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News Release

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Sunovion Submits New Drug Application for Dasotraline to the FDA for the Treatment of Patients with ADHD

- Pharmacokinetic properties and clinical studies of dasotraline, a new chemical entity, support potential for continuous therapeutic effect over 24-hour dosing interval with once-daily dosing -

Marlborough, Mass., August 31, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for dasotraline, a novel investigational, dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI), for the treatment of children, adolescents and adults with attention deficit hyperactivity disorder (ADHD). Dasotraline's pharmacokinetic properties, such as an extended half-life, and clinical study findings support its potential for sustained control of ADHD symptoms over the 24-hour dosing interval with once-daily dosing.

"This milestone embodies Sunovion's commitment to advancing psychiatry and neurology through the development of novel treatment options to improve the lives of those living with behavioral health conditions. People with ADHD suffer from inattention, as well as hyperactive-impulsive behaviors that may interfere with school, work and social functioning," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. "Dasotraline is a once-daily medication that may add to current treatment options by providing sustained symptom improvement without wearing off between doses. In addition, studies indicate that dasotraline is associated with a relatively low potential for abuse. We look forward to working closely with the FDA to bring this important new treatment option to people living with ADHD."

The NDA submission is supported by data from the clinical program for dasotraline in ADHD, which included four placebo-controlled safety and efficacy studies, as well as two long-term studies that assessed the safety of dasotraline in patients with ADHD for up to one year. In total, approximately

2,500 patients with ADHD were evaluated in these studies utilizing dasotraline dosages in the range of 2 mg/day to 8 mg/day. Dasotraline was generally well tolerated.

Dasotraline is also being investigated for the treatment of binge eating disorder (BED) in adults.

About Dasotraline

Dasotraline is a new chemical entity that acts as a dual dopamine and norepinephrine reuptake inhibitor (DNRI). It has an extended half-life (47-77 hours) that supports the potential for stable plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.

Dasotraline was discovered by Sunovion Pharmaceuticals Inc. and is currently in development to evaluate its use in treating attention deficit hyperactivity disorder (ADHD) and binge eating disorder (BED). It has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD, BED or any other disorder.

About Attention Deficit Hyperactivity Disorder (ADHD)

Attention deficit hyperactivity disorder (ADHD) is a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning and development, as characterized by inattention (e.g., distractibility, forgetfulness) and/or hyperactivity and impulsivity (e.g., fidgeting, restlessness).[1] Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the United States.[2] Up to 60 percent of children with ADHD continue to experience symptoms into adulthood.[3] It is estimated that 4.4 percent of adults between ages 18 and 44 years experience some symptoms and disabilities from ADHD in the U.S.[4]

In children, ADHD is associated with social rejection and reduced school performance.[5] Children with a history of ADHD are 10 times as likely to have difficulties with friendships and can have more frequent and severe injuries than peers without ADHD.[6] In adults, symptoms reduce the quality of social or occupational functioning.[7] Studies have shown that ADHD is associated with higher levels of unemployment, and those who are employed may experience workplace impairment, reduced productivity and behavioral issues.[8] Adults with ADHD are also at increased risk of trauma, workplace injuries and traffic accidents, are more likely to be diagnosed with comorbid mental health conditions and have a higher incidence of separation and divorce.[8,9,10]

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to

support people with psychiatric, neurological and respiratory conditions. Sunovion's track record of discovery, development and commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCI) and Aptiom® (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on Twitter, LinkedIn, Facebook and YouTube.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

For a copy of this release, visit Sunovion's web site at www.sunovion.com

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