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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.

FDA Approves Five-Day Dosing Regimen for Dacogen®

New Regimen Offers a New Outpatient Dosing Option for Myelodysplastic Syndromes

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that its U.S. subsidiary Eisai Inc. received approval from the U.S. Food and Drug Administration (FDA) on March 11 (U.S. Eastern Standard Time) for a five-day dosing regimen of the hypo-methylating agent Dacogen® (generic name: decitabine) for Injection to treat patients with myelodysplastic syndromes (MDS).

Dacogen® was approved by the FDA in May 2006 as a treatment for MDS. The product has been marketed by Eisai Inc. since January 2008 in the United States.

The previously approved dosing regimen for Dacogen® is administered at a dose of 15mg/m^2 by continuous intravenous infusion over three hours repeated every eight hours for three consecutive days per cycle and repeated every six weeks. The newly approved five-day dosing regimen will be administered at a dose of 20mg/m^2 by continuous intravenous infusion over one hour repeated daily for five days per cycle. The cycle is repeated every four weeks.

The approval of the new five-day dosing regimen offers patients with MDS and healthcare professionals the flexibility of choosing the appropriate dosing regimen. It is also expected to make a contribution in outpatient treatment with reduced infusion time.

MDS is a potentially life-threatening group of bone marrow diseases that alter the production of functional blood cells. Over time, MDS can progress to acute myelogenous leukemia. In the United States, between 10,000 and 15,000 new cases of MDS are diagnosed each year.

Eisai has been conducting clinical development of an additional dosing regimen of Dacogen® in order to address the unmet medical needs of patients with MDS and healthcare professionals. By providing the newly approved five-day dosing regimen as an alternative treatment option, Eisai will continue to make contributions to increasing benefits for patients living with MDS.

[Please see the following notes for product information]

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<Notes to Editors>

■About Dacogen® (Product Outline of the United States)

Product Name:
Dacogen® for Injection

Generic Name:
decitabine

Formulation:
Injectable

Indications and Usage:
Dacogen® for Injection 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 anaemia, refractory anaemia with ringed sideroblasts, refractory anaemia with excess blasts, refractory anaemia with excess blasts in transformation, chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System (IPSS) groups.

Dosage and Administration:
- Dacogen is administered at a dose of 15mg/m^2 by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. This cycle should be repeated every 6 weeks.
- Dacogen is administered at a dose of 20mg/m^2 by continuous intravenous infusion over 1 hour repeated daily for 5 days. This cycle should be repeated every 4 weeks.

Major Adverse Events:
- The highest incidences of Grade 3 or Grade 4 adverse events (Phase III trials) :
  Neutropenia (87%), thrombocytopenia (85%), febrile neutropenia (23%), leukopenia (22%)
- The highest incidences of Grade 3 or Grade 4 adverse events (the single-arm study (N=99) when Dacogen was dosed at 20mg/m2 intravenous, infused over 1 hour daily for 5 consecutive days)
  Neutropenia (37%), thrombocytopenia (24%), anaemia (22%)