Sunovion Announces Results from Its Open-Label Extension Study of SEP-363856 in Schizophrenia

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— SEP-363856 was generally safe and well tolerated throughout the six-month study —

— Treatment with SEP-363856 was associated with clinically meaningful improvement across all efficacy measures —

MARLBOROUGH, Mass.—(BUSINESS WIRE)—Sunovion Pharmaceuticals Inc. today announced results from study SEP361-202 which evaluated the long-term safety and effectiveness of SEP-363856, a novel non-dopamine 2 (D2) agent under investigation for the treatment of patients with schizophrenia. Results of study SEP361-202, the open-label extension study of the four-week, double-blind, placebo-controlled study SEP361-201, were presented at the 58th Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Orlando, Fla.

The study results were presented as a poster titled “Safety and Effectiveness of SEP-363856 in Schizophrenia: Results of a 6-Month, Open-Label Extension Study,” (Poster #W204). The study completion rate was relatively high at 66.9 percent1 and SEP-363856 was found to be generally safe and well tolerated. No clinically meaningful changes were observed on metabolic parameters (including weight, lipids and glucose) or prolactin levels. The study also showed that patients treated with SEP-363856 demonstrated clinically meaningful improvements across all efficacy measures, including the Positive and Negative Syndrome Scale (PANS) total score (-22.6), the Clinical Global Impression Scale - Severity (CGI-S) score (-1.0), and the Brief Negative Symptom Scale (BNSS) total score (-11.3).

“The results of our six-month, open-label extension study in patients living with schizophrenia demonstrate that SEP-363856 has an excellent long-term safety profile, with continued, clinically meaningful improvement seen in the Positive and Negative Syndrome Scale (PANS) total score,” said Justine M. Kent, M.D., Head of Global Clinical Research, Psychiatry, at Sunovion. “We look forward to swiftly progressing our global Phase 3 clinical studies of SEP-363856 in both adult and adolescent patients with schizophrenia.”

SEP-363856 does not bind to dopamine 2 (D2) or serotonin 2A (5-HT2A) receptors, which are thought to mediate the effects of currently available atypical antipsychotic medicines. Instead, SEP-363856 activates TAAR1 (trace amine-associated receptor 1) and 5-HT1A (serotonin 1A) receptors. SEP-363856 is being studied in a global development program for schizophrenia and in the U.S. for Parkinson’s disease psychosis, with additional indications under consideration. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for SEP-363856 for schizophrenia in May 2019.

In addition to the SEP361-202 open-label extension data for SEP-363856, Sunovion presented two posters highlighting new data at ACNP 2019. The first poster titled, “The Novel, Non-D2 Psychotropic Agent SEP-363856 Modulates Presynaptic Dopamine Function in Mice,” (Poster #M178) presented data in support of the novel mechanism of action of SEP-363856. Poster #T215 titled “Effects of SEP-363856 on Negative Symptoms in Schizophrenia: Analysis of an Acute, Placebo-controlled Trial of a Novel Psychotropic Agent with No Dopamine-D2/5-HT2A Antagonist Activity” discussed the effect of SEP-363856 on negative symptoms in schizophrenia.

About SEP361-202
SEP361-202 was a flexibly-dosed (25 – 75 mg/day), 26-week, open-label extension study which enrolled 157 people living with schizophrenia who had completed the four-week double-blind treatment phase of SEP361-201, a randomized, placebo-controlled, double-blind, registration study.

The study had a completion rate of 66.9 percent, and the discontinuation rate due to an adverse event was 11.5 percent. Adverse events occurring in at least five percent of patients included exacerbation of schizophrenia (12.2 percent), headache (11.5 percent), insomnia (8.3 percent), and anxiety (5.1 percent). Additionally, effects on weight, lipids, glycemic indices, prolactin and extrapyramidal symptoms (EPS) measures were negligible and not clinically meaningful. The proportion of patients who experienced EPS during the 26 weeks of treatment with SEP-363856 was 3.2 percent.
About SEP361-201
SEP361-201, a randomized, placebo-controlled, double-blind, registration study, met its primary endpoint, demonstrating that hospitalized patients with acute exacerbation (worsening) of schizophrenia treated with SEP-363856 showed statistically significant and clinically meaningful improvement in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo after four weeks of treatment (-17.2 vs. -9.7, respectively; p=0.001). Patients treated with SEP-363856 also showed improvement in the overall severity of illness as assessed by the Clinical Global Impression Scale - Severity (CGI-S) (p<0.001). In addition, improvement was found in all PANSS subscales (positive, negative and general psychopathology, p<0.02) and for the Brief Negative Symptom Scale (BNSS) total score (p<0.001).

SEP-363856 was found to be generally well-tolerated. The overall discontinuation rate was comparable for SEP-363856 and placebo (21.7 percent and 20.8 percent, respectively). The proportion of patients experiencing extrapyramidal symptoms or akathisia (restlessness) and the proportion of patients experiencing a change in metabolic parameters (including weight, lipids and glucose) or prolactin were similar between the SEP-363856 and placebo treatment groups.

About SEP-363856
SEP-363856 is a TAAR1 agonist with 5-HT1A agonist activity that is under investigation for the treatment of schizophrenia and other psychiatric conditions. Sunovion discovered SEP-363856 in collaboration with PsychoGenics based on a mechanism-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Clinical trial results to date demonstrate a predictable pharmacokinetic (PK) profile suitable for once daily use.

SEP-363856 is being studied in a global Phase 3 development program for schizophrenia and is currently in Phase 2 studies in the United States for Parkinson's disease psychosis, with additional indications under consideration.

About Schizophrenia
Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 23 million people worldwide and approximately one in 100 adults (about 2.4 million people) in the United States. It is characterized by positive symptoms, such as hallucinations, delusions and disorganized thinking as well as negative symptoms, such as lack of emotion, social withdrawal, lack of spontaneity and cognitive impairment that includes problems with memory, attention and the ability to plan, organize and make decisions.

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.


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 https://www.ds-pharma.com.

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References