This material is an English translation of the press release announced on April 27, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

April 27, 2021

Notification of the results of the Phase III clinical study of HP-5070 in Japan (primary palmar hyperhidrosis treatment drug)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces the results of the Phase III clinical study in Japan for the primary palmar hyperhidrosis treatment drug (Development code: HP-5070, generic name: oxybutynin hydrochloride, hereinafter referred to as "the investigational product").

In the Phase III clinical study, the efficacy and safety of administration of the investigational product had been compared with a placebo in patients with primary palmar hyperhidrosis. As a result, there was a statistically significant difference in the primary endpoint when compared the investigational product group with the placebo group. In addition, there were no adverse reactions that could cause major concerns in development.

The investigational 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.

Based on the results of the ongoing Phase III long-term study in Japan, Hisamitsu Pharmaceutical aims to apply for manufacturing and marketing approval during FY2022.