

News Release

September 7, 2017 Maruho Co., Ltd.

Maruho Launches Anti-Herpes Virus Agent "Amenalief[®] Tab. 200mg" in Japan

Osaka (Japan), September 7, 2017 – Maruho Co., Ltd ("Maruho", Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that today it has launched 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 the first herpes zoster treatment in the world to inhibit the activity of the helicase-primase complex. It has been 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.

As a pharmaceutical company specializing in dermatology, Maruho hopes to further contribute to patients suffering from herpes zoster (shingles) in Japan by expanding treatment options and promoting the proper use of the product.



Product Profile: Amenalier® Tab. 200mg	
INN	Amenamevir
Formulation/Dose	Film coated tablets containing 200mg of amenamevir in 1
	tablet
Indication	Herpes Zoster
Dosage and	General administration for adults is 400mg of amenamevir
Administration	once a day administered orally after a meal.
NHI Drug Price	1 tablet 1469.70yen
Standard	
Date of Approval	July 3, 2017
Date of NHI Price	August 30, 2017
Listing	
Date of Launch	September 7, 2017
Manufacturer	Maruho Co., Ltd

Product Profile: Amenalief® Tab. 200mg

About herpes zoster (shingles)

Herpes zoster (shingles) is a disease caused by reactivation of the chickenpox varicella-zoster virus in latently-infected nerve ganglia.

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.

Maruho's Initiatives towards treatment for herpes zoster (shingles)

Maruho markets anti-herpes virus drugs "Famvir[®] Tablets 250 mg" and "Casal[®] Cream 3%" as drugs related to the treatment of herpes zoster. In addition, inspections using the in vitro diagnostic (varicella-zoster virus antigen kit), (Brand name: "DermaQuick[®] VZV"), received insurance coverage on August, 2017. Maruho plans to launch the product in January 2018.

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 <u>www.maruho.co.jp/english</u>

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