Sunovion Highlights Data from its Late-Stage Psychiatric Medicine Pipeline at the American College of Neuropsychopharmacology (ACNP) Annual Meeting 2020

MARLBOROUGH, Mass., December 10, 2020 1:15 pm (BUSINESS WIRE) — Sunovion Pharmaceuticals Inc. (Sunovion) today announced that new data and analyses of late-stage compounds SEP-363856 and SEP-4199 were presented at the 59th Annual Meeting of the American College of Neuropsychopharmacology virtual meeting, which took place December 6-9. SEP-363856 is a trace amine-associated receptor 1 (TAAR1) agonist with serotonin 5-HT1A agonist activity that is under investigation for the treatment of schizophrenia, and SEP-4199 is an investigational non-racemic ratio of amisulpride enantiomers (85% aramisulpride to 15% esamisulpride) being evaluated for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression).

“SEP-363856 and SEP-4199 represent innovative approaches to the way serious mental health conditions like schizophrenia and bipolar depression may be treated in the future,” said Armin Szegedi, MD, PhD, Senior Vice President and Chief Medical Officer of Sunovion. “While our industry has made great strides in the development of therapies to address these conditions, there remains an unmet need to develop medicines that may manage multiple aspects of these disorders while minimizing potential side effects. We look forward to continuing clinical investigation of these important compounds and sharing additional data in the future.”

In a poster titled, “Effects of SEP-363856, a Novel TAAR1 Agonist, on Negative Symptoms in Schizophrenia: Results of a 6-Month, Open-label Treatment Study,” (Poster M108), secondary endpoint data from the pivotal double-blind four-week study and the subsequent six-month open label extension study were presented. Previously-reported data from the four-week study demonstrated significant improvement in the Brief Negative Symptom Scale (BNSS) total score (effect size [ES], 0.48) in addition to other negative symptom assessments. Further analysis showed that patients additionally saw improvements in BNSS factor scores including blunted affect (ES, 0.51), asociality (ES, 0.47) and avolition (ES, 0.42). Continued negative symptom improvements were observed during 26 weeks of additional treatment with SEP-363856 on the BNSS total score and other negative symptom assessments. SEP-363856 was generally well tolerated. The most common adverse events occurring in more than five percent of patients and more frequently in the SEP-363856 treatment group than placebo in the four-week double-blind trial were somnolence, agitation and nausea. In the 26-week open-label extension, the most frequently reported adverse events, occurring in more than five percent of patients included schizophrenia, headache, insomnia and anxiety.

In addition, results from SEP380-201, a clinical study evaluating the efficacy, safety and tolerability of SEP-4199 were presented in a poster titled, “A Randomized, Double-blind, Placebo-controlled Study of SEP-4199 for the Treatment of Patients with Bipolar Depression” (Poster M54). The primary analysis of the randomized, double-blind, placebo-controlled, parallel-group, fixed-dose multi-regional study showed numerical improvement in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score after six weeks of treatment (200 mg: -19.5 vs -16.2, 400 mg: -19.3 vs -16.2 respectively, both dose groups vs placebo, P=0.054; 200 mg group effect size [ES] = -0.31 and 400 mg group ES = -0.29). In the full intent-to-treat (ITT) analysis, including those enrolled in Japan, the least squares (LS) mean reduction from baseline at Week 6 in MADRS total score showed improvement vs placebo for both the SEP-4199 200 and 400 mg doses (-3.68 [P=0.016] and -3.38 [P=0.024], for the 200 mg and 400 mg doses, respectively). Improvements were also observed vs placebo, in the ITT population, on the Quick Inventory of Depressive Symptomatology (Self-Report) (QIDS-SR-16) for the 200 mg dose (P=0.049; ES, 0.28) and the 400 mg dose (P=0.038; ES, 0.29).

SEP-4199 was well tolerated by patients enrolled in the study, with relatively low rates of adverse events. The most commonly reported adverse events occurring more frequently in the SEP-4199 treatment group than in the placebo group, and in at least two percent of patients, included QTc interval prolongation (observed in the 400 mg arm), somnolence, constipation, galactorrhea, nausea, akathisia, dizziness, hypomania and diarrhea.

Additional posters presented at the ACNP 2020 virtual meeting include, “SEP-363856, a Novel TAAR1 Agonist, Lacks Abuse Liability in Preclinical Models and Attenuates Cocaine Cue-Induced Relapse in Rats,” (Poster T149) which indicated that SEP-363856 may not pose a risk for recreational abuse in humans and, “Discovery and Development of SEP-4199 and Characterization of its Enantiomer-specific Pharmacology,” (Poster W96) which discussed study results that allowed the discovery of the ratio of aramisulpride and esamisulpride to optimize the antidepressant efficacy of SEP-4199.

About SEP-363856
SEP-363856 is a TAAR1 agonist with 5-HT^{1A} agonist activity that is under investigation for the treatment of schizophrenia and other psychiatric conditions. Sunovion discovered SEP-363856 in collaboration with PsychoGenics based in part on a mechanism-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. SEP-363856 is being studied in a global Phase 3 development program for schizophrenia (DIAMOND) with additional indications under consideration. The U.S. FDA granted Breakthrough Therapy Designation for SEP-363856 for schizophrenia in May 2019. The full results of a four-week pivotal study (SEP361-201) evaluating the safety and efficacy of SEP-363856 in patients with schizophrenia were published in the New England Journal of Medicine (NEJM) in April 2020.

About Schizophrenia
Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 23 million people worldwide[1] and approximately one in 100 adults (about 2.4 million people) in the United States.[2] 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.[2]

About SEP-4199
SEP-4199 is a non-racemic ratio of amisulpride in clinical development for the treatment of bipolar depression. The pharmacological effect of SEP-4199 is distinct from racemic amisulpride, which is approved in several countries outside the U.S. for the treatment for schizophrenia and other psychiatric conditions. Sunovion improved the antidepressant activity in amisulpride, which is believed to be driven by 5-HT7 receptor (5-HT7R) antagonism, and adjusted the dopamine D2/D3-mediated antipsychotic activity by discovering that each enantiomer favors a different receptor. The targeted levels of 5-HT7R antagonist and D2R/D3R blockade were independently studied for antidepressant effects in early human studies to discover that an 85:15 ratio of aramisulpride to esamisulpride provides antidepressant benefit and reduces D2 receptor-related extrapyramidal side effects, while still retaining D2 receptor binding-related benefit in bipolar disorder.

About Bipolar Disorder
Bipolar disorder affects approximately 12.6 million individuals in the United States and an estimated 29 million people worldwide.3,4 A person is usually diagnosed with bipolar disorder after experiencing at least one manic episode, with symptoms that are not better explained by another mental health condition, such as schizophrenia.5 Bipolar disorder is characterized by debilitating mood swings, interspersed with periods of stable mood and behavior.6 When individuals with bipolar disorder are experiencing symptoms, most tend to be depressed, rather than manic.4.

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-10 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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