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PRESS RELEASE

NOVEN SUBMITS NEW DRUG APPLICATION FOR INVESTIGATIONAL DEXTROAMPHETAMINE TRANSDERMAL SYSTEM FOR ADHD

February 22, 2021 – Miami, FL and Jersey City, NJ -- Noven Pharmaceuticals, Inc., (“Noven”) a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today confirmed it has submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market its dextroamphetamine transdermal system (“ATS”). Noven’s ATS, in 4.5mg/9 hours, 9.0 mg/9 hours, 13.5mg/9 hours and 18.0mg/9 hours dosage strengths, is an investigational therapy developed for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) for patients six years and older. Currently, there is no amphetamine-based transdermal treatment option available for ADHD.

The NDA submission is supported by results from a multicenter, laboratory classroom study which evaluated the safety and efficacy of ATS in over 100 pediatric patients with ADHD.

“The submission of the ATS NDA for consideration by the FDA represents a significant step toward our goal of offering a new option for clinicians, caregivers and patients for the treatment of ADHD. If approved, this investigational product will provide the first transdermal patch available for the treatment of ADHD in adults,” said Joel Lippman, M.D., Chief Operating Officer and Chief Medical Officer, Noven Pharmaceuticals, Inc.

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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