**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 Pivotal Study Results for Novel Drug Candidate Dasotraline Demonstrating Significantly Improved Attention Deficit Hyperactivity Disorder Symptoms in Children Compared to Placebo

*- Data presented at the 2017 American Professional Society of ADHD and Related Disorders (APSARD) Annual Meeting -*

**Marlborough, Mass., January 14, 2017** – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that results of a pivotal Phase 2/3 study (SEP360-202) evaluating novel drug candidate dasotraline in children ages 6 to 12 years with attention deficit hyperactivity disorder (ADHD) showed statistically significant improvement in the 4mg/day dose arm compared to placebo. The 2mg/day dose arm did not demonstrate a statistically significant difference from placebo. Sunovion announced top-line results from this study on September 20, 2016.

The full study results will be presented today at the 2017 American Professional Society of ADHD and Related Disorders (APSARD) Annual Meeting, being held January 13-15 in Washington, D.C.

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.

“Sunovion is dedicated to advancing the treatment of serious neuropsychiatric conditions, such as ADHD,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion, Head of Global Clinical Development for Sumitomo Dainippon Pharma Group. “These study results are encouraging and support the efficacy and safety of dasotraline for the treatment of ADHD.”

### Results from SEP360-202 pivotal study

Children taking dasotraline 4mg/day experienced a statistically significant improvement in ADHD symptoms compared to placebo, as measured by the ADHD Rating Scale IV: Home Version (ADHD RS-IV HV) total score (least squares [LS] mean change from Baseline at Week 6: -17.53 [95% CI:-20.12, -14.95] vs -11.36 [-13.89, -8.83], respectively; effect size (ES)=0.48, $p<0.001$).[1] This statistically significant and clinically relevant improvement over placebo was maintained each week through Week 6. Improvements in Clinical Global Impression-Severity of Illness Scale (CGI-S) scores were also statistically

significant in the 4 mg/day dose arm compared to placebo. The 2 mg/day dose arm did not demonstrate a statistically significant difference from placebo in the ADHD RS-IV total score and did not statistically separate from placebo in the CGI-S scores.

Both dasotraline 4mg and 2mg arms were generally well tolerated with an adverse event (AE) profile consistent with completed adult dasotraline studies.[1] The most common treatment-emergent adverse events (TEAE) (reported in 5 percent or more of patients and greater than placebo) included insomnia, decreased appetite and weight decreased.

**About Study SEP360-202**

SEP360-202 was a Phase 2/3, six-week, randomized, double-blind, multi-center, placebo-controlled, parallel-group efficacy and safety trial conducted in the United States, that compared dasotraline with placebo in children ages 6 to12 years with a primary diagnosis of ADHD (DSM-5 criteria), ADHD RS-IV HV score of ≥28 and CGI-S score of ≥4 at study baseline. 342 patients were randomized 1:1:1 to receive dasotraline 2mg/day (n=111) or 4mg/day (n=115), or placebo (n=116) once-daily. Patients in the 4mg/day arm started at the 2mg/day dose for the first week of the trial and were increased to 4mg/day at Week 2. The primary efficacy endpoint was change from Baseline at Week 6 in ADHD symptoms as measured by the ADHD RS-IV total score. Secondary efficacy endpoints included change from Baseline in ADHD symptoms as measured by ADHD RS-IV HV score at Weeks 1-5 (and subscales at Weeks 1–6), CGI-S score at Weeks 1-6 and percentage of responders (defined as ≥30% reduction in ADHD RS-IV HV total score at Weeks 1-6).

**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 was discovered by Sunovion Pharmaceuticals Inc. and is currently in development to evaluate its use in treating ADHD in adults and children and binge eating disorder (BED) in adults in the United States. It has not been approved by the FDA for the treatment of ADHD, BED or any other disorder.

**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). [2] Approximately 11% of children 4-17 years of age have been diagnosed with ADHD in the United States.[3] Up to 60% of children with ADHD continue to experience symptoms into adulthood.[4] It is estimated that 4.4% of adults between ages 18 and 44 years experience some symptoms and disabilities from ADHD in the United States.[5]

In children, ADHD is associated with social rejection and reduced school performance. [6] 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.[7] In adults, symptoms reduce the quality of social or occupational functioning. [8] 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.[9] 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.[10,11,12]

**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.[13] The lifetime prevalence of BED among adult women and men in the United States is 3.6% and 2.1%, respectively.[14,15]

BED typically begins in adolescence or young adulthood but can also start later.[16] 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).[17] It is also associated with increased healthcare utilization, medical morbidity and mortality.[18]

**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.

BROVANA is a registered trademark of Sunovion Pharmaceuticals Inc.
LATUDA is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.
APTIOM is used under license from BIAL.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.


For a copy of this release, visit Sunovion's web site at www.sunovion.com

**References**


[1] Data on file, Sunovion Pharmaceuticals Inc.
[2] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[3] 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.
[4] Targum S. and Adler L. Our Current Understanding of Adult ADHD. *Innov Clin Neurosci*. 2014 Nov-Dec; 11(11-12): 30–35.
[5] 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.
[6] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[7] 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.
[8] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[9] 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.
[10] Assessing Adults With ADHD and Comorbidities. Prim Care Companion J Clin Psychiatry 2009;11(1).
[11] 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.
[12] 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.
[13] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[14] 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.
[15] 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.
[16] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.
[17] Mayo Clinic. Binge-Eating Disorder. [Internet]. Available from: http://www.mayoclinic.org/diseases-conditions/binge-eating-disorder/basics/complications/con-20033155. Accessed December 2016.
[18] American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.