Sunovion, Sumitomo Dainippon Pharma and Otsuka Enter Worldwide Development and Commercialization Collaboration

-Companies to advance four promising Sunovion compounds for people living with serious neuropsychiatric conditions-

---

MARLBOROUGH, Mass. & OSAKA, Japan & TOKYO, Japan--(BUSINESS WIRE) -- Sunovion Pharmaceuticals Inc. (Sunovion),its parent company Sumitomo Dainippon Pharma Co., Ltd. (Sumitomo Dainippon Pharma) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) announced today that the companies have entered into a worldwide license agreement for the joint development and commercialization of four compounds: ulotaront (SEP-363856), non-racemic ratio of amisulpride enantiomers (SEP-4199), SEP-378614 and SEP-380135.

Leveraging their complementary therapeutic area expertise and capabilities, the companies expect to fully explore the medical potential of the compounds in the collaboration, and accelerate development timelines, to bring forward important treatments for people living with neuropsychiatric health conditions worldwide. Otsuka's subsidiary, Otsuka Pharmaceutical Development & Commercialization, Inc., will jointly lead, together with Sunovion, the effort to advance the research and development program worldwide, as well as plan for future commercial activities.

"Sunovion, with our parent company Sumitomo Dainippon Pharma, is proud to collaborate with Otsuka in a shared mission to contribute towards improved lives and better health globally," said Antony Loebel, M.D., President and Chief Executive Officer of Sunovion. "Otsuka's recognition of the significant value of these assets reflects the innovative discovery and development efforts at Sunovion over the past decade, as well as our neuropsychiatry commercialization expertise and capabilities. We look forward to working with Otsuka colleagues as we advance novel compounds to treat patients with serious neuropsychiatric conditions."

"We are pleased to have signed this agreement with Otsuka, which has wide global reach and significant neuropsychiatry expertise. We will work together to more rapidly and reliably develop and commercialize valuable pharmaceuticals for patients around the world with the expectation that these new medications will grow," said Hiroshi Nomura, President and Chief Executive Officer of Sumitomo Dainippon Pharma. "Sumitomo Dainippon Pharma aims to achieve sustained growth through global collaboration in anticipation of future changes in the business environment. This collaboration is a major step forward in this initiative."

"Otsuka has been committed to providing new antipsychotics that contribute to patients worldwide in the field of neuropsychiatry by leveraging internal capabilities and external collaborations, starting with the launch of antipsychotics in the U.S. in 2002," said Makoto Inoue, President and Representative Director of Otsuka. "We are advancing in new areas such as the development of drugs to treat agitation associated with dementia of the Alzheimer's type and the deployment of the world's first digital medicine. Through this agreement, we are confident the companies will be able to deliver even more value to patients through the experience and networks that we have cultivated over many years worldwide."

This collaboration recognizes that there is a great need for novel treatments in the area of neuropsychiatric medicine development. The companies are focused on working together on solutions to address these areas of unmet medical need by advancing four promising compounds—ulotaront (SEP-363856), SEP-4199, SEP-378614 and SEP-380135—that address serious neuropsychiatric disorders. The goal of the co-development programs is to contribute to changing the course of serious medical conditions and provide new treatment options to patients and healthcare providers globally.

Upon the completion of the agreement, in addition to an upfront payment of USD 270 million, Sunovion is eligible for development milestone payments of up to USD 620 million for the four compounds and relevant sales milestone payments. Sunovion and Otsuka will share profits from the four compounds, as well as all expenses for clinical studies, applications for approval, and commercialization in each country. Additional details regarding terms of the agreement are not being disclosed.

About Sunovion Compounds

The four clinical-stage assets—ulotaront (SEP-363856), non-racemic ratio of amisulpride enantiomers (SEP-4199), SEP-378614 and SEP-380135—included within the collaboration span early- to late-stage development.

