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

News Release

Contact: Patrick Gaffey
Senior Director, Corporate Communications
Sunovion Pharmaceuticals, Inc.
508-357-7740
patrick.gaffey@sunovion.com

Investigational Drug Dasotraline Significantly Improved Symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in a Placebo-Controlled Study in Adults

Data Support Further Clinical Development of Novel Dopamine and Norepinephrine Reuptake Inhibitor (DNRI)

MARLBOROUGH, Mass., December 11, 2014 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced positive results from the first placebo-controlled clinical study of the company's investigational drug dasotraline for the treatment of adult patients with attention deficit hyperactivity disorder (ADHD). The findings were presented at the 53rd Annual Meeting of the American College of Neuropsychopharmacology (ACNP) held December 7-11 in Phoenix, Arizona.

Dasotraline, a new chemical entity discovered by Sunovion, inhibits the pre-synaptic reuptake of dopamine and norepinephrine. In the 4-week, double-blind, randomized, placebo-controlled clinical trial, adults with ADHD were randomized to dasotraline 4 mg/day, dasotraline 8 mg/day or placebo.

"ADHD symptoms, such as restlessness, impulsiveness and inattention, can disrupt patients' lives and adversely impact work, family and social functioning," said Scott H. Kollins, Ph.D., Professor in the Department of Psychiatry & Behavioral Science, Duke University School of Medicine, and a lead investigator of the study. "It is important to continue to study novel therapeutic options that have the potential to help patients manage their ADHD symptoms and improve overall functioning."

Dasotraline 8 mg/day demonstrated statistically significant improvement in symptoms of ADHD compared to placebo as measured by the ADHD Rating Scale-Version IV (RS-IV) total score (LS mean -13.9 vs. -9.7; p=0.019), the primary efficacy endpoint of the study, and the inattentiveness (LS mean -8.0 vs. -5.6; p=0.016) and hyperactivity/impulsivity (LS mean -5.9 vs. -4.1; p=0.027) subscale scores. The dasotraline 4 mg/day dose was associated with improvement on the ADHD RS-IV total (LS mean -12.4 vs. -9.7; p=0.076) and subscale scores compared to placebo. Both dasotraline 4 mg/day (LS mean -1.1 vs. -0.7; p=0.021) and 8 mg/day (LS mean -1.1 vs. -0.7; p=0.013) demonstrated statistically significant improvement compared to placebo on the Clinical Global Impression-Severity of Illness (CGI-S) – modified for ADHD scale, a secondary efficacy endpoint of the study.

The most common treatment-emergent adverse events (incidence ≥5% and ≥2-times placebo) leading to discontinuation for dasotraline 4 mg/day and 8 mg/day vs. placebo were insomnia (2.6% and 10.8% vs. 0%), anxiety (2.6% and 1.8% vs. 0%) and panic attacks (0% and 2.7% vs. 0%).

Sunovion recently initiated a second study that will evaluate the use of dasotraline in the treatment of adults with ADHD. The results from the first study and the recently initiated second study are intended to support a future New Drug Application in this patient population. Sunovion also intends to initiate a clinical development program to assess the safety and efficacy of dasotraline in pediatric patients with ADHD.

About Dasotraline

Dasotraline is a new chemical entity that blocks pre-synaptic dopamine transporters (DAT) and norepinephrine transporters (NET). Dasotraline has an extended half-life that supports the potential for plasma concentrations yielding therapeutic effect over the 24-hour dosing interval at steady state. Dasotraline was discovered by Sunovion Pharmaceuticals Inc. and is currently in development for the treatment of ADHD. Dasotraline has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of ADHD or any other disorder.

About Attention Deficit Hyperactivity Disorder (ADHD) in Adults

Attention deficit hyperactivity disorder (ADHD) is characterized by persistent symptoms of hyperactivity (e.g., restlessness, impulsiveness) and inattention (e.g., distractibility, forgetfulness), affecting approximately 4% of American adults.[1,2] ADHD is associated with clinically significant impairment in social, academic or occupational functioning.[1]

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry & Neurology and Respiratory disease areas. Sunovion's drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Aptiom® (eslicarbazepine acetate), Latuda® (lurasidone HCl) tablets, Lunesta® (eszopiclone) tablets, Xopenex HFA® (levalbuterol tartrate) inhalation aerosol, Brovana® (arformoterol tartrate) inhalation solution, Omnaris® (ciclesonide) nasal spray, Zetonna® (ciclesonide) nasal aerosol and Alvesco®(ciclesonide) inhalation aerosol.

Sunovion, an indirect, wholly-owned U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce 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

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

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[1] American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Washington, DC, 2013.
[2] Kessler RC, et al. American Journal of Psychiatry 2006; 163:716-23.