This material is an English translation of the press release announced on April 6, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

April 6, 2020

Notification of marketing of Secuado® in the US (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 Noven Pharmaceuticals, Inc. (Head Office: Florida USA, hereinafter referred to as "Noven Pharmaceuticals") launched Secuado®, Transdermal, Schizophrenia treatment patch (Development code: HP-3070, Generic name: Asenapine maleate, hereinafter referred to as "the product") in the US from March 2, 2020.

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.

Reference:

Trade name	Secuado® transdermal system 3.8mg/24hours Secuado® transdermal system 5.7mg/24hours Secuado® transdermal system 7.6mg/24hours
Generic name	Asenapine maleate
Indication	Treatment of adults with Schizophrenia
Dosage and Administration	Initiate Secuado® at a dosage of 3.8 mg/24 hours. The dosage may be increased to 5.7 mg/24 hours or 7.6 mg/24 hours, as needed, after one week. Application sites include: the upper arm, upper back, abdomen, or hip. Apply the transdermal system to a different application site each time a new Secuado® transdermal system is applied.
Size of formulation	Secuado® transdermal system 3.8mg/24hours 20 cm^2 Secuado® transdermal system 5.7mg/24hours 30 cm^2 Secuado® transdermal system 7.6mg/24hours 40 cm^2
Date of Approval by US FDA	October 11, 2019 (Eastern Standard Time in the US).
Manufacturer	Hisamitsu Pharmaceutical Co., Inc.
Distributor	Noven Pharmaceuticals, Inc.
Launch date	March 2, 2020 (Eastern Standard Time in the US).