Sunovion Announces Results from Pivotal Study Evaluating Novel Drug Candidate Dasotraline in Children with ADHD

- Topline data show trial met primary endpoint with a statistically significant change from baseline compared to placebo at Week 6 in ADHD symptoms as measured by ADHD RS IV HV in the 4mg/d dose arm -

Marlborough, Mass., September 20, 2016 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that its pivotal study (SEP360-202) evaluating dasotraline in children ages 6 to 12 years with attention deficit hyperactivity disorder (ADHD) met its primary efficacy endpoint in the 4mg/d dose arm.

“We are encouraged that dasotraline has demonstrated in this study the potential to help children with 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. “We recognize that there are still significant gaps in the treatment of ADHD, particularly a need for products that provide sustained therapeutic effects. We look forward to the overall results of the dasotraline development program, which is evaluating this potential therapy in children and adults with ADHD.”

The SEP360-202 trial was a Phase 2/3, six-week, randomized, double-blind, multi-center, placebo-controlled, parallel-group, fixed dose safety and efficacy trial that evaluated once-daily dasotraline (2mg/d and 4mg/d dose arms) in 342 children ages 6 to 12 years with ADHD. The primary efficacy endpoint was the change from baseline to Week 6 in the ADHD Rating Scale-IV: Home Version (ADHD RS IV HV) total score. Results show that the 4mg/d dose arm demonstrated a statistically significant and clinically relevant difference compared to placebo. The 2mg/d dose arm was not statistically significantly different compared to placebo. Dasotraline was generally well tolerated. 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. The overall discontinuation rate due to TEAEs in dasotraline treated individuals was 9.3 percent.

The full results of the study are being analyzed, and Sunovion will present data from this study at upcoming scientific meetings.

Dasotraline is a novel drug candidate that also is being evaluated in binge eating disorder (BED) in adults in the United States.
About SEP360-202

SEP360-202 was a Phase 2/3, six-week, randomized, double-blind, multi-center, placebo-controlled, parallel-group efficacy and safety trial comparing dasotraline with placebo in children ages 6 to 12 years with ADHD in the United States. Dasotraline 2mg, dasotraline 4mg or placebo was administered once-daily. Patients in the 4mg/d arm started at the 2mg/d dose for the first week of the trial and were increased to 4mg/d at week 2. The primary endpoint was the change from baseline at Week 6 in ADHD symptoms as measured by ADHD RS IV HV total score.

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 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 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). Approximately 11 percent of children 4-17 years of age have been diagnosed with ADHD in the United States. Up to 60 percent of children with ADHD continue to experience symptoms into adulthood. 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.

In children, ADHD is associated with social rejection and reduced school performance. 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. In adults, symptoms reduce the quality of social or occupational functioning. 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. 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.

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. The lifetime prevalence of BED among adult women and men in the United States is 3.6 percent and 2.1 percent, respectively.
BED typically begins in adolescence or young adulthood but can also start later. 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). It is also associated with increased healthcare utilization, medical morbidity and mortality.

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 spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. The Company 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 HCl), and most recently Aptiom® (eslicarbazepine acetate).


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.

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References
