



Announcement of the Sales Partnership Agreement in Japan between Shionogi and Mochida regarding Insomnia Treatment Drug Daridorexant

OSAKA, Japan, November 1, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; President: Naoyuki Mochida, hereafter "Mochida") wish to announce that they have entered into a sales partnership agreement (hereafter "Sales Partnership Agreement") for the insomnia treatment drug, daridorexant (development code: ACT-541468, generic name: daridorexant hydrochloride) in Japan.

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). 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™.

In Japan, 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 it. 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 Japan¹. After receiving manufacturing and marketing approval, Idorsia Japan and Mochida will jointly sell it in Japan. In addition, Shionogi will work with Mochida to sell the drug based on this Sales Partnership Agreement.

Shionogi and Mochida aim to expand treatment options for insomnia with this partnership and meet the needs of patients and medical professionals.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: <https://www.shionogi.com/global/en/contact.html>

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References

1. Press release on October 31, 2023 by Mochida
<https://www.mochida.co.jp/english/news/docs/2023/231031.pdf>