

News Release

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Sunovion Announces Positive Results from Pivotal Study Evaluating Novel Drug Candidate Dasotraline in Adults with Binge Eating Disorder at Annual American Psychiatric Association Meeting

– Positive pivotal study met primary endpoint, showing a significant reduction in binge eating episodes compared to placebo, as well as key secondary efficacy endpoints –

Marlborough, Mass., May 23, 2017 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced positive results of a pivotal Phase 2/3 study (SEP360-221) evaluating the efficacy and safety of novel drug candidate dasotraline in adults 18 to 55 years of age with moderate to severe binge eating disorder (BED). Dasotraline, a dopamine and norepinephrine reuptake inhibitor (DNRI), showed significant reductions in the frequency of binge eating days per week compared to placebo and was generally well tolerated.¹

The full study results were presented in a poster session today at the 170th Annual Meeting of the American Psychiatric Association (APA) in San Diego, California.

“Binge eating disorder is the most common eating disorder in adults in the United States and has the potential for serious, long-term health implications if left untreated,” 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. “Continued study of BED is important, as effective treatment options which are well tolerated are needed for those living with this condition.”

These results add to a large and growing body of data on dasotraline. 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 attention deficit hyperactivity disorder (ADHD), as well as a supplemental New Drug Application (sNDA) for the treatment of BED in fiscal year 2018 (April 2018-March 2019).

“We are encouraged by these results suggesting that dasotraline may offer a novel, well-tolerated and efficacious treatment for binge eating disorder,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “Limited treatment options are available for this challenging illness, and there is a substantial need for additional well-tolerated and effective therapies.”

Results from SEP360-221 pivotal study

In this study, adults 18 to 55 years of age taking flexibly-dosed dasotraline 4-8 mg/day experienced statistically significant and clinically meaningful improvement compared to placebo on the primary endpoint, change from baseline in the number of binge eating days per week at Week 12 ($p < 0.0001$) with an effect size (ES) of 0.74.

Dasotraline treatment was also associated with statistically significant improvement on all key secondary efficacy assessments: Clinical Global Impression of Severity of Illness Scale (CGI-S), the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) and percent of subjects with four-week cessation of binge eating. Change from baseline in CGI-S and YBOCS-BE scores was statistically significant, favoring dasotraline over placebo (ES=0.95 and 0.96, respectively, $p < 0.0001$), and 46.5 percent of participants in the dasotraline group achieved at least four consecutive weeks cessation of binge eating versus 20.6 percent in the placebo group ($p < 0.0001$).

Dasotraline was generally well tolerated with an adverse event (AE) profile consistent with completed adult studies. The most common treatment-emergent adverse events (TEAEs) (reported in 5 percent or more of patients and greater than placebo) included insomnia, dry mouth, decreased appetite, anxiety, nausea, headache, decreased weight, dizziness, irritability, diarrhea, dyspepsia, constipation and thirst.

About Study SEP360-221

The SEP360-221 study was a Phase 2/3, 12-week, randomized, double-blind, parallel-group, multi-center, placebo-controlled, flexible-dose study comparing dasotraline with placebo in 317 adults (18 to 55 years of age) with moderate to severe BED in the U.S. Dasotraline was flexibly dosed once-daily in doses ranging from 4 to 8 mg or placebo. The primary endpoint was the change from baseline in number of binge eating days (defined as days during which at least one binge episode occurs) per week at Week 12. Secondary efficacy endpoints included Clinical Global Impression of Severity of Illness Scale (CGI-S), the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) and percent of subjects with four-week cessation from binge eating.

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). 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 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.³ The lifetime prevalence of BED among adult women and men in the United States 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, obesity 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 health care utilization, medical morbidity and mortality.⁸

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).⁹ Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the United States.¹⁰ Up to 60 percent of children with ADHD continue to experience symptoms into adulthood.¹¹ 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.¹²

In children, ADHD is associated with social rejection and reduced school performance.¹³ 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.¹⁴ In adults, symptoms reduce the quality of social or occupational functioning.¹⁵ 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.¹⁶ 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.^{17,18,19}

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) inhalation solution, Latuda® (lurasidone HCl) 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.

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