

Kaken Pharmaceutical Co., Ltd.
Mitsubishi Tanabe Pharma Corporation

TFDA approves Clenafin/Jublia for the treatment of Onychomycosis in Taiwan

June 14, 2018 - Kaken Pharmaceutical Co., Ltd. (“Kaken”, head office Bunkyo-ku, Tokyo; President and Representative Director, Tetsuo Onuma) and Mitsubishi Tanabe Pharma Corporation (“Mitsubishi Tanabe”, head office Chuo-ku, Osaka; President and Representative Director, Masayuki Mitsuka) announced today that Tai Tien Pharmaceuticals Co., Ltd. (“Tai Tien”, head office Taipei, Taiwan; General Manager Tony Chu), which is a consolidated subsidiary of Mitsubishi Tanabe, has been granted the Marketing Authorization (the “MA”) for Jublia (the “Product”, generic name: Efinaconazole, brand name in Japan: Clenafin), for the treatment of Onychomycosis by the Taiwan Food and Drug Administration (“TFDA”).

Kaken and Tai Tien have concluded an exclusive distribution agreement (the “Agreement”) for the Product on November 7, 2017, and Kaken granted to Tai Tien the exclusive right for sales of the Product in Taiwan. The MA was originally submitted to TFDA by Kaken and then succeeded by Tai Tien according to the Agreement. Tai Tien is preparing the earliest launch.

About Tai Tien

Company name: Tai Tien Pharmaceuticals Co., Ltd.

General Manager: Tony Chu

Headquarters: Taipei, Taiwan

Tai Tien, which was established in 1987, has marketed a lot of products in the area of dermatology in Taiwan. Based on its sales performance and experience in such area, Tai Tien will try to quick spread of the Product into the Taiwanese market.

About Jublia

Jublia contains efinaconazole, a novel triazole anti-fungal compound discovered by Kaken, as the active ingredient. Efinaconazole has low binding affinity with keratin, the main component of nails, meaning that the Product has superior nail-penetrating properties.

The Product was launched under the trade name of Clenafin in Japan by Kaken in 2014. Overseas, the Product was launched under the trade name of Jublia in the United States and Canada in 2014 and in Korea in 2017.

For further information, please contact:

Kaken Pharmaceutical Co., Ltd.
Corporate Communications,
General Affairs Department
2-28-8 Honkomagome, Bunkyo-ku, Tokyo
TEL: +81 3 5977 5002

Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department
3-2-10, Doshomachi, Chuo-ku, Osaka
Media contacts: [TEL: +81 6 6205 5119](tel:+81662055119)
Investor contacts: [TEL: +81 6 6205 5110](tel:+81662055110)