

**FOR IMMEDIATE RELEASE**

October 26, 2009

Eisai Co., Ltd.  
TSD Japan, Inc.

**Eisai and TSD Japan Enter into a License and Joint Development  
Agreement of Denileukin Diftitox in Japan**

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, “Eisai”) and TSD Japan, Inc. (Headquarters: Osaka, President and CEO: Yoshiharu Sakashita, “TSD”) today announced that they had concluded a license and joint development agreement for the development of denileukin diftitox (generic name) in Japan. Under the terms of the agreement, Eisai shall grant TSD the exclusive right to co-develop the drug in Japan, while Eisai will retain the exclusive right to market the product once marketing authorisation has been granted.

Denileukin diftitox is a solution for intravenous injection for the treatment of patients with cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of the interleukin (IL)-2 receptor (CD25+). In February 1999, the drug was granted accelerated approval as a biological product in the United States by the U.S. Food and Drug Administration under Subpart E, an FDA regulation. It has been made available for healthcare professionals since then, and in October 2008, the accelerated approval was converted to full approval. Denileukin diftitox has been granted orphan drug status in the U.S. and is currently marketed by Eisai’s U.S. subsidiary under the brand name of ONTAK<sup>®</sup>.

CTCL is a type of cutaneous non-Hodgkin’s lymphoma that comes in a variety of forms. In CTCL, T cells, a type of lymphocyte that plays a role in the immune system, become cancerous and develop into skin lesions. The quality of life (QOL) of patients with this disease is greatly reduced due to severe pain and pruritus. While CTCL is often regarded as a low-grade lymphoma, it is slowly progressive and can take anywhere from several years to upwards of ten to reach tumour stage. By the time it has reached this stage, the cancer is highly malignant and has usually spread to the lymph nodes and internal organs, which may lead to a poor prognosis. There has been no known cure for CTCL as yet and treatment of this disease can still be very difficult.

Eisai and TSD will work closely together in an effort to meet unmet medical needs and will expedite the development of the drug so as to bring a new treatment option to patients with CTCL and healthcare professionals as early as possible.

**[Please refer to the following notes for the information on CTCL and TSD Japan.]**

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## <Notes to editors>

### ■ Cutaneous T-Cell Lymphoma (CTCL)

CTCL is a type of cutaneous non-Hodgkins lymphoma that comes in a variety of forms. Mycosis fungoides (MF) and Sézary Syndrome are the most common forms of this disease. While CTCL is often regarded as a low-grade lymphoma, it is slowly progressive and can take anywhere from several years to upwards of ten to reach tumour stage (stage IIB - IVB by tumour-node-metastasis classification). By the time it has reached this stage, the cancer is highly malignant, and has usually spread to the lymph nodes and internal organs, which may lead to a poor prognosis. There has been no known cure for CTCL as yet and treatment of this disease can still be very difficult.

### ■ About TSD Japan, Inc.

TSD Japan, Inc. (“TSD”) was set up in 2005 to develop drugs, especially for oncology, refractory diseases and its adjuvant treatments, which have not been on the Japanese market and are required by the patients as soon as possible.

To develop new and innovative pharmaceutical products, TSD has established a unique business model combining expertise in partnering between pharmaceutical companies in Japan and domestic or foreign drug-discovery bio-venture companies, in clinical studies with in-house clinical development functions, and in consulting of clinical development.

In January 2009, TSD entered into a license agreement with GenomIdea Inc. to develop, manufacture and distribute HVJ envelope for the treatment of prostate cancer in Japan, which is currently under co-development of its non-clinical studies with GenomIdea Inc. On August 31, 2009, this HVJ-E project was approved by the government-financed aid project for strategic sophistication of Basic Manufacturing Technology by Ministry of Economy, Trade and Industry (METI).

More information about TSD is available on the following Web site <http://www.tsd-japan.co.jp>