Sunovion Pharmaceuticals Inc.
84 Waterford Drive, Marlborough, MA 01752-7010
Tel 508-481-6700

News Release

Contact: Kristina Coppola
Sr. Manager, Portfolio Communications
Sunovion Pharmaceuticals Inc.
508-787-4368
kristina.coppola@sunovion.com

Sunovion Announces Top-line Results from Studies Evaluating Dasotraline in Adults with Binge Eating Disorder and Attention Deficit Hyperactivity Disorder

– Clinical development program continues for dasotraline in binge eating disorder (BED) and attention deficit hyperactivity disorder (ADHD) –

Marlborough, Mass., January 13, 2017 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that a Phase 2/3 study (SEP360-221), the first of two planned pivotal studies, evaluating its novel drug candidate dasotraline in adults ages 18 to 55 years with moderate to severe binge eating disorder (BED) met the primary efficacy endpoint as well as all key secondary efficacy endpoints.[1] Sunovion also announced that the Phase 3 study (SEP360-301) evaluating dasotraline in adults ages 18 to 55 years with attention deficit hyperactivity disorder (ADHD) did not meet its primary endpoint.

"We are pleased to see such strong results in our first major study of dasotraline in patients with 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. "We remain confident in the potential for dasotraline to offer a new, differentiated therapeutic option for adults with BED as well as children and adults with ADHD. We look forward to sharing the results of our ongoing clinical studies."

In 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. In addition, dasotraline treatment was associated with statistically significant improvement on all key secondary 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 from binge eating.

In study SEP360-301, fixed doses of dasotraline 4 mg/day and 6 mg/day did not demonstrate statistically significant improvement at the 8 week primary endpoint on the ADHD Rating Scale (RS) IV (with adult prompts) total score compared to the placebo-treated group.[1] A trend toward greater improvement for the 6 mg/day group at study endpoint compared to placebo was observed (p=0.074). Statistically significant improvement on the CGI-S was observed for the 6 mg/day group (but not the 4 mg/day group) at study endpoint (p=0.011). While the overall improvement associated with the dasotraline treatment groups was

consistent with prior studies, a relatively large improvement was seen in the placebo group on the ADHD RS-IV, which may have contributed to the observed lack of statistical separation at primary endpoint.

The studies reported today add to previously reported efficacy and safety data for dasotraline including a pivotal Phase 2/3 study in children ages 6 to 12 years with ADHD that met its primary endpoint for the 4 mg/day dose and a positive, pivotal adult ADHD Phase 2 study that met its primary endpoint for the 8 mg/day dose. Adverse events for study SEP360-221 and study SEP360-301 were consistent with completed adult dasotraline studies[1] and included insomnia, dry mouth, decreased appetite, anxiety, nausea and decreased weight.

Full results of study SEP360-221 and study SEP360-301 are being analyzed and will be presented at upcoming scientific meetings.

Pending successful completion of ongoing studies and discussions with the U.S. Food and Drug Administration (FDA), Sunovion intends to submit a New Drug Application (NDA) to the FDA in 2017 for ADHD in children and adults.

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 occurs) per week at Week 12. Top-line data show that 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. Adverse events were consistent with completed adult dasotraline studies[1] and include insomnia, dry mouth, decreased appetite, anxiety, nausea and decreased weight.

About Study SEP360-301

SEP360-301 was a Phase 3, eight-week, randomized, double-blind, multi-center, placebo-controlled, fixed-dose study comparing dasotraline with placebo in adults ages 18 to 55 years with ADHD. Dasotraline 4 mg, dasotraline 6 mg or placebo was administered once-daily. The primary endpoint was the change from baseline at Week 8 in ADHD symptoms as measured by ADHD Rating Scale (RS) IV (with adult prompts) total score. Top-line data show that dasotraline 4 mg/day and 6 mg/day were not statistically superior to placebo on the primary endpoint, but a trend to greater improvement for the 6 mg/day group was observed at study endpoint. Additionally, the 6 mg/day group showed statistically significant improvement at its secondary endpoint CGI-S at Week 8 and earlier time points. Adverse events were consistent with completed adult dasotraline studies[1] and include insomnia, headache, dry mouth, decreased appetite and anxiety.

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 at steady state. 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 ADHD in adults and children, and BED in adults 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 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 healthcare 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 4-17 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 United States.[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 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 Brovana® (arformoterol tartrate), Latuda® (lurasidone HCI), 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, 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 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

References

[1] Data on file, Sunovion Pharmaceuticals Inc.
[2] Sunovion press release. Available from: http://www.sunovion.com/news/pressReleases/20160125.pdf. Accessed December 2016.
[3] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[4] Hudson, J. I., Hiripi, E., Pope, H. G., & Kessler, R. C. (2007). The Prevalence and Correlates of Eating Disorders in the National Comorbidity Survey Replication. *Biological Psychiatry*, *61*(3), 348–358.
[5] Smink, F. R. E., van Hoeken, D., & Hoek, H. W. (2012). Epidemiology of Eating Disorders: Incidence, Prevalence and Mortality Rates. *Current Psychiatry Reports*, *14*(4), 406–414.
[6] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[7] Mayo Clinic. Binge-Eating Disorder. [Internet]. Available from: http://www.mayoclinic.org/diseases-conditions/binge-eating-disorder/basics/complications/con-20033155. Accessed December 2016.
[8] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[9] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[10] Centers for Disease Control and Prevention. Attention-Deficit / Hyperactivity Disorder (ADHD) Data and Statistics. [Internet]. Available from: http://www.cdc.gov/ncbddd/adhd/data.html. Accessed December 2016.
[11] Targum S. and Adler L. Our Current Understanding of Adult ADHD. *Innov Clin Neurosci*. 2014 Nov-Dec; 11(11-12): 30–35.

[12] National Resource Center on ADHD. Statistical Prevalence of ADHD [Internet]. Available from: http://help4adhd.org/Understanding-ADHD/About-ADHD/Data-and-Statistics/General-Prevalence.aspx. Accessed December 2016.
[13] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[14] Centers for Disease Control and Prevention. Attention-Deficit / Hyperactivity Disorder (ADHD). Other Concerns & Conditions. [Internet]. Available from: http://www.cdc.gov/ncbddd/adhd/conditions.html. Accessed December 2016.
[15] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[16] Küpper, T., Haavik, J., Drexler, H., Ramos-Quiroga, J. A., Wermelskirchen, D., Prutz, C., Schauble, B. (2012). The negative impact of attention-deficit/hyperactivity disorder on occupational health in adults and adolescents. International Archives of Occupational and Environmental Health, 85(8), 837-47.
[17] Assessing Adults With ADHD and Comorbidities. Prim Care Companion J Clin Psychiatry 2009;11(1).
[18] Küpper, T., Haavik, J., Drexler, H., Ramos-Quiroga, J. A., Wermelskirchen, D., Prutz, C., Schauble, B. (2012). The negative impact of attention-deficit/hyperactivity disorder on occupational health in adults and adolescents. International Archives of Occupational and Environmental Health, 85(8), 837-47.
[19] WebMD (2015). Attention Deficit Hyperactivity Disorder: ADHD in Adults [Internet]. Available from: http://www.webmd.com/add-adhd/guide/adhd-adults?page=2#2. Accessed December 2016.