

## News Release

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### **Sunovion Announces FDA Acceptance for Review of New Drug Application for Dasotraline for the Treatment of ADHD**

**Marlborough, Mass., November 10, 2017** – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for dasotraline, a novel dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) being evaluated for the treatment of attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults.

The NDA submission is supported by multiple placebo-controlled safety and efficacy studies, as well as two long-term studies that assessed the safety of dasotraline in people with ADHD for up to one year. In total, approximately 2,500 people with ADHD were evaluated in these studies, and dasotraline was generally well tolerated.

“While there are a number of approved treatments for people living with ADHD, there remains a significant need for novel therapies that can address the needs of patients,” 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 are pleased that the FDA has accepted our New Drug Application for dasotraline and look forward to working closely with the Agency so that we can bring this important treatment option to people with ADHD.”

#### **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 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).<sup>1</sup> Approximately 11 percent of children four to 17 years of age have been diagnosed with ADHD in the United States.<sup>2</sup> Up to 60 percent of children with ADHD continue to experience symptoms into adulthood.<sup>3</sup> 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.<sup>4</sup>

In children, ADHD is associated with social rejection and reduced school performance.<sup>5</sup> 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.<sup>6</sup> In adults, symptoms reduce the quality of social or occupational functioning.<sup>5</sup> 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.<sup>7</sup> 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.<sup>8,9,10</sup>

### **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/or commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) Inhalation Powder, Seebri™ Neohaler® (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, 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 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](http://www.ds-pharma.com).

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### **References**

<sup>1</sup> American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.

<sup>2</sup> 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 March 2017.

<sup>3</sup> Targum SD. & Adler LA. Our Current Understanding of Adult ADHD. Innovations in Clinical Neuroscience. 2014; 11(11-12): 30-35.

<sup>4</sup> National Resource Center on ADHD. General Prevalence of ADHD [Internet]. Available from: <http://www.help4adhd.org/Understanding-ADHD/About-ADHD/Data-and-Statistics/General-Prevalence.aspx>. Accessed March 2017.

<sup>5</sup> American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition. Washington, DC: American Psychiatric Association, 2013.

<sup>6</sup> 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 March 2017.

<sup>7</sup> Küpper, T, Haavik, J, Drexler, H, et al. The Negative Impact of Attention-Deficit/Hyperactivity Disorder on Occupational Health in Adults and Adolescents. International Archives of Occupational and Environmental Health. 2012; 85(8), 837-47.

<sup>8</sup> Assessing Adults with ADHD and Comorbidities. Primary Care Companion to the Journal of Clinical Psychiatry. 2009;11(1): 25-43.

<sup>9</sup> WebMD. Attention Deficit Hyperactivity Disorder in Adults [Internet]. Available from: <http://www.webmd.com/add-adhd/guide/adhd-adults?page=2#2>. Accessed March 2017.

<sup>10</sup> Koblan, KS, Hopkins SC, Sarma, K, et al. Assessment of Human Abuse Potential of Dasotraline Compared to Methylphenidate and Placebo in Recreational Stimulant Users. Drug Alcohol Dependence. 2015; 159: 26-34.