May 29, 2023
Nobelpharma Co., Ltd.

"HYFTOR" Receives Marketing Authorization in EU
for Facial Angiofibroma associated with Tuberous Sclerosis Complex

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced that HYFTOR (sirolimus 2 mg/g gel) received on May 15 the marketing authorization in the EU for facial angiofibroma associated with tuberous sclerosis complex (TSC) in adults and children aged 6 years and older.

HYFTOR is the first topical gel for the treatment of facial angiofibroma associated with TSC. In Europe, approximately 51,000 people have TSC, of whom estimated 40,800 have facial angiofibroma.

Being the world's first topical formulation approved with the indication of skin lesions associated with TSC in Japan under the SAKIGAKE fast-track review system, this drug was launched under the name of "RAPALIMUS® Gel 0.2%" in June 2018 with orphan drug designation.

This will be our international product following the United States (launched on August 29, 2022) and China (approved on March 28, 2023), which we will provide to patients in Europe through Plusultra pharma GmbH/UK Ltd (headquarters: Dusseldorf, Germany, President & CEO: Takayoshi Yamasaki).

We will be pleased the launch of HYFTOR (sirolimus 2 mg/g gel) becomes a treatment option in Europe 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.

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