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Otsuka and Sumitomo Revise License Agreement

- Otsuka holds exclusive rights to develop, manufacture, and commercialize ulotaront and SEP-380135 worldwide -

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces the revision of the license agreement signed in September 2021 with Sumitomo Pharma Co., Ltd. (Sumitomo Pharma) and its U.S. subsidiary, Sumitomo Pharma America, Inc. (SMPA).

Otsuka originally entered into a licensing agreement with Sumitomo Pharma and SMPA for worldwide joint development and commercialization of four novel candidate compounds under development in the psychiatric and neurology area, namely SEP-363856 (hereinafter ulotaront), SEP-4199, SEP-378614, and SEP-380135. Following revision of the license agreement, Otsuka holds exclusive rights to develop, manufacture, and commercialize ulotaront and SEP-380135 worldwide.

Abstracts from the Revised Agreement:

- Of the four compounds that were under the original licensing agreement, SEP-4199 and SEP-378614 have been excluded through the revision. Otsuka has obtained from SMPA exclusive rights to develop, manufacture, and commercialize ulotaront and SEP-380135 for all indications worldwide.
- Should Otsuka succeed in the development and commercialization of ulotaront and SEP-380135, Otsuka will pay up to a total of 30 million US dollars (approximately 4.5 billion yen) as milestones for both compounds, as well as royalties based on sales.
- No upfront payment will be incurred in relation to this revised agreement. Except for certain studies, Otsuka will bear the full cost of the studies being conducted by both Sumitomo Pharma Group and Otsuka from January 2024.

Ulotaront is a small-molecule oral drug that is a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity, and does not bind to dopamine D_2 or serotonin 5-HT_{2A} receptors. FDA expressed relatively positive feedback about the results of two clinical trials targeting schizophrenia. As a result of comprehensively examining the current status of the ongoing phase 2/3 trials targeting adjunctive treatment for major depressive disorder (aMDD) and generalized anxiety disorder (GAD), as well as marketability, Otsuka determined that ulotaront still has high potential and decided to continue its development.

It has been hypothesized based on non-clinical studies that SEP-380135 may be effective against behavioral and psychological symptoms associated with dementia, such as agitation, aggression, psychomotor hyperactivity, and depression. Phase 1 trials are being conducted in the United States.

Otsuka will continue to develop ulotaront and SEP-380135 and aims to provide new drugs that contribute to people around the world suffering from mental disorders.

Reference press releases:
(September 30, 2021) Sumitomo Dainippon Pharma and Otsuka Announce a Worldwide Collaboration and License Agreement for Four Psychiatry and Neurology Compounds
https://www.otsuka.co.jp/en/company/newsreleases/2021/20210930_1.html

(July 31, 2023) Sumitomo Pharma and Otsuka Announce Topline Results from Phase 3 DIAMOND 1 and DIAMOND 2 Clinical Studies Evaluating Ulotaront in Schizophrenia
https://www.otsuka.co.jp/en/company/newsreleases/2023/20230731_1.html