

## News Release

December 14, 2021  
Maruho Co., Ltd.

### Maruho Files for Additional Indication and Dosage/Administration for Anti-herpes Virus Agent “Amenalief® Tab. 200mg” for the Treatment of Recurrent Herpes Simplex in Japan

Osaka (Japan), December 14, 2021 – Maruho Co., Ltd. (“Maruho”, Head Office: Osaka, Japan, President and CEO: Atsushi Sugita) announces that it has filed an application for approval of a partial change of the indication and dosage/administration for anti-herpes virus agent “Amenalief® Tab. 200mg” (INN: amenamevir; hereinafter referred to as “the product”) for the treatment of recurrent herpes simplex in Japan.

This application for approval of a partial change of the indication and dosage/administration filed is 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”<sup>1)</sup> and it is well known as a standard treatment<sup>2)3)</sup> for recurrent herpes simplex.

This application for a partial change of approval is based on two Phase 3 clinical studies (randomized, placebo-controlled, double-blind, parallel-group comparisons) carried out in Japan on patients with recurrent herpes labialis or recurrent genital herpes.

In these studies, a single dose of amenamevir or placebo was given within 6 hours of the onset of early symptoms of recurrence. In both studies, the amenamevir group showed a statistically significant difference from the placebo group in the primary endpoint, “healing time for all lesions.”

In the safety evaluation, in the amenamevir group (545 cases), causal adverse events were Alpha 1 microglobulin increased 1.8% (10 cases), Beta-N-acetyl-D-glucosamidase increased 1.1% (6 cases), and urinary protein 0.6% (3 cases). No serious adverse events were observed.

Herpes simplex is caused by infection of the skin and mucous membranes by the herpes simplex virus, or by reactivation of herpes simplex virus that has been latently infected in the ganglia. It is characterized by repeated recurrence of symptoms, and many patients are aware of the initial symptoms such as itching, and a tingling discomfort before the onset of skin symptoms such as erythema, papules, and blisters.

By providing new options for the treatment of recurrent herpes simplex, Maruho strives to make greater contributions to patients and healthcare professionals.

#### Note

The information contained in this news release in regard to pharmaceutical and developmental products is not intended for the purpose of promotion, advertising or medical advice.



#### References

- 1) Shinichiro Yasumoto, Patient-initiated-treatment(PIT) in the management of patients with recurrent herpes simplex, Japanese Journal of Clinical Dermatology, 74 (5), 135 (2020)
- 2) Corey L., Herpes Simplex Virus Infection. Dennis L. Kaper, Anthony S. Fauci, Steephen L. Hauser, Dan L. Lomno, Larry Jameson, Joseph Loscalzo, ed. Harisson's principles of internal medicine. 19<sup>th</sup> ed. Vol.2, United States of America: McGraw-Hill Education; 2015: 1175-1183
- 3) Workowski KA: Centers for Disease Control and Prevention. Sexually Transmitted Disease Treatment Guidelines. Mortality Weekly Report, 2015; 64: 27-32

#### **About Amenalief Tab.**

Amenalief Tab. is an oral anti-herpes virus agent with a novel mechanism of action containing the non-nucleic acid analog amenamevir, created in Japan by Astellas Pharma Inc. By inhibiting the activity of the helicase-primase complex, an essential enzyme for DNA replication of the herpesvirus, it exhibits antiviral activity by suppressing double-stranded DNA cleavage and RNA primer synthesis. Maruho manufactures and commercializes the product in Japan and it has been used for the treatment of herpes zoster since 2017.

#### **Maruho's initiatives for disease caused by herpes**

Maruho is working to help patients suffering from herpes labialis and genital herpes to understand the diseases correctly and take appropriate measures in the event of a recurrence.

Through the comprehensive herpes information site "What's herpes?" the causes and remedies for cold sores and genital herpes are explained.

(<https://www.maruho.co.jp/kanja/herpes/>)

(As Maruho markets treatments for customers in Japan, the information is only provided in Japanese).

#### **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 1,542 employees (as of the end of September 2020), and net sales were approximately 80.34 billion yen in its fiscal year ended September 30, 2020. 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 <https://www.maruho.co.jp/english/>

#### **Contact Information:**

Maruho Co., Ltd.

Corporate Communications Dept.

Tel: +81-(0)6-6371-8831 Fax: +81-(0)6-6371-8679

Email: [kouhou@mii.maruho.co.jp](mailto:kouhou@mii.maruho.co.jp)