This material is an English translation of the press release announced on September 5, 2016 in Japanese, and the Japanese release is given priority about the content and the interpretation.

September 5, 2016

Notification of the commencement of the Phase III clinical study of HP-3070 in the United States (a transdermal drug for the treatment of Schizophrenia)

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 an investigational transdermal drug for the treatment of schizophrenia in the United States (Development code: HP-3070, Active pharmaceutical ingredient: asenapine maleate, hereinafter referred to as “the product”).

In the Phase III clinical study, the efficacy and safety of administration of the product will be compared with a placebo in patients with schizophrenia.

The clinical trial will be conducted by a subsidiary in the United States of the Company, Noven Pharmaceuticals, Inc. (Head Office: Florida, U.S.A.; hereinafter referred to as “Noven”).

The product is an investigational 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 schizophrenia.

In the future, we aim to apply for manufacturing and marketing approval during FY 2018.