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

–Approximately 7.5 Million People in The U.S. Are Living with Generalized Anxiety Disorder (GAD) 1,2

MARLBOROUGH, Mass. & PRINCETON, N.J., April 26, 2023 8:00 am (BUSINESS WIRE) — Sunovion Pharmaceuticals Inc. (Sunovion) and Otsuka Pharmaceutical Development & Commercialization, Inc. (Otsuka) today announced that the first patient has been randomized in a Phase 2/3 clinical study evaluating ulotaront, a trace amine-associated receptor 1 (TAAR1) agonist with 5-HT1A agonist activity, for the treatment of generalized anxiety disorder (GAD). In addition to GAD, ulotaront is being investigated in late-stage clinical studies for the treatment of schizophrenia and for the adjunctive treatment of major depressive disorder (MDD).

“Generalized anxiety disorder is a chronic condition characterized by excessive anxiety or worries, sleep disturbances, changes in appetite and impairment of social and occupational activities which can have a profound impact on nearly all aspects of an individual’s life,” said Armin Szegedi, M.D., Ph.D., Senior Vice President, Chief Medical Officer at Sunovion. “Preliminary data from preclinical and clinical studies of ulotaront suggest an anxiety-reducing effect, which we aim to understand further in patients with GAD. We believe that ulotaront is a potentially important novel mechanism and therapeutic advance for the treatment of GAD and other serious mental health conditions.”

The multicenter, randomized, double-blind, placebo-controlled, parallel-group, flexible-dose study will evaluate ulotaront’s efficacy and safety in people living with GAD. A total of 434 patients are expected to be randomized into two treatment groups, receiving either ulotaront (SEP-363856, 50–75 mg/day) or placebo in a 1:1 ratio for eight weeks. The primary endpoint is reduced anxiety symptoms, as measured by a change from baseline in the Hamilton Anxiety Rating Scale (HAM-A) total score, compared to placebo at Week 8.

“With the expansion of ulotaront’s clinical development program to a third indication, we are making significant progress towards goals we set for co-development and co-commercialization with Sunovion to address areas of high unmet need for people living with serious mental illnesses,” said John Kraus, M.D., Ph.D., Executive Vice President and Chief Medical Officer at Otsuka. “We believe that ulotaront has the potential to help those living with GAD safely and effectively manage their symptoms and we look forward to advancing the understanding of this innovative compound.”

About Ulotaront (SEP-363856)

Ulotaront, a TAAR1 agonist with 5-HT1A agonist activity, is currently under investigation for the treatment of schizophrenia, generalized anxiety disorder (GAD) and the adjunctive treatment of major depressive disorder (MDD) with additional indications under consideration.

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 Generalized Anxiety Disorder

An estimated 374 million people globally are impacted by anxiety disorders.[3] Generalized anxiety disorder (GAD)is a type of anxiety disorder characterized by excessive anxiety and worry about a variety of events or activities (e.g., work or school performance) that occurs more days than not, for at least six months.[4] People with GAD find it difficult to control their worry, feel restless or on edge, fatigued, have difficulty concentrating, feel irritable or have trouble falling or staying asleep.[5] GAD may cause impairment in social and occupational functioning, or other areas of daily life and may be brought on or exacerbated by stressful life events.5 Roughly 20 million people in the U.S. will experience GAD at some point in their lifetime.[6,7]

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 has charted new paths to life-transforming treatments

that reflect an ongoing commitment to research and development for people living with serious psychiatric and neurological 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.

As announced on April 3, Sunovion will combine with affiliate companies Sumitomo Pharma America Holdings, Inc., Sumitovant Biopharma, Inc., Myovant Sciences, Inc., Urovant Sciences, Inc., Enzyvant Therapeutics, Inc., and Sumitomo Pharma Oncology, Inc. to form Sumitomo Pharma America, Inc. effective July 1, 2023.

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.

About Otsuka Pharmaceutical Co., Ltd. (Otsuka)

Otsuka 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' 1,700 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 13.1 billion in 2022.

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/.

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

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Source: Sunovion Pharmaceuticals Inc.

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