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*Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.*

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Eisai Co., Ltd.

**EISAI PROVIDES PRELIMINARY EFFICACY UPDATE ON EORTC  
PHASE III TRIAL OF DACOGEN<sup>®</sup> VERSUS SUPPORTIVE CARE  
IN PATIENTS WITH MYELODYSPLASTIC SYNDROMES**

***- Submission of Five Day Dosing Regimen sNDA Targeted for Fiscal Year-end 2008 -***

Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu), a U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito), today announced the preliminary efficacy data from a trial initiated in 2002 comparing Dacogen<sup>®</sup> (decitabine) to best supportive care (BSC) in elderly patients with myelodysplastic syndromes (MDS). The data did not demonstrate a statistically significant advantage of Dacogen treatment on median survival. However, response rates were similar to those observed in other clinical trials of Dacogen in patients with MDS. The trial, conducted by the European Organisation for the Research and Treatment of Cancer (EORTC), was administered on a three-day dosing schedule. In this study, the number of treatment cycles was limited. MDS is a potentially life-threatening group of bone marrow diseases that limit the production of functional blood cells.

Subsequent to database lock and the completion of data analysis, comprehensive results of the study, including secondary efficacy endpoints and safety data, will be presented by EORTC at an upcoming scientific forum.

**Current Development**

Eisai plans to submit a supplemental New Drug Application (sNDA) with the U.S. Food and Drug Administration by the end of the fiscal year for a five-day regimen for Dacogen. The sNDA will be based on a North American, multi-center, open label, single arm Phase II trial (Daco – 020) in which patients received Dacogen every day for five days. The regimen was repeated every four weeks with no limit on the number of treatment cycles that patients could receive as long as they received clinical benefit or until their disease progressed. Median survival at the time of data analysis was 19.4 months and the one-year survival rate for patients treated with Dacogen was 66 percent. An overall complete response rate of 32 percent (International Working Group 2006 Criteria) was achieved with the outpatient administration of Dacogen, confirming

previously reported response rates in the outpatient setting. The safety profile of this dosing regimen was consistent with what has been previously reported.

Eisai is committed to a clinical development program to optimize the utility of Dacogen for all patients with MDS. Recent studies of hypomethylating agents have suggested that treatment of patients should continue for as long as they receive clinical benefit or until their disease progresses. To advance the understanding of optimal treatment for MDS and related conditions, there are currently more than 30 ongoing trials with Dacogen either as a single agent or in combination with other therapies, including a Phase III survival study in older patients with acute myelogenous leukemia (AML).

## **Study Design**

*EORTC-06011:* This Phase III open-label, randomized, multicenter, controlled trial evaluated overall survival of patients receiving Dacogen plus BSC versus BSC only. The study involved 233 elderly patients, greater than or equal to 60 years of age, with predominantly high-risk or Intermediate-2 type MDS.

Patients included in the trial had primary or secondary MDS with or without previous therapy with growth factors, immunosuppressive agents or hydroxyurea. In order to participate in the study, patients had to have bone marrow blast counts between 11 and 30 percent. Patients with blast counts below 10 percent were required to have had poor-risk cytogenetics in order to be eligible for randomization.

*DACO-020:* This is a multicenter, open label, single arm Phase II study of Dacogen in 99 patients with de novo or secondary MDS. Dacogen was administered daily for five days repeated every four weeks. Patients were equal to or greater than 18 years of age with MDS (*de novo* or secondary) of any FAB subtype and International Prognostic Scoring System score of equal to or greater than 0.5. In order to be included in the cytogenetic analysis, patients must have had abnormal cytogenetics at baseline and adequate cytogenetic data available for at least one post-baseline visit.

## **About MDS**

Myelodysplastic syndromes, or MDS, are a group of diseases of the bone marrow characterized by the production of poorly functioning and immature blood cells. People with MDS may experience a variety of symptoms and complications, including anemia, bleeding, infection, fatigue and weakness. Those patients with high-risk MDS may experience bone marrow failure, which may lead to death from bleeding and infection. Over time, MDS can progress to acute leukemia, or AML. The Aplastic Anemia and MDS International Foundation currently estimates that up to 30,000 new cases of MDS are diagnosed annually in the United States.

## **About Dacogen<sup>®</sup>**

Dacogen<sup>®</sup> (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.

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