News Release

February 21, 2019
Maruho Co., Ltd.
Asahi Kasei Pharma Corp.

Maruho and Asahi Kasei Pharma Announce First Approval in Japan of an Additional Dosage and Administration for Anti-herpes Virus Agent "Famvir® Tab 250 mg" for the Treatment of Recurrent Herpes Simplex (Herpes labialis/Herpes genitalis)

Osaka and Tokyo (Japan), February 21, 2019 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) and Asahi Kasei Pharma Corp. (“Asahi Kasei Pharma”, Head Office: Tokyo, Japan, President: Yoshikazu Aoki) announce today that Asahi Kasei Pharma obtained a partial change of approval for anti-herpes virus agent "Famvir® Tab 250 mg" (INN: famciclovir; hereinafter referred to as “the product”) for the treatment of recurrent herpes simplex in Japan.

The additional approval of dosage/administration obtained today is the first treatment in Japan recognized as “Patient Initiated Therapy” in which patients with recurrent herpes simplex can take this prescribed medicine at the outbreak of initial symptoms. Overseas this is called “one day treatment” and it is well known as a standard treatment for recurrent herpes simplex.

With the product prescribed in advance, taking 1,000 mg of the product two times during the outbreak of initial symptoms of recurring herpes simplex, it is possible to treat herpes simplex early in its onset, and an improvement in convenience for patients is expected.

Herpes simplex is a disease caused by the herpes simplex virus initially infecting the skin and mucosa, or reactivation of the virus in latently-infected nerve ganglia. Once infection occurs, symptomatic recurrences may occur. It is characterized by repeated recurrence of symptoms, and many patients are aware of early symptoms such as itching and discomfort before skin symptoms such as erythema, papules, blisters, etc. develop.

This partial change of approval is based on the results of a Phase 3 clinical study carried out jointly by Maruho and Asahi Kasei Pharma in Japan on patients with recurrent herpes. Asahi Kasei Pharma submitted the application for a partial change of approval to the Ministry of Health, Labor and Welfare in 2018.

By obtaining this partial change of approval, Maruho and Asahi Kasei Pharma hope to make further contributions to patients and medical professionals by providing a new option for the treatment of recurrent herpes simplex.

Product Profile

Brand name (INN)	Famvir® Tab 250 mg (famciclovir)
Indication	Herpes simplex, herpes zoster
Dosage and Administration (Additional dosage and administration underlined)	Herpes simplex Usually, adults receive one 250 mg dose of famciclovir orally three times a day. In the case of recurrent herpes simplex, usually adults can receive one 1,000 mg dose of famciclovir orally two times. Herpes zoster Usually, adults receive one 500 mg dose of famciclovir orally three times a day.
Date of Approval	April 16, 2008
Date of NHI Price Listing	June 13, 2008
Date of Launch	July 1, 2008
Date of partial change of approval	February 21, 2019
Marketing	Maruho Co., Ltd.
Manufacturer	Asahi Kasei Pharma Corp.
Licensor	Novartis Pharma AG

About herpes simplex
Herpes simplex is a disease caused by the herpes simplex virus initially infecting the skin and mucosa, or reactivation of the virus in latently-infected nerve ganglia. Once infection occurs, symptomatic recurrences may occur. Classifications of the disease include herpes labialis, herpes facialis, herpes genitalis, and Kaposi varicelliform eruption, depending on the affected area and clinical condition. Initial symptoms include itching and discomfort, followed by the outbreak of cutaneous lesions. Lesions begin with erythema and papules. 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. Although initial infection is often asymptomatic, the disease may cause severe systemic symptoms such as pyrexia, lymphadenopathy, and pain.

About Famvir® Tab 250 mg (INN: famciclovir)
Famciclovir is an anti-herpes virus agent approved in over 50 countries worldwide by Novartis Group. Asahi Kasei Pharma received manufacturing and marketing approval for famciclovir for the treatment of herpes zoster (shingles) in Japan. Maruho has marketed famciclovir in Japan as “Famvir® Tab 250 mg” since July 2008. In February 2013, famciclovir was approved in Japan for the additional indication of herpes simplex (HSV). Famvir® is a registered trademark of Novartis International Pharmaceutical Ltd.

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 1,512 employees (as of the end of September 2018), and net sales were approximately 78.6 billion yen in its 2018 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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