

April 12, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Positive Topline Results from a Phase 3 Study of Novel Drug Candidate Dasotraline Being Evaluated in the Treatment of Children with Attention Deficit Hyperactivity Disorder (ADHD)

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) announced today positive topline results from a Phase 3 study evaluating the novel drug candidate dasotraline (generic name, code name: SEP-225289), a dopamine norepinephrine reuptake inhibitor, being evaluated in children ages 6 to 12 years with attention deficit hyperactivity disorder (ADHD). The study met its primary endpoint.

The Phase 3 study evaluated the efficacy and safety of dasotraline (4mg/day versus placebo) in children ages 6 to 12 years with ADHD in a laboratory classroom setting. The primary endpoint was change from baseline at Day 15 in ADHD symptoms as measured by mean SKAMP-Combined* Score obtained from an average of 7 assessments collected across the 12-hour laboratory classroom day (12-24 hours post-dose).

In this Phase 3 study, dasotraline 4 mg/day demonstrated sustained efficacy over the 12-24 hour time period post-dose and was associated with an acceptable safety profile over the 2 week study duration.

Based on the results of the study, Sunovion Pharmaceuticals Inc., a U.S. subsidiary of Sumitomo Dainippon Pharma, plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in FY2017 for ADHD in adults and pediatric populations. We will also continue to develop dasotraline for binge eating disorder (BED) in adults in the United States.

Full results of the study will be presented in a poster session at 6th World Congress on ADHD in Vancouver, Canada, Apr 20-23, 2017.

* The SKAMP-Combined Score assesses functional impairment related to ADHD.

【Scheduled Presentation at 6th World Congress on ADHD】

No.: P-16 - Guided Poster Tour 012

Session title: Pharmacological treatment children and adolescents I

Title: Dasotraline efficacy throughout the day in children with attention deficit hyperactivity disorder: Results of a phase 3, randomized, double-blind, placebo-controlled study in a laboratory classroom setting

Date and Time: 14.30-16.00 Friday, April 21, 2017 (Canada Time)

Room: Exhibit A

Abstracts are posted on 6th World Congress on ADHD website.

(<https://adhd.congress-online.com/guest/IDff8b8375dc1118/AbstractView?ABSID=9698>)

【Highlights of the abstract】

- Dasotraline 4 mg/day significantly improved mean SKAMP-Combined score versus placebo ($p < 0.0001$, effect size 0.85) with significant effects persisting throughout the day. Mean SKAMP subscores improved significantly for attention ($p < 0.0001$, effect size 0.81) and deportment ($p < 0.001$, effect size 0.70).
- Treatment-emergent AEs were mild or moderate in severity; most frequent were (dasotraline 4 mg/day; placebo) combined insomnia (19.6%; 3.6%), decreased appetite (10.7%; 3.6%), headache (10.7%; 8.9%), affect lability (8.9%; 7.1%), and irritability (5.4%; 3.6%).

(Reference)

【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 is currently in development to evaluate its use in treating ADHD in adults and pediatric populations and binge eating disorder (BED) in adults in the United States.

【About SEP360-305 study】

The SEP360-305 study conducted in the United States was a Phase 3, two-week, multi-center, randomized, placebo-controlled, double-blind, in children with ADHD. This Phase 3 study evaluated the efficacy and safety of dasotraline in children with ADHD throughout the day in a laboratory classroom setting. 112 children, ages 6 to 12 years, with ADHD were administered of dasotraline or placebo (dosed daily at home at approximately 8 p.m.) for a period of two weeks. The laboratory classroom evaluations took place at baseline and Day 15. The primary endpoint was change from baseline at Day 15 in ADHD symptoms as measured by mean SKAMP-Combined Score obtained from an average of 7 assessments collected across the 12-hour laboratory classroom day (12-24 hours post-dose).

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