The compounds represent a scientifically unique approach to treating symptoms that are not adequately addressed by current therapeutic options and/or for which existing treatments have an unsatisfactory safety and tolerability profile.

Ulotaront (SEP-363856), in Phase 3, is a trace amine-associated receptor 1 (TAAR1) agonist with 5-HT1A agonist activity that is under investigation for the treatment of schizophrenia 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. Ulotaront is the first TAAR1 agonist to enter into Phase 3 clinical studies in adults and adolescents (13 to 17 years) with schizophrenia.

Non-racemic amisulpride (SEP-4199) is in Phase 3 clinical development for the treatment of major depressive episodes associated with bipolar I disorder (bipolar depression). Sunovion discovered that the pharmacology of amisulpride is enantiomer-specific and increasing the ratio of R-amisulpride to S-amisulpride increases the potency for serotonin 5-HT7 receptors relative to dopamine D2 receptors. SEP-4199 was designed with an 85:15 ratio of R-amisulpride to S-amisulpride to increase levels of serotonin 5-HT7 activity intended to enhance antidepressant efficacy and produce reduced levels of D2 receptor occupancy appropriate for the treatment of bipolar depression. In September 2021 Sunovion initiated a global clinical Phase 3 study, which is a randomized, double-blind, placebo-controlled, parallel-group, fixed-dosed study for the treatment of bipolar I depression in the U.S. Japan will join this global clinical Phase 3 study.

SEP-378614 and SEP-380135 are in Phase 1 development and can be viewed on the Sunovion pipeline here.

Sunovion discovered ulotaront, SEP-378614, and SEP-380135 in collaboration with PsychoGenics based in part on a mechanism-independent approach using the in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms.

Sunovion has a robust portfolio of clinical and pre-clinical compounds, not included in this agreement, which the company continues to advance for some of the most prevalent, challenging, and underserved neuropsychiatric conditions.

About Neuropsychiatric Disorders

Neuropsychiatric disorders are among the most complex and difficult to treat. Disorders of the brain are often associated with significant and disabling effects on patients, impacting their loved ones and society more broadly. Nearly one in six people worldwide live with a neurological disorder,1 29 million people worldwide are living with bipolar disorder,2 and 20 million people worldwide are living with schizophrenia.3

About 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 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 Dainippon Pharma

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 other Asian countries. 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 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.

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.

SUNOVION is a registered trademark of Sumitomo Dainippon Pharma Co., Ltd.

Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

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

References

1 World Health Organization (WHO) Neurological Disorders: Public Health Challenges 2006. [Internet] Available from: https://www.who.int/mental_health/neurology/neurological_disorders_report_web.pdf. Accessed February 2021.
2 World Health Organization. Global Burden of Disease, 2004 Report. [Internet] Available from: http://www.who.int. Accessed March 29, 2013 (To Access: Health Topics, Global Burden of Disease, The Global Burden of Disease: 2004 Update).
3 World Health Organization. Mental Disorders. [Internet]. Available from: https://www.who.int/news-room/fact-sheets/detail/mental-disorders. Accessed April 2021.

Amy Ryan

Vice President, Corporate Communications
Sunovion Pharmaceuticals Inc.
amy.ryan@sunovion.com
+ 1 617-821-8389

Corporate Communications
Sumitomo Dainippon Pharma Co., Ltd.
+81 6-6203-1407 (Osaka); +81 3-5159-3300 (Tokyo)

Otsuka in Japan
Jeffrey Gilbert (Outside the US)
Leader, Pharmaceutical PR
Otsuka Pharmaceutical Co., Ltd.
gilbert.jeffrey@otsuka.co.jp
+81 3 6361 7379

Source: Sunovion Pharmaceuticals Inc.

---

https://news.us.sumitomo-pharma.com/2021-09-30-Sunovion,-Sumitomo-Dainippon-Pharma-and-Otsuka-Enter-Worldwide-Development-and-Commercialization-Collaboration