News Release

July 3, 2017
Maruho Co., Ltd.

Maruho receives manufacturing and marketing approval for Anti-Herpes Virus Agent “Amenalief® Tab. 200mg” in Japan

Osaka (Japan), July 3, 2017 – Maruho Co., Ltd (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that today it has received manufacturing and marketing approval from the Japanese Ministry of Health, Labor and Welfare (MHLW), for anti-herpes virus agent “Amenalief® Tab. 200mg” (INN: amenamevir) (hereinafter referred to as “the product”) for the treatment of herpes zoster (shingles) in Japan.

The product is an anti-herpes virus agent with a novel mechanism of action created by Astellas Pharma Inc. (“Astellas”; Head Office: Tokyo, President and CEO: Yoshihiko Hatanaka). The product has been observed to inhibit the proliferation of the varicella-zoster virus (hereinafter VZV) by inhibiting the activity of the helicase-primase complex, which is essential for viral DNA replication. In August 2012, Maruho and Astellas agreed on a license agreement for the development and commercialization of the product in Japan, and Maruho has been progressing its development.

Herpes zoster (shingles) is a disease caused by reactivation of the chickenpox VZV in latently-infected nerve ganglia. The main treatment for shingles is anti-herpes virus agents. The product is proven to be effective against VZV when administered once a day after meals. Also, since most of the product is excreted in feces, it is not necessary to adjust the dosage and administration according to creatinine clearance, an indicator of kidney function. Maruho hopes the product will contribute to the expansion of treatment options and improvement in adherence for the treatment of shingles in Japan.

Product Profile: Amenalief® Tab. 200mg

INN	Amenamevir
Formulation/Dose	Film coated tablets containing 200mg of amenamevir in 1 tablet
Indication	Herpes Zoster
Dosage and Administration	General administration for adults is 400mg of amenamevir once a day administered orally after a meal.
Approval Requirements	A pharmaceutical risk management plan should be properly designed and implemented

About herpes zoster (shingles)

Herpes zoster (shingles) is a disease caused by reactivation of the chickenpox varicella- zoster virus in latently-infected nerve ganglia. Although a large peak is observed in patients in their 50's-60's it is possible for young people to develop the disease triggered by overwork and stress.

Prodromal symptoms include neuralgia-like pain and sensory abnormalities, followed by a rash outbreak in a striped band at the site of the pain. Symptoms in the skin include cutaneous lesions that begin with zonal erythema and papules at the site of pain. These are followed by vesicles, pustules, erosion, and ulcers, which lead to the development of crusts. The skin eventually heals as the crusts fall off in 2-3 weeks after the onset. In addition, the pain caused by postherpetic neuralgia sometimes remains long term even after the rash heals. Currently available oral treatments include famciclovir, aciclovir and valaciclovir hydrochloride.

About Maruho

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,398 employees (as of the end of September 2016), and net sales were approximately 70.1 billion yen in its 2016 fiscal year. Pursuing its long-term corporate vision of "Excellence in Dermatology," Maruho is striving to improve the health and quality of life of people all over the world.

For more information, please visit www.maruho.co.jp/english

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