

**PRESS RELEASE**

**Phase III Study Results for HP-3070 (Asenapine) Transdermal Patch for the Treatment of Schizophrenia to be Presented at the Society of Biological Psychiatry 74<sup>th</sup> Annual Meeting**

-- New Drug Application for investigational product HP-3070 under FDA review --

**Miami, FL and Jersey City, NJ – May 16, 2019** -- Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., announced today that the primary and key secondary efficacy endpoints and safety results from the pivotal Phase III study for HP-3070 (asenapine) transdermal drug delivery system (TDDS), an investigational product for the treatment of schizophrenia, will be featured as an oral presentation at the 74th Society of Biological Psychiatry (SOBP) Annual Meeting in Chicago, May 16 – 18, 2019.

The oral presentation will feature data from the pivotal HP-3070 Phase III clinical study, highlighting HP-3070's efficacy in the treatment of schizophrenia, as well as the transdermal patch's safety and tolerability profile.

Details for the upcoming presentation are listed below:

**SOBP Presentation:**

- **Abstract Title:** Efficacy and Safety of an Asenapine Transdermal Patch (Asenapine Transdermal System, HP-3070) in the Treatment of Adults with Schizophrenia: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 6-Week Inpatient Study
- **Abstract Number:** 3004934
- **Session Date/Time:** Oral presentation will occur during the “Novel Tools and Techniques for Disease Prediction, Progression and Intervention” session on May 18, 2019 from 3:00-4:45 PM with the oral presentation scheduled from 4:30-4:45 PM
- **Location:** Marquette Room, Hilton Chicago

“We are excited to share our research at this prestigious meeting with the psychiatric community who help identify, treat and manage patients with schizophrenia,” said Dr. David Walling, Ph.D., investigator from the HP-3070 pivotal Phase III study as well as author and presenter on the HP-3070 presentation. “Schizophrenia is often difficult to treat, and having multiple treatment options for patients is crucial as individuals have unique needs. The data presented here are

encouraging to patients and their families who are living with schizophrenia and who may benefit from delivery of medication via a patch. If approved, HP-3070 will not only be a novel treatment option to add to the armamentarium, but would be the first and only transdermal antipsychotic for the treatment of schizophrenia.”

This randomized, double-blind, placebo-controlled Phase III clinical trial evaluated the efficacy and safety of HP-3070 in 617 patients diagnosed with schizophrenia. The primary endpoint of the study was change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at Week 6 versus placebo. The study results showed that when compared to placebo, HP-3070 achieved statistically significant improvement from baseline in PANSS total score.

The systemic safety profile for HP-3070 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.

The primary and key secondary efficacy endpoints and safety results from the pivotal Phase III study for HP-3070 will also be featured at the American Society of Clinical Psychopharmacology (ASCP) 2019 Annual Meeting in Scottsdale, AZ from May 28 – 31, 2019.

### **About HP-3070**

Asenapine is a second generation atypical antipsychotic currently available as a sublingual formulation for the treatment of schizophrenia in adults. HP-3070 is an investigational asenapine-containing Transdermal Drug Delivery System (TDDS), developed by Hisamitsu Pharmaceutical, to be applied to the skin for the treatment of schizophrenia. If approved by the U.S. Food and Drug Administration (FDA), HP-3070 may provide a novel treatment option for patients, caregivers, and physicians, as the first and only transdermal patch antipsychotic available for the treatment of schizophrenia in the U.S. A New Drug Application (NDA) for HP-3070 is under review by the FDA. The NDA is supported by a robust clinical program, including nine clinical studies, which establish the safety and efficacy profile of HP-3070. The development of HP-3070 represents Noven and Hisamitsu Pharmaceutical’s commitment to improving the lives of the community of patients who live with schizophrenia.

## **About Schizophrenia**

Schizophrenia is a severe, chronic psychiatric disease with a heterogeneous course and symptom profile. The symptoms associated with schizophrenia are disabling and lifelong, and greatly affect a patient's quality of life and social functioning. Symptoms such as hallucinations and delusions usually start between ages 16 and 30. Schizophrenia presents clinically as negative (affective flattening, social withdrawal, and restriction in the fluency and productivity of thought and speech and in the initiation of goal-directed behavior), positive (delusions, hallucinations, disorganized speech, and disorganized or catatonic behaviors) and cognitive symptoms. Cognitive symptoms such as impairment in sustained attention, impaired executive functioning, and impaired working memory may also be present.<sup>1</sup>

## **About Noven Pharmaceuticals, Inc.**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., serving as Hisamitsu's U.S. platform in prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For information about Hisamitsu, visit <http://global.hisamitsu/>.

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<sup>1</sup> National Institute of Mental Health. Schizophrenia. [Internet]. Available from: <https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml> Accessed April 2019.