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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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® (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

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 re

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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