

October 2, 2026
Nobelpharma Co., Ltd.

HYFTOR[®] (sirolimus topical gel) 0.2%
Four Years of Sales in the U.S. Since Launch

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo; Managing Director and CEO: Jin Shiomura) is pleased to announce that HYFTOR[®] (sirolimus topical gel) 0.2% has been prescribed to a cumulative total of 2,339 patients and has achieved cumulative sales of 29,169 tubes as of the end of August 2026 since its launch in the United States.

HYFTOR[®] received marketing approval in the United States from the U.S. Food and Drug Administration (FDA) on March 22, 2022, for the treatment of facial angiofibroma associated with tuberous sclerosis complex (TSC)* for patients 6 years and older. The product was launched in the United States on August 29 of the same year. Sales volumes since the product's launch are shown below. Nobelpharma America LLC, the Company's U.S. subsidiary, turned a single-year profit in fiscal 2024.

Period	FY 2022 Aug. ~Dec.	FY 2023 Jan.~ Dec.	FY 2024 Jan.~ Dec.	FY 2025 Jan.~ Dec.	FY 2026 Jan.~ Aug.
Sales volume (tubes)	960	4,752	7,779	9,240	6,438

HYFTOR[®] is the first and only topical treatment indicated for facial angiofibroma associated with TSC. Although sales volumes have been increasing through the efforts of our U.S. subsidiary, we recognize there remain challenges in order to expand the awareness of the product as a treatment option, which we determined to be attributable to factors including the hard-to-reach medical institutions and healthcare professionals dispersed across the vast geographic area of the U.S.; the difficulty of uncovering and creating the market for rare diseases; the insurance reimbursement system that differ from that in Japan, requiring negotiations with numerous insurance companies and PBMs**; and the availability of compounded topical sirolimus preparations produced by compounding pharmacies.

Indicated for a rare disease that has received Orphan Drug Designation from the FDA, the product has seven years of exclusive marketing rights in the U.S. Through Nobelpharma America LLC, we will continue to promote the wider adoption and appropriate use of HYFTOR[®] so that it can reach as many patients as possible.

Nobelpharma will continue to contribute to society by providing medicines and medical devices that address unmet medical needs.

* Tuberous sclerosis complex: A hereditary rare disease that causes tumor-like lesions in various organs throughout the body, including the brain, skin, and kidneys, and may be associated with developmental disorders.

** Pharmacy Benefit Management: A company that manages prescription drug benefits.

【Contact Information】

<https://www.nobelpharma.co.jp/en/contact/general-form/>

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