

This material is an English translation of the press release announced on January 31, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

January 31, 2018

**Notification of the results of the Phase III clinical study of HP-3070
(transdermal patch for the treatment of schizophrenia) in the US**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces that the transdermal patch for the treatment of schizophrenia (Development code: HP-3070, generic name: asenapine maleate, hereinafter referred to as "the investigational product") achieved the primary endpoint of the Phase III clinical trial in the US.

This study was a Phase III clinical trial to evaluate the efficacy and safety of the investigational product in 617 patients diagnosed with schizophrenia. The primary endpoint of the study was change from baseline of the Positive and Negative Syndrome Scale (PANSS, hereinafter "PANSS") total score. Efficacy and safety was assessed during the six-week application period.

The study results showed that when compared to placebo the investigational product achieved statistically significant improvement from baseline in the change of the total PANSS score at six-weeks. Secondary endpoints and safety data are still under review.

Based on these study results, Hisamitsu Pharmaceutical will schedule a pre-New Drug Application (pre-NDA) meeting with FDA and expects to submit the NDA for the investigational product in the US in FY 2018. Additional details on the study results are planned for publication at future medical/scientific forums.

The investigational product is a transdermal formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology. Hisamitsu Pharmaceutical expects HP-3070 to be a promising new option in the treatment of schizophrenia, and will contribute improvement of Quality of Life of the patients through the development of HP-3070.



Delivering Patch Culture Hand by Hand

Hisamitsu Pharmaceutical Co., Inc. was established in 1847 and has marked its 170th anniversary since its foundation thanks to the support of many people.