This material is an English translation of the press release announced on October 15, 2019 in Japanese, and the Japanese release is given priority about the content and the interpretation.

October 15, 2019

Notification of FDA approval for SECUADO® in the U.S. (Transdermal, schizophrenia treatment patch, development code: HP-3070)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces that the U.S. Food and Drug Administration (FDA) approved the New Drug Application (NDA) for SECUADO®, transdermal, schizophrenia treatment patch (Development code: HP-3070, generic name: asenapine maleate, hereinafter referred to as "the product") in the U.S. as of October 11, 2019 (Eastern Standard Time).

The product is a systemic transdermal formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology and the first transdermal patch formulation for the treatment of schizophrenia in the U.S.

Transdermal formulation is expected to show improved efficacy and be well-tolerated by maintaining a stable drug concentration in blood and can also provide visual confirmation that a treatment is being utilized.

Hisamitsu Pharmaceutical expects the products to fulfill unmet needs for the improvement of adherence in the patients and healthcare providers through providing a new option for the treatment of schizophrenia. Hisamitsu Pharmaceutical will contribute to further improving the quality of life of patients who live with schizophrenia through the development of the product.