September 6, 2022
Nobelpharma Co., Ltd.

“HYFTOR™ (sirolimus topical gel) 0.2%” Launched in the U.S.

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) debuted, on August 29 in the United States, HYFTOR™ (sirolimus topical gel) 0.2% which had received U.S. Food and Drug Administration (FDA) approval on March 22 this year for the treatment of facial angiofibroma associated with tuberous sclerosis complex (TSC) for patients 6 years and older.

HYFTOR™ is the first topical treatment indicated for facial angiofibroma associated with TSC. In U.S., approximately 50,000 people have TSC, and estimated 40,000 have TSC-related facial angiofibroma.

This is our first-ever overseas launch, and HYFTOR™ will be provided to patients throughout U.S. through Nobelpharma America, LLC (Bethesda, Maryland, U.S.A. President and CEO: Yoshiki Kita). This drug is indicated for a rare disease designated as orphan disease by the U.S. FDA, having 7-year market exclusivity.

This drug has been distributed since June 2018 in Japan for the treatment of tuberous sclerosis-associated skin lesions, after receiving SAKIGAKE “fast-track” designation and orphan drug status for the indication of angiofibroma associated with tuberous sclerosis.

With this launch, we hope that HYFTOR™ (sirolimus topical gel) 0.2% will be an option in the United States for the treatment of patients with facial angiofibroma associated with TSC.

*HYFTOR™ had been granted in the United States Fast Track as well as Priority Review designations.

We are determined to continue contributing to society by providing critical but neglected pharmaceuticals and medical devices.

[Contact for inquiries]
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