



**Eisai Co., Ltd.**

**4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan**

**Phone: 03-3817-5120**

**Fax: 03-3811-3077**

*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.*

---

**FOR IMMEDIATE RELEASE**

No. 09-27

July 8, 2009

Eisai Co., Ltd.

**FDA Accepts sNDA for Alternative Dosing of Dacogen<sup>®</sup>  
to Treat Patients with Myelodysplastic Syndromes (MDS)**

Eisai Corporation of North America (Headquarters: New Jersey, Chairman and CEO: Hajime Shimizu), a US subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito), announced today that the US Food and Drug Administration (FDA) has accepted for review the Company's supplemental new drug application (sNDA) for an alternative five-day dosing regimen of Dacogen<sup>®</sup> (decitabine) for Injection to treat patients with myelodysplastic syndromes (MDS).

Dacogen<sup>®</sup> was approved by the US FDA in May, 2006 for treatment of patients with MDS. Currently, Dacogen<sup>®</sup> is approved for use as a three-day dosing regimen, administered at a dose of 15 mg/m<sup>2</sup> by continuous intravenous infusion over three hours repeated every eight hours for three consecutive days per cycle. The cycle is repeated every six weeks. The alternative five-day dosing regimen of Dacogen<sup>®</sup> submitted to the US FDA is a single daily dose with a significantly reduced administration time. If approved, patients with MDS may experience increased convenience with the new dosing regimen.

MDS is a potentially life-threatening group of bone marrow diseases that limit the production of functional blood cells. Over time, MDS can progress to acute myelogenous leukemia, or AML. It is estimated that up to 30,000 new cases of MDS are diagnosed annually in the US.

With the application for the alternative five-day dosing regimen, Eisai will aim to provide a new dosing option for patients and healthcare professionals. Eisai continues to make further contributions to addressing unmet medical needs of patients with MDS and to improving their benefits.

Contact:

PR Department

Eisai Co., Ltd.

+81 - (0)3 - 3817 - 5120