



Regarding the Conclusion of Sales Partnership Agreement with Nxera Pharma Japan for the Insomnia Treatment “QUVIVIQ®”

OSAKA, Japan, October 1, 2024 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced the conclusion of a sales partnership agreement with Nxera Pharma Japan Co., Ltd. (hereafter "Nxera Pharma Japan"), a group company of Nxera Pharma Co., Ltd. (Head office: Tokyo, Chief Executive Officer: Christopher Cargill), for the insomnia treatment "QUVIVIQ® Tablets" 25mg and 50mg (daridorexant, hereafter "QUVIVIQ®"). NXERA Pharma Japan has obtained the manufacturing and marketing approval in Japan for QUVIVIQ® as a treatment for adult patients with insomnia, as of September 24, 2024.

QUVIVIQ® is an oral insomnia treatment that selectively binds to the receptors (OX1R and OX2R) for the wake-promoting neuropeptide orexin, inhibiting excessive wakefulness and facilitating the transition to sleep. In Japan, Nxera Pharma Japan and Mochida Pharmaceutical Co., Ltd. (Head Office: Tokyo, Japan; President: Naoyuki Mochida, hereafter "Mochida") jointly conducted a domestic Phase III clinical trial, and based on the clinical efficacy and safety data obtained, they have obtained the manufacturing and marketing approval of QUVIVIQ®.

Shionogi has acquired the exclusive distribution rights for QUVIVIQ® in Japan through this sales partnership agreement with Nxera Pharma Japan. In conjunction with the agreement, Shionogi will pay an upfront fee and royalties to Nxera Pharma Japan. The existing sales partnership agreement with Mochida has been terminated, and Shionogi will now independently handle distribution and sales activities in Japan. In conjunction with this, Shionogi will pay an upfront fee to Mochida. Nxera Pharma Japan will become the manufacturing and marketing authorization holder and will be responsible for part of the product supply, while Mochida's subsidiary, Mochida Pharmaceutical Plant Co., Ltd., will handle exclusively finished product manufacturing.

Shionogi has identified Contributing to a Healthy and Prosperous Life as a material focus. We are committed to creating a society where everyone can lead a longer, more vibrant life, realizing their goals. We will continue to make efforts to deliver QUVIVIQ® to patients suffering from insomnia as soon as possible.

References

1. [Press release on September 24, 2024 by Nxera Pharma](#)
2. [Press release on November 1, 2023](#)
3. [Press release on October 31, 2023 by Mochida](#)

【About QUVIVIQ®】

QUVIVIQ® (generic name: daridorexant) is a Dual Orexin Receptor Antagonist (DORA) that works by inhibiting the binding and activity of a wake-promoting neuropeptide called orexin. In October 2022, it achieved favorable top-line results in a domestic Phase III clinical trial for insomnia patients in Japan, and a new drug application was submitted in Japan in October 2023. QUVIVIQ® is approved in the United States and Europe and is sold by Idorsia Ltd under the brand name QUVIVIQ™, including other approved regions.

【About Nxera Pharma】

Nxera Pharma (formerly Sosei Heptares) is a technology powered biopharma company, in pursuit of new specialty medicines to improve the lives of patients with unmet needs in Japan and globally. In addition to several products being commercialized in Japan, we are advancing an extensive pipeline of over 30 active programs from discovery through to late clinical stage internally and in partnership with leading pharma and biotech companies. This pipeline is focused on addressing major unmet needs in some of the fastest-growing areas of medicine across neurology, GI and immunology, metabolic disorders and rare diseases, and leverages the power of our unique and industry leading GPCR-targeted structure-based drug discovery “NxWave™” platform to provide a sustainable source of best- or first-in-class candidates. For more details, please see [here](#).

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>