This material is an English translation of the press release announced on Decmber 9, 2015 in Japanese, and the Japanese release is given priority about the content and the interpretation.

December 9, 2015

Notification of the commencement of the Phase III clinical study of HP-3060 in Japan (a transdermal drug 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 that it has commenced 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 will be compared with a placebo and with a positive drug (oral drug) in patients with allergic rhinitis.

The product is a transdermal formulation developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology. We expect the product to be a new option for the treatment of allergic rhinitis by realizing its long-lasting effect by means of maintaining a stable blood concentration.

In the future, we aim to apply for manufacturing and marketing approval during FY 2016.