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News Release

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Sunovion Announces Positive Results from Pivotal Study Evaluating Novel Drug Candidate Dasotraline in Children with ADHD

– In a classroom setting, dasotraline demonstrated significantly improved ADHD symptoms in children six to 12 years of age up to 24 hours after once-daily dosing –

– Full results presented at the 6th World Congress on ADHD –

Marlborough, Mass., April 21, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced positive results of a pivotal Phase 3 study (SEP360-305) evaluating the efficacy and safety of novel drug candidate dasotraline, a dopamine and norepinephrine reuptake inhibitor (DNRI) being evaluated in children six to 12 years of age with attention deficit hyperactivity disorder (ADHD). In a laboratory classroom setting, dasotraline showed persistent, statistically significant improvement in ADHD symptoms compared to placebo throughout the day (12 to 24 hours post-dose), demonstrating a duration of effect of up to 24 hours, and was generally well tolerated.[1]

The full study results were presented in a poster session today at the 6th World Congress on ADHD, being held April 20-23, 2017, in Vancouver, Canada.

“ADHD symptoms can have a significant impact on all aspects of a child’s life, inside and outside of the classroom,” said Ann C. Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine, Las Vegas, Nevada. “Treatment options that provide sustained improvement in ADHD symptoms throughout the day can have a profound effect on the lives of children living with ADHD and their parents or caregivers.”

Sunovion plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in fiscal year 2017 (April 2017-March 2018) for the treatment of ADHD. Dasotraline is also being investigated for the treatment of binge eating disorder (BED) in adults in the U.S.

“We are encouraged by these data showing the long-acting and robust therapeutic benefits dasotraline may provide children with ADHD,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “These results add to our body of knowledge about dasotraline and reinforce its potential as a treatment option poised to address significant gaps in available treatment.”

Results from SEP360-305 pivotal study

In this study, children six to 12 years of age with ADHD taking dasotraline 4 mg/day experienced statistically significant and clinically meaningful improvement compared to placebo on the primary endpoint, change from baseline at Day 15 in ADHD symptoms as measured by mean Swanson, Kotkin, Agler, M-Flynn and Pelham Scale Combined Score (SKAMP-CS) obtained from an average of seven assessments collected over the 12-hour classroom day, 12 to 24 hours post-dose (least squares [LS] mean change from baseline at Day 15: -3.19 [95% CI: -5.06, -1.32] vs 1.99 [0.11, 3.88], respectively; effect size (ES) = 0.85, $p<0.0001$). Dasotraline maintained significant separation from placebo on the SKAMP-CS over time, 12 to 24 hours post-dose, supporting up to 24-hour duration of effect.

Dasotraline demonstrated statistically significant improvement compared to placebo on multiple secondary endpoints, including SKAMP subscales measuring attention (least squares [LS] mean change from baseline at Day 15: -0.67 [95% CI: -1.22, -0.11] vs 0.79 [0.23, 1.35], respectively; effect size (ES) = 0.81, $p<0.0001$) and deportment (least squares [LS] mean change from baseline at Day 15: -1.44 [95% CI: -2.14, -0.75] vs 0.16 [-0.55, 0.86], respectively; effect size (ES) = 0.70, $p\leq0.0006$). Statistically significant improvement was also seen on the Permanent Product Measure of Performance (PERMP) scale measuring attention and performance based on the number of attempted and completed math problems.

Dasotraline 4 mg/day was generally well tolerated with an adverse event (AE) profile consistent with completed studies in children and adults. The most common treatment-emergent adverse events (TEAEs) (reported in 5 percent or more of patients and greater than placebo) included insomnia, decreased appetite, affect lability (rapid change in emotion), headache and irritability.

About Study SEP360-305

The SEP360-305 study was a Phase 3, two-week, randomized, double-blind, multi-center, placebo-controlled, fixed-dose study comparing dasotraline with placebo in 112 children six to 12 years of age with ADHD in the U.S. Dasotraline 4 mg or placebo was administered once daily. The primary endpoint was the change from baseline at Day 15 in ADHD symptoms as measured by the mean Swanson, Kotkin, Agler, M-Flynn and Pelham Scale Combined Score (SKAMP-CS) obtained from an average of seven assessments collected across the 12-hour classroom day (12 to 24 hours post-dose) compared to the placebo-treated group. Secondary efficacy endpoints included SKAMP subscales measuring attention and deportment and the Permanent Product Measure of Performance (PERMP) scale measuring performance based on the number of attempted and completed math problems.

About Dasotraline

Dasotraline is a new chemical entity that is considered to be a dopamine and norepinephrine reuptake inhibitor (DNRI). It has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval. Dasotraline has shown a lower potential for abuse than methylphenidate in clinical testing.[2] 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) in the United States. 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).[3] Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the United States.[4] Up to 60 percent of children with ADHD continue to experience symptoms into adulthood.[5] 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.[6]

In children, ADHD is associated with social rejection and reduced school performance.[7] Children with a history of ADHD are ten times as likely to have difficulties with friendships and can have more frequent and severe injuries than peers without ADHD.[8] In adults, symptoms reduce the quality of social or occupational functioning.[9] 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.[10] 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.[11,12,13]

About Binge Eating Disorder (BED)

Binge eating disorder (BED) is characterized by recurrent episodes of binge eating that occur at least once per week for three months. An episode of binge eating is defined as eating an abnormally large amount of food in a discrete period of time. This is typically accompanied by a sense of lack of control. Binge eating must be characterized by marked distress and at least three of the following: eating more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because of embarrassment and feeling disgusted, guilty or depressed afterwards.[14] The lifetime prevalence of BED among adult women and men in the United States is 3.6 percent and 2.1 percent, respectively.[15,16]

BED typically begins in adolescence or young adulthood but can also start later.[17] BED can lead to a number of psychological and physical problems, such as social isolation, feeling bad about oneself,

problems functioning at work, obesity and related medical conditions (e.g., gastroesophageal reflux disease, joint problems, heart disease, type 2 diabetes and some sleep-related breathing disorders).[18] It is also associated with increased health care utilization, medical morbidity and mortality.[19]

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), 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, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, and Sunovion CNS Development Canada ULC, based in Toronto, 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.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

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

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