

NewsRelease

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Sunovion and PsychoGenics Initiate DIAMOND Phase 3 Clinical Studies for SEP-363856 in the Treatment of Adults and Adolescents with Schizophrenia

— First patient in the Global Phase 3 program enrolled —

— Approximately one in 100 adults and one in 1,000 adolescents in the United States are living with schizophrenia¹ —

Marlborough, Mass., and Paramus, N.J. , September 27, 2019 – [Sunovion Pharmaceuticals Inc.](#) (Sunovion) and [PsychoGenics Inc.](#) (PsychoGenics), today announced the initiation of the DIAMOND (Developing Innovative Approaches for Mental Disorders) Phase 3 studies for SEP-363856, a novel agent for the treatment of adults and adolescents with schizophrenia. The global, multicenter program includes four studies that are designed to evaluate the safety, efficacy and tolerability of SEP-363856. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) for SEP-363856 in May 2019.

SEP-363856 does not block dopamine 2 (D2) or serotonin 2A (5-HT2A) receptors in vivo, which are thought to mediate the effects of currently available antipsychotic medicines. Although the exact mechanism of action requires further elucidation, SEP-363856 is believed to activate TAAR1 (trace amine-associated receptor 1) in addition to 5-HT1A (serotonin 1A) receptors. More than 1,000 patients living with schizophrenia will be enrolled across the DIAMOND studies evaluating SEP-363856.

The four DIAMOND studies include:

- **DIAMOND 1:** A six-week, randomized, double-blind, parallel-group, placebo-controlled, fixed-dose, multicenter study to evaluate the efficacy and safety of SEP-363856 in acutely psychotic adults and adolescents (13 to 17 years of age) with schizophrenia [[NCT04072354](#)]
- **DIAMOND 2:** A six-week, randomized, double-blind, parallel-group, placebo-controlled, fixed-dose, multicenter study to evaluate the efficacy and safety of SEP-363856 in acutely psychotic adults with schizophrenia [[NCT04092686](#)]

- **DIAMOND 3:** A 52-week, outpatient, multicenter, flexible-dose, open-label long-term safety and tolerability extension study of SEP-363856 in adults and adolescents with schizophrenia who completed either the DIAMOND 1 or DIAMOND 2 study
- **DIAMOND 4:** A 52-week, randomized, double-blind, active comparator-controlled long-term safety and tolerability study of SEP-363856 in adults with schizophrenia

“Schizophrenia is a chronic, serious and often severely disabling brain disorder impacting more than 23 million people worldwide. The disorder can lead to hallucinations, delusions, social withdrawal and cognitive impairment, among other symptoms,” said Justine M. Kent, M.D., Head of Global Clinical Research, Psychiatry, at Sunovion. “We look forward to replicating our pivotal Phase 2 results and expanding beyond adults to include adolescents in our clinical program. Now, with Breakthrough Therapy Designation, our intention is to advance the SEP-363856 program forward as quickly as possible.”

About SEP-363856

SEP-363856 is an investigational psychotropic agent with a novel, non-D2 mechanism of action, distinct from currently marketed antipsychotics. 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 was optimized for antipsychotic activity by Sunovion medicinal chemists based on quantitative structure-activity relationship analysis, in collaboration with PsychoGenics. Clinical trial results to date demonstrate a predictable pharmacokinetic (PK) profile suitable for once daily use. SEP-363856 is jointly owned by Sunovion and PsychoGenics. Under the terms of the agreement, Sunovion assumed sole responsibility for global development and commercialization of SEP-363856. PsychoGenics is entitled to receive payments upon Sunovion’s achievement of certain development milestones for SEP-363856, as well as royalty payments for any sales of SEP-363856.

Results from the pivotal Phase 2 study, SEP361-201, showed that hospitalized adult 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. SEP-363856 was found to be generally well tolerated with notable similarities to placebo treatment in discontinuation rates; proportion of patients experiencing extrapyramidal symptoms or akathisia (restlessness); and change in metabolic parameters such as weight, lipids, glucose and prolactin.

SEP-363856 is being studied in a global development program for schizophrenia and 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.² Approximately one in 100 adults (about 2.4 million adults) and one in 1,000 adolescents (about 1 million adolescents) in the United States is living with schizophrenia.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 PGI Drug Discovery LLC and PsychoGenics Inc. (collectively PsychoGenics)

PsychoGenics Inc. and its discovery arm PGI Drug Discovery LLC (collectively known as PsychoGenics) have pioneered the translation of rodent behavioral and physiological responses into robust, high-throughput and high-content phenotyping. PsychoGenics' drug discovery platforms, SmartCube[®], NeuroCube[®] and PhenoCube[®], have been used in shared-risk partnerships with major pharmaceutical companies, resulting in the discovery of several novel compounds now in clinical trials or advanced preclinical development.

PsychoGenics' capabilities also include standard behavioral testing, electrophysiology, translational electroencephalogram (EEG), molecular biology, microdialysis and quantitative immunohistochemistry. In addition, the company offers a variety of in-licensed transgenic mouse models that support research in areas such as Huntington's disease, autism spectrum disorders, psychosis/schizophrenia, depression/ post-traumatic stress disorder (PTSD), Alzheimer's disease,

Parkinson's disease, muscular dystrophy, amyotrophic lateral sclerosis (ALS) and seizure disorders. For more information on PsychoGenics Inc., visit www.psychogenics.com.

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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² National Institute of Mental Health. Schizophrenia. [Internet]. Available from: <https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml>. Accessed September 2018.

³ Bo S, Haahr UH. Scand J Child Adolesc Psychiatr Psychol. 2016; 4(1):1-3.