No.11-54

July 14, 2011
Eisai Co., Ltd.

EISAI ANNOUNCES FDA ACCEPTANCE OF sNDA SUBMISSION FOR DACOGEN® IN ACUTE MYELOID LEUKEMIA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review its supplemental New Drug Application (sNDA) seeking approval of DACOGEN® (decitabine) for injection in the treatment of acute myeloid leukemia. Acute myeloid leukemia (AML) is a life-threatening cancer of the blood for which there are few treatment options.

Acceptance of the sNDA indicates that the FDA has found the company's submission to be sufficiently complete to review. The sNDA was submitted to the FDA on May 6, 2011.

The application is based on the Phase III randomized open-label, multi-center trial (DACO-016) comparing DACOGEN® versus patient's choice with physician's advice of either supportive care or low-dose cytarabine in patients 65 years and older with newly diagnosed *de novo* or secondary acute myeloid leukemia (AML) and with poor-or intermediate-risk cytogenetics.

DACOGEN® has been marketed by Eisai in the United States since 2006 as a treatment for Myelodysplastic syndromes (MDS). If approved, the additional AML indication will allow Eisai to further increase the benefits it provides to patients and their families.

[Please refer to the following notes for further information on Acute Myeloid Leukemia (AML), DACOGEN® and the DACO-016 Study]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

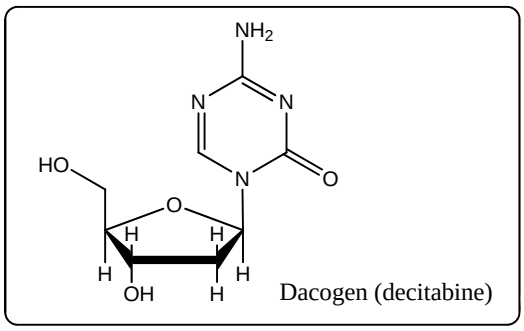
[Notes to editors]

1. About Acute Myeloid Leukemia (AML)

Acute Myeloid Leukemia is a form of leukemia characterized by abnormal growth of immature leukemia cells known as myeloblasts caused by the differentiation arrest of hematopoietic stem cells. Proliferative leukemia cells take over the bone marrow where they crowd out normal hematopoietic cells and interfere with the production of healthy normal blood cells. The resulting decrease in red blood cells, white blood cells and blood platelets leads to a variety of symptoms such as bleeding, infections and anemia. AML is a life-threatening disease as leukemia cells that have spilled out into peripheral blood invade various organs throughout the body, ultimately causing the destruction of organ tissue.

2. About DACOGEN®

DACOGEN® is approved in the United States for the 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 leukemia), and Intermediate-1, Intermediate-2 and High-Risk International Prognostic Scoring System (IPSS) groups.



Dacogen (decitabine)

3. About the DACO-016 Study

DACO-016 was a Phase III randomized open-label, multi-center trial comparing DACOGEN® versus patient's choice with physician's advice of either supportive care or low-dose cytarabine in patients 65 years and older with newly diagnosed *de novo* or secondary acute myeloid leukemia (AML) and with poor- or intermediate risk cytogenetics.

Of the 485 patients, 242 were randomized to DACOGEN® and 243 to patient's choice of supportive care or low-dose cytarabine. DACOGEN® was administered at 20 mg/m^2 for one hour by intravenous infusion once daily for five consecutive days repeated every four weeks, continued as long as the patient derived benefit. Patients treated with cytarabine received 20 mg/m^2 subcutaneously once daily for 10 consecutive days every four weeks. The median duration of treatment for patients on DACOGEN® was 4.4 months, compared with 2.4 months in the cytarabine group.