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Sunovion Announces Positive Top-Line Results from Pivotal Study Evaluating Dasotraline in Adults with Binge Eating Disorder

– Study met its primary endpoint demonstrating fewer binge days per week with dasotraline versus placebo in the treatment of adults with moderate to severe binge eating disorder –

Marlborough, Mass., July 25, 2018 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that a study ([SEP360-321](#)) evaluating the efficacy and safety of dasotraline in adults (18 to 55 years of age) with moderate to severe binge eating disorder (BED) met its primary endpoint, demonstrating a statistically significant decrease in number of binge days per week (defined as days per week during which at least one binge episode occurs) from baseline to Week 12 in the group treated with dasotraline 6 mg/day versus the placebo-treated group. The study did not meet its primary endpoint for the group treated with dasotraline 4 mg/day. For both dasotraline dose groups, statistically significant improvement was demonstrated compared to placebo treatment in the Binge Eating Clinical Global Impression-Severity (BE-CGI-S) score and the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) total score (these results reflect secondary efficacy analyses without control for multiplicity).

“Binge eating disorder is associated with significant challenges for patients, ranging from marked distress and depression, to chronic health issues including heart disease and type 2 diabetes,” said Susan L. McElroy, M.D., Chief Research Officer at Lindner Center of HOPE, Professor of Psychiatry and Behavioral Neuroscience at the University of Cincinnati College of Medicine. “These study results suggest that dasotraline may be an important new treatment option for adults with BED, which is encouraging news and provides hope for patients with this difficult disorder.”

Dasotraline, a novel dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI), was generally well tolerated in both dose groups. The rate of study discontinuation due to adverse events in the dasotraline 4 mg/day, 6 mg/day and placebo-treatment groups was 8.6 percent, 14.1 percent and 1.2 percent, respectively. The most common (≥ 10 percent) adverse events in either dasotraline dose group were insomnia, dry mouth, headache, decreased appetite, nausea and anxiety, consistent with previous dasotraline studies.

In the previous pivotal study ([SEP360-221](#)), flexibly dosed dasotraline 4-8 mg/day demonstrated statistically significant improvement at the 12-week primary endpoint on the change from baseline in number of binge days per week compared to the placebo-treated group. Additionally, dasotraline was associated with statistically significant improvement in the BE-CGI-S score, the Y-BOCS-BE total score and the percent of subjects with four-week cessation from binge eating.¹ Sunovion announced [top-line results from study SEP360-221 on January 13, 2017](#) and [additional results on May 23, 2017](#) at the American Psychiatric Association Meeting.

“While binge eating disorder is the most common eating disorder in the U.S., few approved treatment options are available,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “We’re encouraged by the positive top-line results of flexible-dose study SEP360-221, and now fixed-dose study SEP360-321, which taken together suggest that dasotraline may provide an important new treatment option for people with binge eating disorder.”

Following completion of study SEP360-321, patients had the option to enroll in a currently ongoing 12-month, open-label extension study ([SEP360-322](#)), evaluating the long-term safety and tolerability of dasotraline in the treatment of BED.

BED is characterized by recurrent episodes of binge eating that occur at least once per week for three months and was officially recognized by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders (DSM), Fifth Edition, in 2013.^{2,3}

Data from SEP360-321 and SEP 360-221 will support submission of a marketing application for dasotraline to treat moderate to severe binge eating disorder in adults in the U.S. in FY2018. Full results are being analyzed and will be presented at a future scientific congress.

In August 2017, Sunovion submitted a New Drug Application (NDA) for dasotraline for the treatment of attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults. In November 2017, the U.S. Food and Drug Administration (FDA) accepted the NDA for review, with a PDUFA date set for August 30, 2018.

About Study SEP360-321

SEP360-321 was a Phase 3, 12-week, randomized, double-blind, parallel-group, multi-center, placebo-controlled, fixed-dose study comparing dasotraline versus placebo in adults 18 to 55 years of age with moderate to severe BED. Subjects were randomized to receive fixed, once-daily doses of dasotraline 4 mg, dasotraline 6 mg or placebo. The primary efficacy endpoint was the change from baseline in number of binge days (defined as days during which at least one binge episode occurred) per week at Week 12. Key secondary endpoints included change from baseline in the Binge Eating Clinical Global Impression-Severity (BE-CGI-S) score at Week 12, change from baseline in the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) total score at Week 12, and percent of subjects with a four-week cessation in binge eating prior to Week 12 or the end of study visit. Based on the pre-specified statistical

analysis plan, these efficacy endpoints could be tested with control for multiplicity if the primary endpoint for both dose groups were met.

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 or BED.

About Binge Eating Disorder (BED)

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.² The lifetime prevalence of BED among adult women and men in the U.S. is 3.6 percent and 2.1 percent, respectively.^{4,5}

BED typically begins in adolescence or young adulthood but can also start later.⁶ BED can lead to a number of psychological and physical problems, such as social isolation, feeling bad about oneself, problems functioning at work, and related medical conditions (e.g., gastroesophageal reflux disease, joint problems, heart disease, type 2 diabetes and some sleep-related breathing disorders).⁷ It is also associated with increased healthcare utilization, medical morbidity and mortality.²

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.

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,

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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 U.S., China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area, the Oncology area and Regenerative medicine/Cell therapy field, 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 more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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