

# PRESSRELEASE



## SHIONOGI and Nxera Pharma Launch QUVIVIQ™ in Japan for Adults with Insomnia

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**OSAKA, Japan, December 19, 2024** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") and Nxera Pharma Co., Ltd. (Head office: Tokyo, Chief Executive Officer: Christopher Cargill, hereafter "Nxera Pharma") announced that QUVIVIQ™ (daridorexant) 25 and 50 mg has been launched and is now available in Japan as a new treatment for adults with insomnia.

QUVIVIQ™ is an oral Dual Orexin Receptor Antagonist for the treatment of insomnia that selectively binds to receptors of the wake-promoting neuropeptide orexin (OX1R and OX2R), inhibiting excessive wakefulness and facilitating the transition to sleep.

Shionogi will be solely responsible for distribution and sales activities for QUVIVIQ™ in Japan under the commercial partnership agreement with Nxera Pharma announced on 1 October 2024. Nxera Pharma Japan Co., Ltd. (a wholly owned subsidiary of Nxera Pharma) is the approval holder and will be responsible in part for provision of drug product<sup>1,2</sup>.

For Nxera, reaching this important milestone highlights its ability to develop novel therapeutics for patients in Japan and reinforces its ambition to be a partner of choice for companies looking to develop and commercialize new therapeutics for the Japanese market.

As a new pillar, Shionogi is focusing on the 'QOL disease area,' which is less affected by trends. Starting with the launch of QUVIVIQ™, we are working to strengthen the 'QOL disease area' as a solid pillar

Together, Nxera and Shionogi are committed to deliver QUVIVIQ™ as quickly as possible as a product that has the potential to meet the needs of insomnia patients for a long time to come.

### References

1: [Press release on October 1, 2024 by Shionogi](#)

2: [Press release on October 1, 2024 by Nxera Pharma](#)

Product Information	
Product name	QUVIVIQ™ 25 mg, 50 mg
Non-proprietary name	daridorexant
Indication	Insomnia
Dosage regimen	The usual adult dosage is 50 mg of daridorexant to be taken orally once daily immediately before bedtime. In addition, depending on the patient's condition, 25 mg can be administered once daily.
Date of approval	24 September 2024
Date of NHI price listing	20 November 2024
Date of launch	19 December 2024
Drug price	JPY57.30 per 25 mg tablet JPY90.80 per 50 mg tablet
Approval holder	Nxera Pharma Japan Co., Ltd.
Distributor	Shionogi & Co., Ltd.

### About QUVIVIQ™

QUVIVIQ™ (daridorexant) is a dual orexin receptor antagonist, discovered by Idorsia Pharmaceuticals Ltd, that blocks the binding and activity of the wake-promoting neuropeptides known as orexins. In October 2022, daridorexant achieved positive Phase 3 top-line results in Japanese patients with insomnia and 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\*. Daridorexant is approved in the US, Europe and Canada, and marketed in these territories under the brand name QUVIVIQ™ by Idorsia Pharmaceuticals Ltd.

\* [Press release on September 24, 2024 by Nxera Pharma](#)

### About Insomnia Disorder

Insomnia disorder is defined as difficulty initiating or maintaining sleep, causing clinically significant distress or impairment in important areas of daytime functioning. As defined this impact on sleep quantity or quality should be present for at least three nights per week, lasts for at least three months, and occurs despite an adequate opportunity to sleep.

Insomnia is a condition of overactive wake signaling and studies have shown that areas of the brain associated with wakefulness remain more active during sleep in patients with insomnia. According to a survey by Japan's Ministry of Health, Labour and Welfare in 2018, about 20% of Japanese adults struggle to get enough rest from sleep.

Insomnia as a disorder is quite different from a brief period of poor sleep, and it can take its toll on both physical and mental health. It is a persistent condition with a negative impact on daytime functioning. Research has shown that poor quality sleep can affect many aspects of daily life, including the ability to concentrate, mood, and energy levels.

The goal of treatments for insomnia is to improve sleep quality and quantity, as well as daytime functioning, while avoiding adverse events and next-morning residual effects. Current recommended treatment of insomnia includes sleep hygiene therapy, cognitive behavioral therapy, and pharmacotherapy.

**About Shionogi**

Shionogi strives constantly to supply the best possible medicine (healthcare solutions) to protect the health and wellbeing of the patients we serve, and as a united group. We have 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.

For more information, please visit <https://www.shionogi.com/global/en/>

**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. For more information, please visit [www.nxera.life](http://www.nxera.life)

**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.htm>

Nxera Pharma Website Inquiry Form: <https://www.nxera.life/contact>