This material is an English translation of the press release announced on December 17, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

December 17, 2018

Notification of a New Drug Application for HP-3070 (Transdermal Patch for the Treatment of Schizophrenia) in the U.S.

Hisamitsu Pharmaceutical Co., Ltd. (Headquarters: Tosu City, Saga Prefecture, Chairman and Chief Executive Officer (CEO): Hirotaka Nakatomi, hereinafter "Hisamitsu Pharmaceutical") announces that a New Drug Application has been submitted to the U.S. Food and Drug Administration (FDA) seeking approval of HP-3070 (asenapine) transdermal system for the treatment of schizophrenia (Development code: HP-3070, generic name: asenapine, hereinafter referred to as "the investigational product").

The investigational product is a systemic transdermal formulation developed using Hisamitsu Pharmaceutical's Transdermal Drug Delivery System (TDDS) technology. Hisamitsu Pharmaceutical expects the investigational product to be a new option in the treatment of schizophrenia. The development of the investigational product represents Hisamitsu Pharmaceutical's commitment to improving the lives of the community of patients who live with schizophrenia.