September 1, 2023
Nobelpharma Co., Ltd.

HYFTOR (sirolimus 2 mg/g gel) Approved by
The Medicines and Healthcare products Regulatory Agency (MHRA)

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) announced that HYFTOR (sirolimus 2 mg/g gel) has been approved in the United Kingdom on September 1 for the indication of facial angiofibroma associated with tuberous sclerosis complex (TSC) in adults and children aged 6 years or older.

HYFTOR is the first topical gel for the treatment of facial angiofibroma associated with TSC. In the United Kingdom, approximately 4,700 people have TSC, of whom estimated 3,700 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), China (registered on March 28, 2023) and EU (approved on May 15, 2023), which we will provide to patients in the United Kingdom 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 the United Kingdom 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]
Noboru Kudo, Head of Communications
Nobelpharma Co., Ltd.
1-17-24, Shinkawa, Chuo-ku, Tokyo 104-0033
Tel: 03-6670-3800