

News Release

November 30, 2017
Maruho Co., Ltd.
Asahi Kasei Pharma Corp.

Maruho and Asahi Kasei Pharma Announce Phase 3 Clinical Study Results of Famciclovir for the Treatment of Recurrent Herpes Simplex

Osaka and Tokyo (Japan), November 30, 2017 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) and Asahi Kasei Pharma Corp. (“Asahi Kasei”, Head Office: Tokyo, Japan, President: Yutaka Shibata) announce that they have obtained the results of a phase 3 clinical study jointly performed in Japan for the use of anti-herpes virus agent famciclovir (INN) for the treatment of recurrent herpes simplex (hereinafter referred to as “the study”).

The study was a multicenter, placebo-controlled, randomized, double-blind, parallel-group comparison study for patients with recurring herpes simplex (recurrent herpes labialis, recurrent genital herpes). It was divided into a famciclovir treated group and placebo treated group and efficacy and safety were examined when 1 to 1000 mg of famciclovir was administered twice a day for a period of one day, early in the recurrence of herpes simplex.

As a result of the study, a statistically significant difference was demonstrated for famciclovir against placebo at the primary endpoint measurement “time until all herpes simplex lesion sites healed”. The incidence rates of adverse events were 19.0% for famciclovir and 11.6% for placebo.

With the results of the study, Asahi Kasei Pharma plans to submit a partial change of approval in 2018 to include recurrent herpes simplex as an indication.

Notice

The medical information contained in this news release is not intended as advertisement or medical advice.

About famciclovir (INN)

Famciclovir is an anti-herpes virus agent approved in over 50 countries worldwide by Novartis Pharma Inc. 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 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. Prodromal symptoms include itching and discomfort, followed by the outbreak of lesions. Cutaneous 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. Currently available treatments include aciclovir, valaciclovir hydrochloride and famciclovir.

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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