This material is an English translation of the press release announced on Apr 21, 2022 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Apr 21, 2022

Notification of application for manufacturing and marketing approval of HP-5070 (primary palmar hyperhidrosis treatment drug) in Japan

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces that it has been submitted a new drug application for the primary palmar hyperhidrosis treatment drug (Development code: HP-5070, generic name: oxybutynin hydrochloride, hereinafter referred to as "the product") in Japan as of today.

The product is a topical formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology, and the first drug in Japan to demonstrate efficacy and safety compared with placebo group in a Phase III clinical study conducted in patients with primary palmar hyperhidrosis. Hisamitsu Pharmaceutical expects it to be a new option for the treatment of primary palmar hyperhidrosis.

Hisamitsu Pharmaceutical aims to obtain a manufacturing and marketing approval during FY2023.