

FOR IMMEDIATE RELEASE

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

Eisai and Minophagen Pharmaceutical Conclude License Agreement Concerning the Development and Commercialization of Cutaneous T-Cell Lymphoma Treatment Bexarotene in Asia, Oceania, the Middle East and Eastern Europe, etc.

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") and Minophagen Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Representative Director & President: Tokuichiro Utsunomiya, "Minophagen Pharmaceutical") announced today that they have concluded a license agreement concerning bexarotene (generic name), a treatment for cutaneous T-cell lymphoma (CTCL).

Under the terms of the agreement, Eisai shall grant Minophagen Pharmaceutical the exclusive rights to develop and commercialize bexarotene in Asia, Oceania, the Middle East and Eastern Europe, amongst other regions. However, Eisai retains the right of first negotiation for the commercialization of the agent in the licensed territories, if and when it is approved. In addition, Eisai will receive from Minophagen Pharmaceutical a one-time lump sum payment upon conclusion of the agreement as well as milestone payments and royalties on future sales.

Bexarotene was granted orphan drug status in the United States in 1999, and is currently approved and marketed as a treatment for recurrent and refractory CTCL in over 20 countries worldwide including the United States and those in Europe. Eisai obtained the exclusive worldwide rights to bexarotene when it acquired the agent from U.S.-based Ligand Pharmaceuticals Inc. in October 2006. Bexarotene is currently marketed in the United States by Eisai's U.S. subsidiary Eisai Inc. under the brand name Targretin[®]. The exclusive rights to develop and commercialize the agent in Japan were granted to Minophagen Pharmaceutical by Eisai in March 2011.

CTCL is a type of cutaneous lymphoma that is characterized by the proliferation of T-cells in the skin. This type of lymphoma may reoccur in the same spot or spread to other parts of the body, progressing slowly over anywhere between a few years to a few decades, and is rarely associated with poor prognosis. Mycosis fungoides and Sézary syndrome are known as the two most common forms of CTCL. An extremely rare disease, CTCL affects between 16,000 and 20,000 patients in the United States, with approximately 1,500 new cases being diagnosed each year¹⁾. Bexarotene is recommended as a treatment for CTCL in NCCN (National Comprehensive Cancer Network) and other major treatment guidelines in the United States and Europe.

With the conclusion of the agreement, Eisai and Minophagen Pharmaceutical will work closely together to provide bexarotene as a new treatment option as early as possible in order to help address the unmet medical needs of CTCL patients in Japan, Asia, Oceania, the Middle East and Eastern Europe, amongst other regions.

1) Source: Ivan V. Litvinov, et al. Clin Cancer Res 2010; 16:2106-2114

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

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[Notes to editors]

1. Glossary of Terms

1) Bexarotene (Brand name: Targretin®)

Bexarotene, discovered and developed by U.S.-based Ligand Pharmaceuticals Inc., is a synthetic retinoid that selectively binds retinoid X receptors and regulates the function of genes that control cellular differentiation and proliferation. The agent was launched first in the United States in 1999 as a treatment for recurrent and refractory cutaneous T-cell lymphoma (CTCL) under the brand name Targretin®, and is currently approved and marketed in over 20 countries including the United States and those in Europe. Eisai obtained the exclusive worldwide rights to bexarotene when it acquired the agent from Ligand Pharmaceuticals in October 2006. Bexarotene is currently marketed in the United States by Eisai's U.S. subsidiary Eisai Inc. in both capsule and topical formulations—Targretin® Capsules and Targretin® Gel 1%, with Targretin® Capsules also being sold in Europe. The exclusive rights to develop and commercialize bexarotene in Japan were granted to Minophagen Pharmaceutical by Eisai in March 2011.

2) 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, patches of red skin (erythema) 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 in the same spot or spreading to other parts of the body, mycosis fungoides progresses slowly from the erythema stage to the squamous invasive (plaque) stage. In some cases, the disease progresses to the tumor stage (advanced stage) and metastasizes to the lymph nodes or internal organs, in which case prognosis tends to be poor. Unless patches turn tumorous, however, mycosis fungoides is a relatively low-grade form of lymphoma.

3) Sézary Syndrome

Like mycosis fungoides, Sézary syndrome is a common form of CTCL. It is characterized by the appearance of erythroderma, systemic lymph node enlargement, and the presence of atypical lymphocytes (T-cells) with a convoluted nucleus known as Sézary cells in the peripheral blood. Patients with this form of CTCL may also experience erythroderma accompanied by itching, alopecia (hair loss) and hyperkeratosis of the palms of the hand and/or soles of the feet. Sézary syndrome typically evolves as a more aggressive variant of mycosis fungoides, however, it may also present *de novo* as a separate disease entity. Compared to mycosis fungoides, it is a relatively high-grade form of lymphoma.