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News Release

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Sunovion Announces Results from a Study Evaluating the Abuse Potential of Investigational Drug Dasotraline

Study published in *Drug & Alcohol Dependence*

Marlborough, Mass., January 25, 2016 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced results from a human abuse liability study of dasotraline, the company's investigational medicine in late-stage development to evaluate its use in treating the symptoms of attention deficit hyperactivity disorder (ADHD) and binge-eating disorder. Human abuse liability studies are conducted to evaluate the abuse potential associated with drugs that affect the central nervous system.[1]

This Phase I study found that dasotraline single doses of 8 mg, 16 mg and 36 mg were not significantly different compared to placebo on the primary endpoint and most secondary endpoints – all of which assessed the potential for abuse – and were associated with significantly lower "drug liking"* compared to 40 mg and 80 mg single doses of methylphenidate. Results of the study were published online in *Drug & Alcohol Dependence*, an international journal sponsored by the College on Problems of Drug Dependence, and will also appear in a forthcoming print edition of the journal.

"Assessing abuse potential is critically important in the clinical development process for any therapy affecting the central nervous system, especially those that may act on dopamine and norepinephrine neurotransmitter systems," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion, and Head of Global Clinical Development for Sumitomo

Dainippon Pharma Group. "We are encouraged by these study findings and look forward to sharing future results from our comprehensive clinical trial program."

In this randomized, double-blind, double-dummy, 6-way crossover study, the abuse potential of single doses of dasotraline (8 mg, 16 mg and 36 mg) was compared to placebo and methylphenidate (40 mg and 80 mg; positive controls) in a total of 48 randomized subjects who were healthy adult recreational stimulant users. Dasotraline 16 and 36 mg doses were included in the study for the purpose of assessing abuse potential. The 36 mg dose is considered supratherapeutic.

The pharmacodynamic effect was assessed pre-dose and over 72 hours post-dose using the Drug Liking Visual Analog Scale (VAS). The primary endpoint was the drug liking VAS score at the time of peak effect (E_{max}). This is a standard measure of abuse liability in human abuse liability studies and is considered one of the most sensitive indices of abuse liability.[2,3]

Both doses of methylphenidate were associated with significantly higher VAS-drug liking scores at E_{max} compared with dasotraline 8 mg ($P<0.001$), 16 mg ($P<0.001$) and 36 mg ($P<0.01$). There were no significant differences between dasotraline (8 mg, 16 mg) and placebo across secondary endpoints. Results showed that 36 mg of dasotraline was associated with statistically significant disliking compared to placebo and methylphenidate, as measured by Overall Drug Liking (E_{min}) VAS scores. Additionally, significantly greater peak effects were observed for both doses of methylphenidate compared to placebo, thus confirming the validity of both the study population and the study measures as an assay for potential stimulant abuse liability.

The 8 mg and 16 mg of dasotraline were generally well-tolerated in this study, with an incidence of adverse events that was similar to placebo, with the exception of a higher incidence of insomnia on the two dasotraline doses and headache on the 16 mg dose. A higher incidence of adverse events was observed on dasotraline 36 mg – a dose that is higher than the anticipated maximum therapeutic dose – and on the two doses of methylphenidate.

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).[4] Approximately 11 percent of children 4-17 years of age have been diagnosed with ADHD.[5] Up to 60 percent of children with ADHD continue to experience symptoms into adulthood.[6] It is estimated that 4.4 percent of adults between ages 18 and 44 experience some symptoms and disabilities from ADHD.[7]

In children, ADHD is associated with social rejection and reduced school performance.[8] 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.[9] In adults, symptoms reduce the quality of social or occupational functioning.[10] Studies have shown that ADHD is associated with higher levels of unemployment, and those who are employed experience workplace impairment, reduced productivity and behavioral issues.[11] Adults with ADHD are also at increased risk of trauma, workplace injuries and traffic accidents, are more likely to be diagnosed with comorbid psychiatric conditions and have a higher incidence of separation and divorce.[12,13,14]

About Binge-Eating Disorder

The essential feature of binge-eating disorder is 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.[15] The lifetime prevalence of binge-eating disorder among adult women and men in the United States is 3.6% and 2.1%, respectively.[16,17]

Binge-eating disorder typically begins in adolescence or young adulthood but can also start later.[18] Binge-eating disorder 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).[19] It is also associated with increased healthcare utilization, medical morbidity and mortality.[20]

About Dasotraline

Dasotraline is a new chemical entity that is 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 at steady state. Dasotraline was discovered by Sunovion Pharmaceuticals Inc. and is currently in development to evaluate its use in treating the symptoms of ADHD in adults and children and the symptoms of binge-eating disorder in adults. It has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD, binge-eating disorder, or any other disorder.

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 spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. The Company 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 Brovana® (arformoterol tartrate), Latuda® (lurasidone HCl), and most recently 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 @Sunovion and LinkedIn.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce 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 7,000 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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* *The term "drug liking" appears in the "Guidance for Industry Assessment of Abuse Potential of Drugs" issued by the Food and Drug Administration in January 2010. Available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm198650.pdf. Accessed January 2016.*

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