

**FOR IMMEDIATE RELEASE**

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Eisai Co., Ltd.  
Minophagen Pharmaceutical Co., Ltd.

**Eisai and Minophagen Pharmaceutical Conclude Japan License Agreement for Cutaneous T-Cell Lymphoma Treatment Bexarotene**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") and Minophagen Pharmaceutical Co., Ltd. (Headquarters: Tokyo, President & Representative Director: Tokuchiro Utsunomiya, "Minophagen") announced today that they have concluded a Japan license agreement concerning bexarotene (generic name), a treatment for cutaneous T-cell lymphoma (CTCL). Under the terms of the agreement, Eisai shall grant Minophagen the exclusive rights to develop and commercialize bexarotene in Japan while Eisai will retain the option to co-promote the agent in Japan, if and when it is approved.

Bexarotene, acquired from U.S.-based Ligand Pharmaceuticals Inc. in October 2006, is a product for which Eisai holds worldwide exclusive rights. Ligand Pharmaceuticals obtained orphan drug status for bexarotene in the United States in 1999 and subsequently went on to launch it under the brand name Targretin<sup>®</sup>. The agent is now available in 26 countries in Europe, North America and South America for the treatment of patients with recurrent or refractory CTCL.

CTCL is a type of primary cutaneous lymphoma characterized by proliferation and manifestations of T-cells in the skin. This type of lymphoma may reoccur on the same site or spread to other parts of the body, progressing slowly over anywhere between a few years to a few decades, and rarely leading to poor prognosis. Mycosis fungoides and Sézary syndrome are known to be the two most common forms of CTCL. CTCL is extremely rare with an annual incidence of approximately 0.3 to 0.9 cases per 100,000 population overseas. According to a nationwide survey<sup>1)</sup> carried out by the Japanese Skin Cancer Society, 278 new cases of the CTCL were diagnosed in Japan in 2008.

Targretin<sup>®</sup> is defined as a standard of care for CTCL in leading treatment guidelines<sup>2)</sup> such as those issued by the European Organization for Research and Treatment for Cancer (EORTC). With the conclusion of this agreement, Eisai and Minophagen will work in tandem to expedite the delivery of the agent as a new treatment option in an effort to satisfy the unmet medical needs of CTCL patients in Japan.

1) Hamada T. A 2008 nationwide survey on cutaneous lymphomas

2) Trautinger, F et al. Eur J Cancer. 2006;42(8):1014

**[Please refer to the following notes for a glossary of terms]**

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## **[Notes to editors]**

### **1. Glossary of Terms**

#### **1) Mycosis fungoides**

Mycosis fungoides is the most common form of CTCL, accounting for over 50% of CTCL cases in Japan. While the cause of mycosis fungoides remains unknown, red skin patches (erythroderma) similar to eczema appear on the stomach, buttocks, thighs, back and other parts of the body during the early-stage of the disease (erythema (patch) stage). Reoccurring on the same site or spreading to other parts of the body, mycosis fungoides progresses slowly from the erythema stage to the squamous invasive (plaque) stage, and in some cases, develops into tumor stage (advanced stage) which may metastasize to the lymph nodes or internal organs, leading to a poor prognosis. Unless patches turn tumor, mycosis fungoides is a relatively low-grade form of lymphoma.

#### **2) Sézary Syndrome**

Like mycosis fungoides, Sézary syndrome is a common form of CTCL that is characterized by the appearance of erythroderma, systemic lymph node enlargement, and atypical lymphocytes with characteristic convoluted nuclei known as Sézary cells in the peripheral blood. Other symptoms may include erythroderma, alopecia (hair loss), and hyperkeratosis of the palms of the hand or soles of the feet accompanied by itching. Sézary syndrome is typically generated from mycosis fungoides, however, it may also be the result of a separate disease entity. Compared to mycosis fungoides, it is a high-grade form of lymphoma.

#### **3) EORTC**

EORTC is an acronym for the European Organization for Research and Treatment of Cancer, an international organization comprised of network of member institutions from across Europe who work together to improve cancer research and treatment. The EORTC is responsible for developing international cancer treatment guidelines.