

Announcement of Application for Manufacturing and Marketing Approval of Insomnia Treatment Daridorexant in Japan

This material is an English translation of the press release to be issued on October 31, 2023 in Japanese, and the Japanese release is given priority regarding content and interpretation.

October 31, 2023

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; President: Naoyuki Mochida, hereinafter “Mochida”) and Idorsia Pharmaceuticals Japan Co., Ltd. (Head Office: Minato-ku, Tokyo; President: Satoshi Tanaka, hereinafter “Idorsia Japan”), a subsidiary of SOSEI Group Corporation, have been jointly developing the insomnia treatment drug, daridorexant (development code: ACT-541468; generic name: daridorexant hydrochloride), and today, Idorsia Japan submitted an application for its manufacturing and marketing approval to the Ministry of Health, Labour and Welfare.

Daridorexant is an oral insomnia treatment drug that selectively inhibits bindings of the neuronal peptide (orexin) that promotes wakefulness to the receptors (OX1R and OX2R) and is expected to exert its effects by suppressing excessive wakefulness and transitioning into a sleep state. It is a dual orexin receptor antagonist (DORA). The application for manufacturing and marketing approval was made based on the results examining effectiveness and safety obtained in Phase III clinical trials targeting insomnia patients in Japan.

Daridorexant was approved in the US and Europe in January and April 2022, respectively, and is marketed by Idorsia Pharmaceuticals Ltd. (Head Office: Allschwil, Switzerland; CEO: Jean-Paul Clozel) in these and other approved territories as QUVIVIQ™. For Japan, in December 2019, Mochida and Idorsia Pharmaceuticals Ltd. signed an exclusive license agreement for the supply, co-development, and co-marketing of daridorexant for insomnia (including related diseases), and under this agreement, Mochida and Idorsia Japan have been jointly developing it. After receiving manufacturing and marketing approval, Idorsia Japan and Mochida will jointly sell it in Japan.

It is estimated that approximately 20% of adults do not get enough rest through sleep according to the National Health and Nutrition Survey conducted by the Ministry of Health, Labor and Welfare in 2018. By expanding treatment options with daridorexant, we hope to contribute further to improving the quality of life of patients.