Nxera Pharma Submits Marketing Authorization Application for Daridorexant in South Korea

- Daridorexant is a dual orexin receptor antagonist being developed in South Korea by Nxera for the treatment of adult patients with insomnia and is approved and marketed in Japan as QUVIVIQ®

- Phase 3 trial of daridorexant in South Korea met both primary and secondary efficacy endpoints of subjective total sleep time (sTST), subjective latency to sleep onset (sLSO) and subjective wake after sleep onset (sWASO)

Tokyo, Japan and Cambridge, UK, 4 March 2026 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) announces that it has submitted a marketing authorisation application (MAA) to the Ministry of Food and Drug Safety (MFDS) in South Korea for daridorexant, a dual orexin receptor antagonist, for the treatment of adult patients with insomnia. This submission follows positive data from the Phase 3 trial of daridorexant in South Korea which met both primary and secondary efficacy endpoints(Link).

Insomnia, characterized by difficulties in sleep onset and/or sleep maintenance, impacts both physical and mental health. The condition is highly prevalent in South Korea, affecting 15-25% of the adult population, or approximately 6.5-11 million people[1,2].

Mr. MinBok Lee, President and Representative Director of Nxera Pharma Korea, commented: "This submission represents a key milestone in our efforts to expand access to daridorexant in South Korea. With the medicine already approved and marketed in Japan, we look forward to sharing further progress as it advances through the regulatory review process in South Korea towards anticipated approval in 2027."

Daridorexant is approved and marketed in Japan as QUVIVIQ® under a commercialization agreement between Nxera and Shionogi. QUVIVIQ®, discovered by Idorsia Pharmaceuticals, is marketed by Idorsia in the US, Canada, and multiple European countries, and marketed by Simcere in China and Hong Kong.

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Notes to Editors

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. 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.

According to multiple epidemiological studies, insomnia affects around 15% to 25% of the adult population in South Korea, or approximately 6.5-11 million people[1,2]. The condition is notably more prevalent among women and older adults. Recent data from Korea's Health Insurance Review and Assessment Service (HIRA) revealed that the number of chronic insomnia patients treated has increased by 21% from 597,529 in 2018 to 722,440 in 2022. Of these patients, 50% are aged 60 or above, and 61% are women.

[1]Epidemiology of Insomnia in Korean Adults: Prevalence and Associated Factors (Print ISSN 1738-6586 / On-line ISSN 2005-5013)
[2]The Prevalence and Incidence of Insomnia in Korea during 2005 to 2013 / Print ISSN 1738-3684 / On-line ISSN 1976-3026)

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 the Phase 3 study
The Phase 3 trial was a multicenter, randomized, double-blind, placebo-controlled, parallel-group trial designed to evaluate the efficacy and safety of daridorexant in adult and elderly patients with insomnia. Patients were randomized to receive daridorexant 50 mg or placebo once daily for 28 days.

The study met both its primary and secondary efficacy endpoints. At Day 28, daridorexant significantly improved the primary efficacy endpoint, the change from baseline in subjective total sleep time (sTST), compared with placebo ($p<0.0001$ for the 50 mg dose). Daridorexant also significantly improved the secondary efficacy endpoints, the change from baseline at Day 28 in subjective latency to sleep onset (sLSO) and subjective wake after sleep onset(sWASO), compared with placebo (both $p<0.0001$ for the 50 mg dose). The incidence of adverse events was comparable between the daridorexant and placebo treatment groups. The rate of treatment-emergent adverse events (TEAEs) during the double-blind treatment period was comparable between placebo and daridorexant, reported in 13.41% of patients treated with daridorexant 50 mg and 14.81% for placebo.

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, and powered by its unique NxWave™ GPCR structure-based drug discovery platform, the Company is advancing an extensive pipeline internally and in partnership with leading pharma and biotech companies. 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
LinkedIn: @NxeraPharma | X: @NxeraPharma | YouTube: @NxeraPharma

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Enquiries

Media and Investor Relations
Shinya Tsuzuki, VP, Head of Investor Relations
Maya Bennison, Communications Manager
+81 (0)3 5962 5718 | +44 (0)1223 949390 |IR@Nxera.life

MEDiSTRAVA (for International Media)
Mark Swallow, Frazer Hall, Erica Hollingsworth
+44 (0)203 928 6900 | Nxera@medistrava.com

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.