This material is an English translation of the press release announced on July 25, 2016 in Japanese, and the Japanese release is given priority about the content and the interpretation.

July 25, 2016

Notification of the results of Phase III clinical study on HP-3060 in Japan (a transdermal system for the treatment of allergic rhinitis)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as Hisamitsu) hereby announces the results of the Phase III clinical study for a transdermal drug for the treatment of allergic rhinitis in Japan (Development code: HP-3060, Active pharmaceutical ingredient: emedastine fumarate, hereinafter referred to as "the product").

In the Phase III clinical study, the efficacy and safety of administration of the product once per day were compared with a placebo and with a positive drug (oral drug) in patients with allergic rhinitis. As a result, a statistically significant difference was confirmed for improvement in the primary efficacy endpoint compared with the placebo group. For safety, no serious adverse reactions were observed.

The product is a systemic transdermal tape formulation developed by utilizing Hisamitsu's TDDS (Transdermal Drug Delivery System) technology. Hisamitsu expects it to be a new option for the treatment of allergic rhinitis by realizing its long-lasting effect by means of maintaining a stable blood drug concentration.

Hisamitsu aims to apply for manufacturing and marketing approval during FY 2016.