

PRESS RELEASE

NOVEN TO PRESENT PIVOTAL STUDY RESULTS FOR INVESTIGATIONAL DEXTROAMPHETAMINE TRANSDERMAL SYSTEM FOR PEDIATRIC ADHD PATIENTS

April 27, 2021 – Miami, FL and Jersey City, NJ -- Noven Pharmaceuticals, Inc., (“Noven”) a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced it will present the results of a multicenter, phase 2, laboratory classroom study which evaluated the safety and efficacy of its investigational dextroamphetamine transdermal system (“ATS”) in over 100 pediatric patients (ages 6-17 years) with ADHD at the 2021 virtual American Psychiatric Association (APA) Annual Meeting May 1-3, 2021.

Results from the study, entitled “A Randomized, Double-Blind, Placebo-Controlled, Crossover, Laboratory Classroom Study to Evaluate the Safety and Efficacy of d-Amphetamine Transdermal Drug Delivery System,” will be presented at the APA Annual Meeting virtual poster hall. The study was designed to evaluate the efficacy and safety of ATS in pediatric patients aged 6-17 years with ADHD compared with placebo.

In a laboratory classroom setting, patients receiving investigational ATS demonstrated significant improvement vs placebo in ADHD symptoms, as measured by the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) total score (difference in LS means (95% CI) of ATS versus placebo was -5.87 (-6.76, -4.97; $p < 0.001$)), which was the primary endpoint. A secondary objective of the study was to assess onset of efficacy of ATS compared to placebo. The initial onset of ATS efficacy was observed at 2 hours post-dose and continued through all post-dose time-points up to 12 hours post-dose. The most common adverse events included decreased appetite, headache, insomnia, affect lability, abdominal pain upper, vomiting, and nausea.

Details for the upcoming presentation are listed below:

Session Information

- **Poster Title:** Efficacy and Safety of a Dextroamphetamine Transdermal System in the Treatment of Children and Adolescents With ADHD: Results From a Phase 2 Trial
- **Session:** Poster Session 9
- **Date:** Monday, May 3, 2021
- **Time:** 11:00 - 11:30 AM EST
- **Poster:** P9-066

“We are excited to present the results of this study. ADHD is one of the most common mental health issues in the US. Currently, there is no amphetamine-based transdermal treatment option available for patients with ADHD,” said poster presenter Andrew J. Cutler, MD, Clinical Associate Professor of Psychiatry at SUNY Upstate Medical University, and Chief Medical Officer at the Neuroscience Education Institute.

“In February, Noven announced the submission of a New Drug Application with the U.S. Food and Drug Administration for its investigational ATS,” said Joel Lippman, M.D., Chief Operating Officer and Chief Medical Officer, Noven Pharmaceuticals, Inc. “If approved, Noven’s ATS would be the first amphetamine transdermal patch approved for ADHD in the U.S.”

ATS is an investigational agent and is not currently approved for use in any country. It is currently under review at the U.S. Food and Drug Administration.

About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is one of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviors (may act without thinking about what the result will be), or be overly active. ADHD can last into adulthood. Some adults have ADHD but have never been diagnosed. The symptoms can cause difficulty at work, at home, or with relationships. Symptoms can become more severe when the demands of adulthood increase and may look different at older ages, for example, hyperactivity may appear as extreme restlessness.

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 for prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For more information about Noven, visit <http://www.noven.com/>. For information about Hisamitsu, visit <https://global.hisamitsu/>.

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