Nxera Pharma Enrols First Insomnia Patient in its Phase 3 Clinical Trial of Daridorexant in South Korea

- Daridorexant is a dual orexin receptor antagonist being developed by Nxera for the treatment of adult patients with insomnia

- QUVIVIQ™ (daridorexant) 25 and 50 mg was recently approved and is expected to launch in Japan in Q4 2024

Tokyo, Japan and Cambridge, UK, 5 December 2024 – Nxera Pharma Co., Ltd. ("Nxera" or "the Company"; TSE 4565) – formerly known as Sosei Group or Sosei Heptares – today announces randomization of the first patient in a Phase 3 clinical trial evaluating daridorexant, its novel dual orexin receptor antagonist, for the treatment of adult patients in South Korea with insomnia.

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.

The randomized, double-blind, placebo-controlled Phase 3 study aims to recruit adult and elderly subjects with insomnia at multiple centers in South Korea. The purpose of the trial is to provide additional efficacy and safety data, alongside the substantial data already generated in earlier trials completed in North America, Europe and Japan, that are required by the Ministry of Food and Drug Safety (MFDS) to grant marketing authorization for the drug in South Korea. The trial is expected to run for approximately 12 months with results expected during 1H 2026.

Daridorexant 25mg and 50mg was approved in Japan in September 2024 based on robust clinical efficacy and safety data, including from a Phase 3 trial in Japan that met all primary and secondary endpoints. Nxera owns the Japanese and APAC (ex-China) rights for daridorexant, which will be marketed in Japan as QUVIVIQ™ under a commercialization agreement between Nxera and Shionogi. QUVIVIQ™ is expected to be launched in Japan in Q4 2024. QUVIVIQ™ is also approved in the US, Europe and certain other countries where it is marketed by Idorsia Pharmaceuticals.

Mr. MinBok Lee, President and Representative Director of Nxera Pharma Korea, commented: "Insomnia is highly prevalent in South Korea and is associated with several significant comorbidities, underscoring the point that this disorder is more than just a lack of sleep; it is a serious health concern that impacts the daily life of millions of people. Following the approvals of QUVIVIQ™ in various markets, including the US, Europe and most recently, Japan, we are committed to conducting this new trial and providing the additional data necessary to make this drug available to the many insomnia patients in South Korea."

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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. Under normal circumstances, orexin levels rise throughout the day as wakefulness is promoted and then fall at night. Overactivity of the wake system is an important driver of insomnia.

About the South Korea Phase 3 Trial
The trial is entitled "A randomized, double-blind, multi-center, placebo-controlled, parallel, Phase 3 study to evaluate the efficacy and safety of daridorexant in adult and elderly subjects with insomnia disorder".

The primary objective of the trial is to evaluate the efficacy of daridorexant on subjective total sleep time (sTST) based on an electronic sleep diary (eDiary) over a 4-week period in adult and elderly subjects with insomnia. Secondary objectives include an assessment of the efficacy and safety of daridorexant on subjective latency to sleep onset (sLSO) and subjective wake after sleep onset (sWASO).

Participants will be randomly assigned to receive either a 50mg dose of daridorexant or a placebo once daily.

The study duration for each patient will be a maximum of 12 weeks. Topline results are expected in 1H 2026.

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.

Nxera employs over 350 talented people 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).

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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.