

2023 年 4 月 18 日 ノーベルファーマ株式会社

Sirolimus Gel Approved by China's National Medical Products Administration

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced today that the company's sirolimus gel, the product "RAPALIMUS® Gel 0.2%" in Japan, was approved on March 28 by China's National Medical Products Administration for the indication of facial angiofibroma associated with tuberous sclerosis in adults and children aged 6 years or older.

It is estimated that there exist approximately 63,000 tuberous sclerosis (TSC) patients in China, of whom 45,000 suffer facial angiofibromas.

This drug is the world's first topical product approved for the treatment of skin lesions associated with tuberous sclerosis in Japan. It was designated as an orphan drug and launched in June 2018 as "RAPALIMUS® Gel 0.2%" after reviewed under SAKIGAKE "fast-track" review system.

This is our second product approved overseas following HYFTOR® in the United States (launched on August 29, 2022). We will deliver this product to patients through the promotional activities by Jiangsu Nobelpharma Co., Ltd. (China Taizhou, Jiangsu: President & CEO: Jiang Rongzhe) which is a Chinese subsidiary of Nobelpharma. We are determined to continue contributing to society by providing critical but neglected pharmaceuticals and medical devices.

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