

February 1, 2016

Minophagen Pharmaceutical Co., Ltd.

### **Minophagen Pharmaceutical Got Approved for Targretin® Capsules 75mg in Japan**

Minophagen Pharmaceutical Co., Ltd. (Headquarters: Tokyo; Representative Director and President: Tokuichiro Utsunomiya, Ph.D.) (hereinafter referred to as "Minophagen") announced that Targretin® Capsules (bexarotene) 75 mg have been approved (on January 22, 2016) by the Ministry of Health, Labour and Welfare for the treatment of cutaneous T-cell lymphoma (CTCL).

Bexarotene was approved in the USA in 1999, under the brand name Targretin®. The drug is under distribution in 39 countries and regions. In Europe and America, the NCCN (National Comprehensive Cancer Network) and EORTC (European Organisation for Research and Treatment of Cancer) treatment guidelines recommend the application of Targretin® to treat CTCL.

Bexarotene, a type of retinoid, is effective for treating malignant tumors, and it can selectively combine with the retinoid X receptor (RXR). Bexarotene can induce apoptosis and is effective in arresting cell cycle; these effects are considered to suppress tumor growth.

CTCL appears gradually when malignant transformed T cells grow and progress in the skin, with frequent and repeated occurrence for years or even several decades. It is a cutaneous lymphoma with poor prognosis, and the two most common subtypes of CTCL are mycosis fungoides and Sèzary's syndrome. According to a survey conducted in 2011 by the Information Department of the Minister's Secretariat at the Ministry of Health, Labour and Welfare (Basic classification of diseases, all patients, 97<sup>th</sup> tabulation of results), it is estimated that there are 1,000 patients in Japan suffering from mycosis fungoides, being a rare disease. We started R&D on bexarotene after the Ministry of Health, Labour and Welfare designated the drug for the treatment of a rare disease.

Approval of the drug was based on Phase I/II clinical trials (trials of B-1101) in Japan, and clinical trial results overseas.

Through the launch of Targretin® Capsules 75 mg, Minophagen aims to provide a new option for the treatment of CTCL (a rare disease) in order to contribute to the patients' quality of life (QOL). We shall obey the approval conditions of properly conducting specific use-results survey (all cases to be investigated), and shall market the drug with information on its proper use.