April 25, 2022
Nobelpharma Co., Ltd.

"HYFTOR™ (sirolimus topical gel)" Approved by FDA

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced that "HYFTOR™ (sirolimus topical gel)" has been approved in the United States by the U.S. Food and Drug Administration (FDA) for the indication of facial angiofibroma associated with tuberous sclerosis complex (TSC) in adults and children 6 years of age or older.

"HYFTOR™ (sirolimus topical gel)" is the first topical treatment approved by the FDA for facial angiofibroma associated with TSC. In the United States, approximately 50,000 people have TSC, and an estimated 40,000 have TSC-related facial angiofibroma.

This is the first drug approved abroad for us, which we will provide to patients in the United States by Nobelpharma America, LLC (Bethesda, Maryland, USA, President & CEO: Yoshiki Kida). HYFTOR™ has Orphan Drug status in the United States with 7-year market exclusivity.

In Japan, this drug was granted SAKIGAKE "fast-track" designation and has been designated as an orphan drug for the indication of angiofibroma associated with TSC. Its launch in June 2018, under the name of "RAPALIMUS® Gel 0.2%" with the indication of skin lesions associated with TSC, has enabled noninvasive treatment.

With this FDA approval, we are pleased that HYFTOR™ will be a new treatment option in the United States for the patients with facial angiofibroma associated with TSC.

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

[Contact for inquiries regarding this matter]
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