Sunovion and Otsuka Initiate Clinical Development of Ulotaront for the Treatment of Generalized Anxiety Disorder

First Trial to Study a Trace Amine-Associated Receptor 1 (TAAR1) Agonist in Major Depressive Disorder (MDD)

PRINCETON, M.J. & MARLBOROUGH, MASS. – December 1, 2022 – Otsuka Pharmaceutical Development & Commercialization, Inc.(Otsuka) and Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the first patient has been enrolled in a Phase 2/3 clinical study to evaluate ulotaront (SEP-363856), a trace amine-associated receptor 1 (TAAR1) agonist with 5HT1A agonist activity, as an adjunctive therapy in the treatment of adults living with major depressive disorder (MDD). Ulotaront, which is also being evaluated in Phase 3 clinical development for the treatment of schizophrenia, is the first TAAR1 agonist to be studied as an adjunctive therapy in the treatment of MDD.

The global, multicenter, randomized, double-blind, placebo-controlled study is designed to examine the efficacy, safety and tolerability of ulotaront as an adjunctive therapy in the treatment of adults with MDD. Patients with an inadequate response to current antidepressant treatment will be randomized to receive ulotaront or placebo in addition to their antidepressant therapy.

The primary endpoint for the study is the reduction of depressive symptoms, as measured by the change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score, compared to placebo at the end of the study.

“MDD is a disabling mental health condition that often requires a combination of first-line antidepressant medication and adjunctive treatments to alleviate symptoms,” said John Kraus, M.D., Ph.D., executive vice president and chief medical officer at Otsuka. “Even with available approaches, many patients do not achieve optimal responses to treatment, in part due to the heterogeneous nature of the condition, highlighting the need for new and different treatment modalities.”

Depressive disorders, including MDD, affect roughly 280 million people worldwide.1 MDD is anticipated to rank first in global burden of disease by 2030.2

“The initiation of the Phase 2/3 study evaluating the use of ulotaront as an adjunctive treatment of major depressive disorder is an important step towards exploring the full medical potential of this novel TAAR1 agonist,” said Armin Szegedi, M.D., Ph.D., senior vice president, chief medical officer at Sunovion. “We have been encouraged by the pre-clinical data showing that ulotaront could have benefits for those living with mood disorder and look forward to enhancing the understanding of this innovative compound in collaboration with Otsuka.”

About Ulotaront (SEP-363856)

Ulotaront, a TAAR1 agonist with 5-HT1A agonist activity, is currently under investigation for the treatment of schizophrenia as well as the adjunctive treatment of MDD, with additional indications under consideration.

Ulotaront was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia in 2019. Ulotaront is the first TAAR1 agonist to enter into Phase 3 clinical studies in adults and adolescents (13 to 17 years) with schizophrenia. It’s also the first TAAR1 agonist to enter into a Phase 2/3 clinical study as an adjunctive therapy for MDD.

Ulotaront is being jointly developed and commercialized as part of a collaboration between Otsuka Pharmaceutical Co., Ltd, Sunovion, and its parent company Sumitomo Pharma Co., Ltd. Sunovion discovered ulotaront in collaboration with PsychoGenics based in part on a mechanism-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms.

About Major Depressive Disorder

Major depressive disorder is a chronic debilitating disease characterized by symptoms that last at least two weeks causing significant functional impairment. While symptoms of depression differ for each individual, some common symptoms may include a depressed mood that affects how a person thinks, feels and behaves, or a loss of interest in activities an individual once enjoyed.

About Otsuka

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: “Otsuka–people creating new products for better health worldwide.” Otsuka researches, develops, manufactures, and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging areas of mental, renal, and cardiovascular health and has additional research programs in oncology and on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a “big venture” company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka established a presence in the U.S. in 1973 and today its U.S. affiliates include Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) and Otsuka America Pharmaceutical, Inc. (OAPI). These two companies’ 2,000 employees in the U.S. develop and commercialize medicines in the areas of mental health, nephrology, and cardiology, using cutting-edge technology to address unmet healthcare needs.

OPDC and OAPI are indirect subsidiaries of Otsuka Pharmaceutical Company, Ltd., which is a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately USD 13.6 billion in 2021.

All Otsuka stories start by taking the road less traveled. Learn more about Otsuka in the U.S. at www.otsuka-us.com and connect with us on LinkedIn and Twitter at @OtsukaUS. Otsuka Pharmaceutical Co., Ltd.’s global website is accessible at www.otsuka.co.jp/en.

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 Pharma Co., Ltd. Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, is a wholly-owned direct subsidiary of Sunovion Pharmaceuticals Inc. Additional information can be found on the company’s websites: www.sunovion.com and www.sunovion.ca. Connect with Sunovion on Twitter, LinkedIn, Facebook and YouTube.

About Sumitomo Pharma Co., Ltd.

Sumitomo Pharma is among the top-10 listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries. Sumitomo 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. Today, Sumitomo Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Pharma is available through its corporate website at https://www.sumitomo-pharma.com.

For a copy of this release, visit Sunovion’s website at www.sunovion.com and Otsuka’s website at www.otsuka-us.com.

References:

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