

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

December 17, 2018 -- Hisamitsu Pharmaceutical Co., Ltd. (Headquarters: Tosu City, Saga Prefecture, Chairman and Chief Executive Officer (CEO): Hirotaka Nakatomi, hereinafter "Hisamitsu Pharmaceutical"), in conjunction with its U.S. subsidiary, Noven Pharmaceuticals, Inc. 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.

Contact:

Stephanie Lamenta Noven Pharmaceuticals 305-253-1916