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FDA Issues a Complete Response Letter for New Drug Application for Dasotraline for the Treatment of ADHD

Marlborough, Mass., August 31, 2018 – [Sunovion Pharmaceuticals Inc.](http://www.sunovion.com) (Sunovion) today announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter for the New Drug Application (NDA) for dasotraline, a novel dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI), for the treatment of attention-deficit hyperactivity disorder (ADHD).

Upon completion of their review, the FDA determined that they cannot approve the dasotraline NDA for the treatment of ADHD in its current form. The Agency indicated that additional clinical data are needed to further evaluate the efficacy and tolerability of dasotraline for the treatment of ADHD. Sunovion plans to meet with the FDA to discuss their comments and determine next steps.

Dasotraline was evaluated in approximately 2,500 children and adults with ADHD in multiple placebo-controlled safety and efficacy studies,^{1,2,3,4} as well as two long-term safety studies.

“While we are disappointed with the FDA’s decision, we remain confident in the future of dasotraline,” 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 plan to discuss next steps for the dasotraline ADHD program with the FDA as soon as possible.”

Dasotraline is also being studied for the treatment of moderate to severe binge eating disorder (BED) in adults in the U.S. Data from two positive pivotal studies^{5,6} will support an expected marketing application submission to the FDA for dasotraline to treat BED in FY2018.

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 in adults; 58-84 hours in children) 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 ADHD and BED. It has not been approved by the FDA for the treatment of ADHD or BED.

About Attention-Deficit Hyperactivity Disorder (ADHD)

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).⁷ Approximately 11.0 percent of children 4 to 17 years of age have been diagnosed with ADHD in the U.S.⁸ Up to 60.0 percent of children with ADHD continue to experience symptoms into adulthood.⁹ 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.¹⁰

In children, ADHD is associated with social rejection and reduced school performance.¹¹ 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.¹² In adults, symptoms reduce the quality of social or occupational functioning.¹¹ 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.¹³ 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.^{14,15,16}

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.

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, 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 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 www.ds-pharma.com.

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

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