North America is a wholly-owned subsidiary of Eisai Co., Ltd. and supports the activities of its operating companies in North America. These operating companies include: Eisai Research Institute of Boston, Inc., a discovery operation with strong organic chemistry capabilities; Morphotek, Inc., a biopharmaceutical company specializing in the development of therapeutic monoclonal antibodies; Eisai Medical Research Inc., a clinical development group; Eisai Inc., a commercial operation with manufacturing and marketing/sales functions; and Eisai Machinery U.S.A., which markets and maintains pharmaceutical manufacturing machinery.

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