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News Release

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New England Journal of Medicine Publishes Pivotal Results Evaluating Sunovion's SEP-363856 for the Treatment of Schizophrenia

—Significantly greater improvement in the Positive and Negative Symptom Scale was demonstrated in schizophrenia patients treated with SEP-363856, a TAAR1 agonist, compared to placebo—

—Effects on extrapyramidal symptoms, weight and other metabolic parameters were similar in the SEP-363856 and placebo treatment groups—

Marlborough, Mass., April 15, 2020 – Sunovion Pharmaceuticals Inc. (Sunovion) today announced that results of a four-week pivotal study (SEP361-201) evaluating the safety and efficacy of SEP-363856 in patients with schizophrenia were published online in the *New England Journal of Medicine (NEJM)*.

In this study, once-daily, flexible-dose (50-75 mg) treatment with SEP-363856 demonstrated a 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 observed in all major PANSS (positive, negative and general psychopathology) subscales (p<0.02). SEP-363856 was well tolerated throughout the study and the overall discontinuation rate was comparable for SEP-363856 and placebo.[1]

"These data represent an exciting step forward in schizophrenia research. The steps that led to identifying this new mechanism of action, targeting TAAR1, were very novel and they reflected a courageous and innovative approach by Sunovion to identifying new ways to treat schizophrenia," said John Krystal, M.D., Chair of Psychiatry and Co-Director, Yale Center for Clinical Investigation at Yale School of Medicine and co-author of the *NEJM* publication. "For the last 60 years, antipsychotics that bind to dopamine receptors have been the standard of care, despite their side effect profile. It is my hope that these results for SEP-363856 support a new schizophrenia treatment for people who have been

diagnosed with this serious mental health condition. SEP-363856 could have a big impact on people with schizophrenia, their families, and on the public health burden posed by schizophrenia."

SEP-363856 is a novel trace amine-associated receptor 1 (TAAR1) agonist with serotonin 1A ($5\text{-}HT_{1A}$) agonist activity that is being evaluated in patients with schizophrenia. SEP-363856 does not bind to dopamine 2 (D2) or serotonin 2A ($5\text{-}HT_{2A}$) receptors, which are thought to mediate the effects of currently available atypical antipsychotic medicines. SEP-363856 is being studied in the DIAMOND (**D**eveloping **I**nnovative **A**pproaches for **M**ental **D**isorders) Phase 3 global development program for schizophrenia with additional indications under consideration. The U.S. FDA granted Breakthrough Therapy Designation for SEP-363856 for the treatment of schizophrenia in May 2019.

"Publication of these findings in the *New England Journal of Medicine* demonstrates the potential of SEP-363856 to be the first TAAR1 agonist for the treatment of schizophrenia," said Kenneth Koblan, PhD, Chief Scientific Officer of Sunovion. "This innovative approach to the treatment of schizophrenia may provide a completely new option for the 23 million people worldwide who live with this serious mental health condition. Sunovion is committed to developing new treatment options for these patients and continuing to study SEP-363856 to further evaluate its clinical benefit in schizophrenia and other neuropsychiatric conditions."

As noted in the *NEJM* publication, in the six-month, open-label extension study, SEP-363856 demonstrated continued improvement across efficacy measures, including the PANSS total score, the CGI-S score, and the Brief Negative Symptom Scale (BNSS) total score and appeared to be safe and well-tolerated.

About SEP-363856

SEP-363856 is a TAAR1 agonist with $5\text{-}HT_{1A}$ 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.

About Schizophrenia

Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects more than 23 million people worldwide[2] and approximately one in 100 adults (about 2.4 million people) in the United States.[3] 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 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 https://www.ds-pharma.com.

For a copy of this release, visit Sunovion's website at www.sunovion.com

References

[1] Koblan, K., Kent, J., Hopkins, S., Krystal, J., Cheng, H., Goldman, R., Loebel, A., "A non-D2 Binding Drug for the Treatment of Schizophrenia." *New England Journal of Medicine.* April 16, 2020, Vol. 382, Issue 16, p. 1497-1506. Available online: https://www.nejm.org/doi/full/10.1056/NEJMoa1911772. Accessed April 2020.
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