



NEWS RELEASE

# Sunovion Announces Acceptance by the U.S. FDA of the New Drug Application for Dasotraline for the Treatment of Adults with Moderate-to-Severe Binge Eating Disorder

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-Binge eating disorder (BED) is estimated to affect 4.1 million Americans and may occur at a rate that is three times higher than anorexia and bulimia combined<sup>1</sup>-

MARLBOROUGH, Mass.--(BUSINESS WIRE)--**Sunovion Pharmaceuticals Inc.** (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for dasotraline, a novel dopamine and norepinephrine reuptake inhibitor (DNRI), for the treatment of patients with moderate-to-severe binge eating disorder (BED). Dasotraline's pharmacokinetic profile, characterized by an extended half-life, supports its potential for sustained control of moderate-to-severe BED symptoms.

The action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is May 14, 2020.

Dasotraline is an investigational, once-daily medication that demonstrated significant efficacy for the treatment of moderate-to-severe BED in two 12-week, randomized, placebo-controlled studies, SEP360-221 and SEP360-321. Dasotraline was found to be generally well tolerated in clinical studies, including a long-term safety study, SEP360-322, that assessed patients with moderate-to-severe BED for up to one year.

"Binge eating disorder is a serious mental health condition for which limited treatment options exist. The disorder is often seen in association with other behavioral conditions such as depression, substance abuse and post-traumatic stress disorder, and it is often under-diagnosed and under-treated," said Antony Loebel, M.D., President and Chief

Executive Officer at Sunovion. “We are confident in the value dasotraline has shown in clinical trials to people living with BED and look forward to working with the FDA to advance this novel treatment option.”

According to the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (DSM-5),<sup>2,3</sup> BED is characterized by recurrent and persistent episodes of binge eating, defined as consuming large quantities of food in a short period of time, perception of loss of control during the episode, and intense feelings of shame, guilt and embarrassment afterwards. Many individuals also suffer from depressive and anxiety symptoms, as well as a number of medical complications, leading to impaired functioning and quality of life.<sup>4</sup>

### **About Study SEP360-221**

SEP360-221 was a Phase 2/3, 12-week, randomized, double-blind, parallel-group, multi-center, placebo-controlled, flexible-dose study comparing dasotraline with placebo in adults ages 18 to 55 years with moderate-to-severe BED. Dasotraline was administered once-daily in doses ranging from 4 to 8 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. Dasotraline was statistically superior to placebo on the primary efficacy endpoint and all key secondary efficacy endpoints: CGI-S, Y-BOCS-BE and percent of subjects with a four-week cessation from binge eating. Dasotraline was generally well tolerated. The most common adverse events were consistent with completed adult dasotraline studies and include insomnia, dry mouth, decreased appetite, anxiety, nausea and decreased weight.

### **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 study met its primary efficacy endpoint and demonstrated a statistically significant decrease in the number of binge days per week at Week 12 in the group treated with dasotraline 6 mg/day versus the placebo-treated group. Dasotraline was generally well tolerated in both dose groups. The most common ( $\geq 10$  percent) adverse events in either dasotraline dose group were insomnia, dry mouth, headache, decreased appetite, nausea and anxiety, consistent with previous dasotraline studies. Following completion of study SEP360-321, patients had the option to enroll in a 12-month, open-label extension study (SEP360-322), evaluating the long-term safety and tolerability of dasotraline for the treatment of BED

### **About Dasotraline**

Discovered and developed by Sunovion, dasotraline is a new chemical entity that inhibits presynaptic reuptake of dopamine and norepinephrine in the central nervous system (CNS). It does not stimulate neuronal release of

dopamine and norepinephrine. Dasotraline is currently being investigated for the treatment of adults with moderate-to-severe binge eating disorder (BED). Dasotraline's pharmacokinetic profile, characterized by an extended half-life, supports its potential for sustained control of moderate-to-severe BED symptoms. The company's New Drug Application (NDA) for BED is under review with the U.S. Food and Drug Administration (FDA). Sunovion is evaluating other potential indications for dasotraline, including attention-deficit hyperactivity disorder (ADHD). Dasotraline has not been approved by the FDA for any indication.

## About Binge Eating Disorder (BED)

BED is characterized by recurrent and persistent episodes of binge eating. 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 symptoms include: 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.<sup>3</sup> BED is estimated to impact 4.1 million people in the U.S. The lifetime prevalence of BED among adult women and men in the U.S. is 3.6 percent and 2.1 percent, respectively.<sup>5,6</sup>

BED typically begins in young adulthood but can also start later.<sup>7</sup> 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).<sup>8</sup> It is also associated with increased healthcare utilization, medical morbidity and mortality.<sup>3</sup> While some people with BED are obese, many people with the condition maintain normal body weights.

## About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people living 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, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's websites: [www.sunovion.com](http://www.sunovion.com), [www.sunovion.eu](http://www.sunovion.eu) and [www.sunovion.ca](http://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 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 <https://www.ds-pharma.com>.

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