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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 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® (denileukin diftitox) solution for intravenous injection for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of the interleukin (IL)-2 receptor (CD25+). A separate efficacy supplement that included data from patients with CTCL whose malignant cells did not test positive for the CD25 component of the IL-2 receptor received a complete response letter.

The FDA's action, following a priority review, marks the conversion of an accelerated approval indication to full approval and is based on data from a Phase III clinical trial that evaluated the overall efficacy and safety of ONTAK in certain patients with CTCL. This trial was the largest Phase III, randomized, double-blind, placebo-controlled trial ever conducted in CTCL. The study enrolled a total of 144 patients with CTCL whose malignant cells expressed the CD25 component of the IL-2 receptor. Patients were randomized to receive either of two doses of ONTAK [18 mcg/kg/day (n=55) or 9 mcg/kg/day (n=45)] or placebo (n=44) for up to eight cycles of therapy.

The study met its primary endpoint of overall response rate (ORR). ORR is the sum of complete and partial responses seen in a study, divided by the number of evaluable patients. The ORR was 46% for the 18 mcg/kg/day dose of ONTAK (p = 0.002 vs. placebo) and 37% for the 9 mcg/kg/day dose (p = 0.03 vs. placebo) vs 15% for placebo.

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-active portion of diphtheria toxin fused to the sequence of human interleukin-2, resulting in a molecule that is cytotoxic for cells bearing the target IL-2 receptor.

ONTAK was granted approval in February 1999 under Subpart E, an FDA regulation that allows the accelerated approval of a biologic agent based on a surrogate endpoint or an effect on a clinical endpoint other than survival. The process by which ONTAK received accelerated approval requires a confirmatory, placebo-controlled Phase III trial. Accelerated approval is most commonly granted in serious diseases or for medications that fill an unmet medical need.