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FOR IMMEDIATE RELEASE

No. 08-56

October 16, 2008

Eisai Co., Ltd.

**FDA Grants Full Approval to ONTAK[®] (denileukin diftitox)
For Use in Patients with Cutaneous T-Cell Lymphoma (CTCL)**

***Conversion from Accelerated Approval to Full Approval Based on Largest
Phase III Placebo-Controlled Trial Ever Conducted in CTCL***

Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu), a U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito), announced on October 15th (EST) that the U.S. Food and Drug Administration (FDA) has approved an efficacy supplemental biologics license application (sBLA) for ONTAK[®]

In addition, analysis of a secondary endpoint, progression-free survival (PFS), suggested a 73% reduction in risk of disease progression in the 18 mcg/kg/day group (hazard ratio = 0.27, $p = 0.0002$, 95% CI 0.14, 0.54) and a 58% reduction in risk of disease progression in the 9 mcg/kg/day group (hazard ratio = 0.42, $p = 0.02$, 95% CI 0.20, 0.86) compared to placebo.

CTCL is a term for a group of rare malignant lymphomas with primary manifestation in the skin. In patients with CTCL, some T-cells, which the body uses to fight infections, become cancerous and result in skin lesions. CTCL is a slowly progressive disease for which there is no known cure. Approximately 2,900 people are diagnosed annually with CTCL in the United States (9.6 cases per million people). The staging of CTCL is based on an evaluation of the type and extent of skin lesions and the extent of lymph node, peripheral blood and visceral involvement. Stage Ia is the earliest stage and stage IVb is the most advanced.

The full approval of ONTAK, which is an orphan drug indicated for a rare disease, is in keeping with our *human health care* mission, to address the unmet medical needs of patients with CTCL. Eisai remains committed to make further contributions to patients with CTCL.

[Please refer to the following note for ONTAK]

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<Notes to Editors>

About ONTAK

ONTAK is indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor. ONTAK is a genetically-engineered cytotoxic fusion protein consisting of the amino acid sequences for the enzymatically-a