October 30, 2023

Nobelpharma Co., Ltd.

HYFTOR (sirolimus 2 mg/g gel) Launched in Europe

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Mr. Jin Shiomura) announced that HYFTOR (sirolimus 2mg/g) has been launched in the EU/EEA countries and the United Kingdom for the treatment of facial angiofibroma associated with tuberous sclerosis complex (TSC) in adults and children aged 6 years and older.

HYFTOR in topical gel formulation is the first treatment approved in the EU/EEA countries and the UK for facial angiofibroma associated with TSC. Approximately 51,000 and 4,700 people have TSC respectively in Europe and the UK, of whom estimated 40,800 and 3,700 have facial angiofibroma respectively.

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 is the second international product launched following the United States (launched on August 29, 2022), which will be provided to patients in Germany and other EU/EEA countries as well as the UK through its European subsidiary, Plusultra pharma GmbH (Headquarters: Düsseldorf, Germany, President & CEO: Mr. Takahiro Yamazaki).

We are 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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《Tuberous Sclerosis Complex》

Tuberous sclerosis complex (hereinafter referred to as “TSC”) is an autosomal dominant disorder characterized by generalized hamartomas, and is designated as a target disease for the Research Program for Overcoming Intractable Diseases in Japan. Two genes, TSC1 and TSC2, have been identified as the genes responsible for TSC. Abnormalities in these genes result in constant activation of the downstream mammalian target of rapamycin (hereinafter referred to as "mTOR") and promotion of cell proliferation, etc., leading to hamartomas in skin, brain, lungs, heart, kidneys, bones, etc. (2008 Guidelines for the Diagnosis and Treatment of TSC, edited by the Japanese Dermatological Association).

The major features of TSC include angiofibroma on the face and forehead and head plaques (connective tissue navi). Such skin lesions are managed by laser treatment, cryocoagulation using liquid nitrogen, and surgical treatment, but each of which is highly invasive.

This drug is a topical gel containing sirolimus as an active ingredient, which inhibits mTOR activity and suppresses cell proliferation. In Japan, the oral formulation "RAPALIMUS®Tablets 1 mg" containing sirolimus was approved in July 2014 for the indication of "lymphangioleiomyomatosis." This drug is a topical drug that enables non-invasive treatment of skin lesions associated with TSC.

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