11960 Southwest 144th Street
Miami, Florida 33186
305-253-1916 ▼ Toll-Free: 888-253-5099
www.noven.com

PRESS RELEASE

Categorical Response and Clinical Relevance as Assessed in a Phase III Study of HP-3070 (Asenapine) Transdermal Patch for the Treatment of Schizophrenia to be Presented at the American Psychiatric Association 172nd Annual Meeting

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

Miami, FL and Jersey City, NJ – May 20, 2019 – Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., announced today that secondary endpoint data 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 a poster presentation at the American Psychiatric Association (APA) 172nd Annual Meeting in San Francisco, May 18 – 22, 2019.

This poster will feature data from the randomized, double-blind, placebo-controlled pivotal HP-3070 Phase III clinical study that have not been previously presented at scientific conferences, including the categorical response and clinical relevance of the efficacy of HP-3070 for the treatment of schizophrenia as well as the transdermal patch's safety and tolerability profile.

Details for the upcoming conference presentation are below:

- **Poster Title:** HP-3070 Asenapine Transdermal System in Adults with Schizophrenia: Categorical Response and Clinical Relevance as Assessed in a Phase 3 RCT
- **Abstract Number:** 5508
- **Poster Number:** P7-078
- **Session Date/Time:** Poster Session 7; May 21, 2019; 10:00 AM–12:00 PM
- **Location:** Moscone Center, Rooms 3/4, Exhibition Level

"In treating persons with schizophrenia, it is useful to be able to offer different options," said Dr. Leslie Citrome, MD, MPH, presenting author of the above-mentioned APA poster. "Presented here are analyses supporting a potentially new way of administering antipsychotics using a transdermal drug delivery system that uses a patch placed on the skin. The primary outcome data from the pivotal Phase III study of HP-3070 have been previously presented and

demonstrated the safety and efficacy of this approach in adults with schizophrenia. New analyses examining response rates support the clinical relevance of these results, and may help the clinician in appraising this new option for their patients."

Secondary and exploratory data to be presented in the APA poster show outcomes for categorical response based on responder analyses performed for Positive and Negative Syndrome Scale (PANSS) total score and Clinical Global Impression–Improvement (CGI-I) change from baseline to Week 6 versus placebo. Responder rates for both PANSS and CGI-I assessments were statistically significantly higher in HP-3070-treated patients versus placebo at various time points, indicating a clinically relevant treatment response in adults treated with either high- or low-dose HP-3070.

Systemic Treatment-Emergent Adverse Events (TEAEs) were mostly mild or moderate in severity and consistent with sublingual asenapine. The most common TEAEs observed in the clinical trial were application site reaction, headache and extrapyramidal disorder.

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 supporting HP-3070 is under review by the FDA. The NDA is supported by a robust clinical program including nine clinical studies performed establishing 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 patients 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.[1]

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/.

Contact:
Monica Lara
Noven Pharmaceuticals, Inc.
305-253-1916

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