



Notification of the results of the Phase III clinical study of HP-3070 (transdermal patch for the treatment of schizophrenia) in the U.S.

January 31, 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. (hereinafter "Noven Pharmaceuticals") 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 U.S.

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 (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 are still under review.

The systemic safety profile for the investigational product is consistent with that known for asenapine. The most common treatment-emergent adverse events observed in the clinical trial were application site reaction, headache and extrapyramidal disorder.

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 U.S. 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 Transdermal Drug Delivery System (TDDS) technology. Hisamitsu Pharmaceutical expects HP-3070 to be a promising new option in the treatment of schizophrenia.

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