MINOPHAGEN PHARMACEUTICAL CO., LTD.

Targretin® (Bexarotene) receives Marketing Authorisation in Hong Kong for Cutaneous T-Cell Lymphoma

July 16, 2024

Minophagen Pharmaceutical (Headquarters: Tokyo; CEO & President: Tokuichiro Utsunomiya, Ph.D.) (hereinafter referred to as "Minophagen") today announced that its partner, Main Life Corp., Ltd (Headquarters: Hong Kong SAR, China; General Manager: JiTi Wang) (hereinafter referred to as "Main Life") obtained the marketing authorisation of Targretin® (bexarotene) capsules in Hong Kong. The approval is given by the Department of Health of Hong Kong for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy.

The availability of Targretin® provides patients living with CTCL in Hong Kong with the option of a drug considered standard-of-care in international clinical practice. The approval is the second marketing approval in China following import license approval from Macau earlier this year, and is also the second approval to be received in Asia (excluding Japan).

Targretin® was first approved by USFDA in 1999 and is currently available in 36 countries or regions [1] for the treatment of CTCL. It is recommended as a treatment option in major treatment guidelines such as the National Comprehensive Cancer Network (NCCN) and the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

Targretin® is an antineoplastic agent that contains a type of retinoid called bexarotene as an active substance. It is thought that bexarotene selectively binds to retinoid X receptor (RXR) and suppresses tumor growth by inducing apoptosis and cell cycle arrest.

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 subtypes of CTCL.

Based on license agreements concluded with Eisai Co., Ltd. in March 2011 and April 2012, Minophagen has exclusive rights to develop and commercialise Targretin® in Japan, Asia, Oceania, the Middle East, and Eastern Europe etc. In Japan, Minophagen obtained approval for the indication of cutaneous T-cell lymphoma in January 2016, and launched sales in June the same year. In mainland China, Minophagen has obtained an Investigational New Drug (IND) approval from the

National Medical Products Administration (NMPA) in order to start clinical trials.

Main Life had applied for marketing approval in Hong Kong and Macau, pursuant to an exclusive agreement between Minophagen and Main Life to grant Main Life exclusive development and commercialisation rights in the territory.

Minophagen will continue to support quality of life of patients in Asia by offering Targretin as a new treatment option for this rare disease.

About Main Life
General Manager: JiTi Wang
Head Office: Hong Kong SAR, China
Founded in Hong Kong in 1971, Main Life is a pharmaceutical distributor with rich experience of marketing Japanese pharmaceutical products in China. In Hong Kong and Macau, its marketing capabilities cover all channels including government and private hospitals, clinics and pharmacies. For more information, visit www.mainlife.com.hk

*1 as of December, 2022

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