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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 to Initiate Clinical Trial of Dacogen® in Pediatric Patients with Acute Myelogenous Leukemia in the US

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, "Eisai") announced today that its US subsidiary, Eisai Medical Research Inc. (Headquarters: New Jersey, President: Masanori Tsuno), will initiate a clinical trial of Dacogen® (decitabine) for Injection in pediatric patients with acute myelogenous leukemia (AML) in the US.

The clinical trial for Dacogen in pediatric patients with AML will be conducted in accordance with a Written Request issued by the US Food and Drug Administration (FDA). The objective of the study is to evaluate the clinical benefits of Dacogen in pediatric patients with AML. In accordance with the FDA's Pediatric Exclusivity Provision and upon completion of the clinical trial, Eisai will seek an additional six months of exclusivity for Dacogen. If the FDA determines that the data from the clinical trial appropriately meet requirements set out in the Written Request, six-month pediatric exclusivity will be granted for Dacogen, extending its patent to November, 2013.

AML is a life-threatening disease and the most common form of acute leukemia. It is estimated that the US incidence of AML in children age 0-14 is 6.9 per 1 million persons.

Dacogen is approved by the FDA and is currently indicated in the US 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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