Sumitomo Pharma Enters into an Agreement to Amend the Worldwide Collaboration and License Agreement for Four Psychiatry and Neurology Compounds Including Ulotaront with Otsuka

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Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura; Securities Code: 4506, Prime Market of TSE) and its U.S.-based subsidiary Sumitomo Pharma America, Inc. (“SMPA”) announced today that they have agreed to amend the collaboration and license agreement for the worldwide joint development and commercialization of the four investigational candidate compounds, including ulotaront, under development in the psychiatry and neurology area, initially concluded between Sumitomo Pharma, SMPA, and Otsuka Pharmaceutical Co., Ltd. (Head Office: Tokyo, Japan; President and Representative Director: Makoto Inoue; “Otsuka”) on September 30, 2021 (“this Amendment Agreement”).

1. Main Content of this Amendment Agreement

- SEP-4199 and SEP-378614, two of the four compounds covered by the collaboration and license agreement, will not be included in this Amendment Agreement, and SMPA grants Otsuka the exclusive worldwide rights to develop, manufacture, and commercialize ulotaront and SEP-380135 for all indications.
- SMPA may receive up to USD 30 million (approximately JPY 4.5 billion) in development milestone payments associated with the progress of development for ulotaront and SEP-380135 and royalties based on revenue from Otsuka.
- There is no upfront payment for this Amendment Agreement. With the exception of certain studies, Otsuka will fully cover expenses of ongoing studies conducted by the Sumitomo Pharma Group and Otsuka after January 2024.

The Sumitomo Pharma Group is currently evaluating the further development strategy for SEP-4199 and SEP-378614.

2. Purposes of this Amendment Agreement

Sumitomo Pharma and SMPA have been collaborating with Otsuka to develop novel candidate compounds, including ulotaront, in psychiatry and neurology as priority disease area. However, with the current status it will be challenging to generate revenue from these compounds in the Mid-term Business Plan 2027 (FY2023-FY2027). Taking this into consideration, the Sumitomo Pharma Group has reviewed its priority products for development and decided to focus on development programs in the oncology area and regenerative medicine/cell therapy business that are expected to be launched during the Mid-term Business Plan 2027. Therefore, the Sumitomo Pharma Group has handed over the development of ulotaront and SEP-380135 described above to Otsuka.

3. Financial impact on business performance

The impact of this Amendment Agreement on Sumitomo Pharma’s consolidated financial results for the year ending March 31, 2024 will be minimal.

*The following press releases have been issued in relation to this Amendment Agreement.

- Sumitomo Dainippon Pharma and Otsuka Announce a Worldwide Collaboration and License Agreement for Four Psychiatry and Neurology Compounds (September 30, 2021 https://www.sumitomo-pharma.com/news/assets/pdf/ene20210930.pdf
- Sumitomo Pharma and Otsuka Announce Topline Results from Phase 3 DIAMOND 1 and DIAMOND 2 Clinical Studies Evaluating Ulotaront in Schizophrenia (July 31, 2023) https://www.sumitomo-pharma.com/news/assets/pdf/ene20230731.1.pdf

Reference

About ulotaront
Ulotaront is a trace amine-associated receptor 1 (TAAR1) agonist with 5-HT_{1A} agonist activity. Ulotaront is

currently under development for the treatment of schizophrenia, the adjunctive treatment of major depressive disorder (MDD), and generalized anxiety disorder (GAD).

Ulotaront was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia in May 2019. Ulotaront is the first and only TAAR1 agonist to enter into Phase 3 studies in people living with schizophrenia.

It’s also the first TAAR1 agonist to enter into Phase 2/3 clinical studies in GAD, and as an adjunctive treatment in MDD.

SMPA 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 SEP-380135
SEP-380135, jointly developed by SMPA and PsychoGenics, is a small-molecule oral agent in Phase 1 studies in the U.S. that acts on the central nervous system. SMPA discovered SEP-380135 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms. Pre-clinical studies showed a broad range of in vivo activities suggesting efficacy against a number of behavioral and psychological symptoms in dementia, including agitation/aggression, psychomotor hyperactivity and depression.

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https://news.us.sumitomo-pharma.com/2024-03-15-Sumitomo-Pharma-Enters-into-an-Agreement-to-Amend-the-Worldwide-Collaboration-and-License-Agreement-for-Four-Psychiatry-and-Neurology-Compounds-Including-Ulotaront-with-Otsuka