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**Dacogen[®] (decitabine for injection) Data Presented on a Phase II Clinical Trial
in Elderly Patients with Acute Myeloid Leukemia (AML)**

*Response Observed Across All Subtypes of AML,
Including Those with Poorest Prognoses*

San Francisco, CA, December 8, 2008 – Eisai Corporation of North America today announced data from a Phase II trial evaluating a five-day dosing regimen of Dacogen[®] (decitabine for injection) in acute myeloid leukemia (AML), the most common form of leukemia. The study involved elderly patients with AML, who often have limited options due to comorbidities and are typically considered ineligible for standard induction chemotherapy. These data were presented today at the American Society of Hematology (ASH) 50th Annual Meeting.

Dacogen[®] is indicated for treatment of patients with myelodysplastic syndromes (MDS), including those with refractory anemia with excess blasts (immature or unformed blood cells) in transformation (RAEB-T - now re-classified by World Health Organization [WHO] as AML). Phase II and III clinical trials evaluating Dacogen[®] in patients with AML are currently underway.

Data from the Phase II study reported a complete response rate of 24 percent. A complete response designation requires that the patient have less than 5 percent blasts in the marrow, no evidence of disease outside of the bone marrow and absolute neutrophil and platelet counts of more than 1,000/uL and 100,000/uL, respectively. The majority of patients in the trial had intermediate or poor risk cytogenetics (bone marrow tests to identify abnormal chromosomes), which are associated with poor prognoses. Responses were observed across all patients including those with poor risk cytogenetics, those whose AML transformed from MDS, or those who developed AML after previous treatment for cancer. The results presented at ASH provide additional support for the ongoing investigation of Dacogen[®] in a Phase III trial currently underway in elderly patients with AML.

“We are enthusiastic about these new data presented at ASH and look forward to seeing results from our ongoing, global Phase III trial evaluating Dacogen in elderly AML patients,” said Edward B. Rubenstein, MD, senior vice president, medical affairs, Oncology & Institutional Care Business Unit, Eisai Inc. “The data presented today

support our commitment to continue to evaluate Dacogen as a treatment option for elderly patients with AML.”

Study Details

The primary objective of this multi-center, open-label, Phase II trial was to establish the morphologic complete response (CR) rate. Dacogen[®] was administered intravenously over one hour for five consecutive days every four weeks at a dose of 20 mg/m².

Of the 55 patients enrolled in the trial, most patients had intermediate (53 percent) or poor (42 percent) risk cytogenetics, which are associated with a poor prognosis. According to the AML response criteria, the expert-reviewed overall response rate in the intent-to-treat (ITT) population was 26 percent, with morphologic CR in 24 percent of patients and CR with incomplete blood count recovery (CRi) in 2 percent. The median time to response was three months, and responses were seen in all subgroups of patients, including patients with the poorest prognoses. Additionally, 44 percent of patients maintained stable disease during a median five cycles of therapy.

“AML is a difficult-to-treat blood cancer, particularly in elderly patients who cannot endure the toxic side effects of standard induction chemotherapy,” said lead investigator, Amanda Cashen, MD, assistant professor, Washington University School of Medicine. “These data indicate that further trials are warranted in this elderly population and we look forward to seeing additional Dacogen results reported.”

Besides myelosuppression, the most commonly reported adverse events considered possibly related to decitabine treatment were febrile neutropenia, fatigue, pneumonia, sepsis, dyspnea and bacteraemia.

The five-day dosing regimen of Dacogen[®] is currently being further evaluated in a global, Phase III survival study in elderly patients with AML.

About Acute Myeloid Leukemia (AML)

Acute myeloid leukemia is a rapidly progressing cancer of the blood and bone marrow characterized by an overgrowth of abnormal blood cells that quickly crowd out the healthy blood cells needed by the body. The National Cancer Institute estimated that more than 13,000 patients would be diagnosed with AML in 2008, and nearly 9,000 deaths would occur as a result of the disease.

The average age of a patient with AML is 67 years old, with diagnoses very rarely occurring before the age of 40. Due to the fast-growing nature of AML, it is important for patients to be treated promptly upon diagnosis to minimize the risk of the disease progression. Induction chemotherapy, the standard front-line AML therapy, is associated

with high toxicity, including bone marrow suppression and increased risk of infection, which often limits use in elderly patients with a poor prognosis.

About Dacogen[®]

Dacogen[®] (decitabine for injection) was approved by the U.S. Food and Drug Administration 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 for full prescribing information.