



Press Release

Maruho Co., Ltd.
Asahi Kasei Pharma Corp.
February 21, 2013

Approval of herpes simplex as additional indication for anti-herpes agent Famvir®Tab.

Maruho Co., Ltd., hereafter "Maruho," (Head Office, Osaka, Japan; President and CEO, Koichi Takagi) and Asahi Kasei Pharma Corp., hereafter "Asahi Kasei Pharma," (Head Office, Tokyo, Japan; President, Toshio Asano) announced today the approval of a new indication in Japan for Famvir®Tab., the tablet form of the anti-herpes virus drug Famvir® (INN: famciclovir). In addition to its original indication for herpes zoster (shingles), the product has now been approved for the additional indication of herpes simplex (HSV).

Famvir® is an anti-herpes virus drug for which Novartis is the Marketing Authorization Holder in around 50 countries worldwide. Asahi Kasei Pharma holds manufacturing and marketing approval in Japan, and Maruho has been selling Famvir®Tab. in Japan since July 2008. As part of a collaborative effort to advance the development of Famvir®Tab. as an effective treatment for herpes simplex, after clinically proving the efficacy through a large clinical trial, the application was made for this additional indication on January 31, 2012.

Both companies look forward to this additional indication for herpes simplex providing medical professionals with a beneficial treatment option to help herpes simplex patients.

Famvir® is a registered trademark of Novartis Pharma AG.

About famciclovir

Famciclovir is the oral prodrug of the antiviral agent penciclovir, which is a nucleoside analogue DNA polymerase inhibitor that suppresses the proliferation of herpes viruses. Once famciclovir is taken by a patient, it is quickly metabolized to penciclovir, which is specifically phosphorylated within cells infected by herpes virus, forming penciclovir triphosphate. This suppresses herpes viral replication by termination of the viral DNA chain.

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 and valaciclovir hydrochloride.

About herpes zoster (shingles)

Herpes zoster (shingles) is a disease caused by reactivation of the chickenpox varicella-zoster virus in latently-infected nerve ganglia. There is a small onset peak 20-30 generations, a large peak is observed in their 50-60 generations, the disease severity increases so as to become old.

Prodromal symptoms include neuralgia-like pain and sensory abnormalities, followed by the outbreak striped eczema of pain lesions. Cutaneous lesions begin with zonal erythema and papules to 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 terms after healing of rash. Currently available treatments include famciclovir, and aciclovir and valaciclovir hydrochloride.