

Nxera Pharma's QUVIVIQ[®] (daridorexant) 25mg and 50mg Receives Approval in Taiwan for the Treatment of Insomnia

- Nxera's partner Holling Bio-Pharma Corp. will commercialize QUVIVIQ[®] in Taiwan, a market with approximately 4–5 million patients, with launch planned during 2026
- QUVIVIQ[®] is approved through Taiwan's Streamlined Review Designation pathway

Tokyo, Japan and Cambridge, UK, 14 April 2026 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) announces that its partner Holling Bio-Pharma Corp. ("Holling"), a leading pharmaceutical distribution and commercialization company based in Taipei, Taiwan, has received approval from the Taiwan Food and Drug Administration ("TFDA") to market and sell QUVIVIQ[®] (daridorexant, marketed in Taiwan under the product name 科唯可[®] film-coated tablets) 25 and 50 mg for the treatment of adults with insomnia. Plans are underway to launch QUVIVIQ[®] in Taiwan during 2026.

Under the terms of the agreement with Holling, Nxera is responsible for the supply of drug product and Holling is responsible for regulatory, commercial and distribution activities. Under this agreement, Nxera will receive a milestone payment upon this approval, the amount of which is undisclosed. Nxera is also eligible for near-term sales milestones plus royalties on net sales from Holling, as well as revenue on the supply of drug product to Holling.

QUVIVIQ[®] is approved by the TFDA under its Streamlined Review Designation (SRD), using the Japanese marketing authorization application dossier. The designation mechanism is designed to expedite the TFDA's review of new chemical entities approved by major overseas regulatory authorities by making use of existing review outcomes and, subject to certain conditions, allowing for a shortened review period in Taiwan.

Insomnia, characterized by difficulties in sleep onset and/or sleep maintenance, impacts both physical and mental health. According to Taiwan's National Health Research Institutes, sleep disorders such as insomnia affected 12-20% of the adult population in 2021, approximately 4-5 million people.

Daridorexant is approved and marketed in Japan as QUVIVIQ[®] under a commercialization agreement between Nxera and Shionogi. In South Korea, Nxera submitted a marketing authorization application for daridorexant to the Ministry of Food and Drug Safety (MFDS) in March 2026. QUVIVIQ[®], discovered by Idorsia Pharmaceuticals, is marketed by Idorsia in the US, Canada, and multiple European countries.

Christopher Cargill, President and CEO of Nxera Pharma, commented: "The approval of QUVIVIQ[®] in Taiwan marks an important milestone in our strategy to expand access to innovative specialty medicines in Japan and across the APAC region. Insomnia remains a significant and under-recognised health burden, impacting both nighttime sleep and daytime functioning for millions of patients. With QUVIVIQ[®], a dual orexin receptor antagonist with a differentiated mechanism of action, we are pleased to bring a new

treatment option to patients in Taiwan. We look forward to working closely with our partner Holling to ensure a successful launch and broad access following this approval.”

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Notes to Editors

About Holling Bio-Pharma Corp.

Headquartered in Taipei, Taiwan, Holling Bio-Pharma has been established for nearly five decades and is now the largest pharmaceutical distributor in Taiwan. Over the years, Holling Bio-Pharma primarily work with companies with innovate products and has continuously introduced the latest therapeutic drugs ranging from small molecule drugs and biologics to vaccines to help patients in Taiwan combat various diseases. With a fully equipped and professional team, Holling Bio-Pharma offers comprehensive services including drug registration, market access, product promotion, warehousing, and logistics. Holling Bio-Pharma also has extensive experience and expertise in the CNS field, with successful launch of innovative CNS products from both EU and US. The company is committed to delivering high-quality services that meet international standards, ensuring the latest medical innovations reach patients efficiently and effectively.

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 Taiwan’s National Health Research Institutes, sleep disorders such as insomnia affected 12-20% of the adult population in 2021, approximately 4-5 million people.

The 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 the Orexin system

Wake and sleep signaling is regulated by intricate neural circuitry in the brain. One key component of this process is the orexin system, which helps promote wakefulness. There are two forms of orexin neuropeptides – small protein-like molecules used by nerve cells (neurons) to communicate with each other in the brain – orexin A and orexin B. Orexin promotes wakefulness through its receptors OX1R and OX2R. Together, these neuropeptides and receptors make up the orexin system. The orexin system stimulates targeted neurons in the wake system – leading to the release of several chemicals (serotonin, histamine, acetylcholine, norepinephrine) – to promote wakefulness. Orexin regulates wake signaling, which might be overactive at night, preventing people with insomnia from falling asleep or staying asleep. Daridorexant is a dual orexin receptor antagonist (DORA) that equipotently antagonizes orexin receptors 1 and 2, consequently decreasing overactive wake signals throughout the entire night.

About Nxera Pharma

Nxera Pharma 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. The Company has built an agile, new-generation commercial business in Japan to develop and commercialize innovative medicines, including several launched products, to address this high-value, large and growing market and those in the broader APAC region. In addition, the Company is advancing an extensive pipeline internally and in partnership with leading pharma and biotech companies, powered by its unique NxWave™ GPCR structure-based drug discovery platform. Nxera Pharma operates at key locations in Tokyo and Osaka (Japan), London and Cambridge (UK), Basel (Switzerland) and Seoul (South Korea) and is listed on the Tokyo Stock Exchange (ticker: 4565).

For more information, please visit www.nxera.life

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QUVIVIQ® is trademark of Idorsia Pharmaceuticals Ltd.

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Forward-looking statements

This press release contains forward-looking statements, including statements about the discovery, development, and commercialization of products. Various risks may cause Nxera Pharma Group's actual results to differ materially from those expressed or implied by the forward looking statements, including: adverse results in clinical development programs; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialize products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialization activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.