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Nxera Pharma receives approval of insomnia drug in Japan

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Plans to make QUVIVIQ available as soon as possible to insomnia patients in Japan are underway

Nxera Pharma, formerly known as Sosei Group or Sosei Heptares, has received approval from the Ministry of Health, Labour and Welfare of Japan (MHLW) of its New Drug Application (NDA) for QUVIVIQ 25mg and 50 mg for the treatment of adult patients with insomnia.

The approval of QUVIVIQ, a novel dual orexin receptor antagonist, is based on robust clinical efficacy and safety data including from a dedicated Japanese Phase 3 trial. Plans to make QUVIVIQ available as soon as possible to insomnia patients in Japan are underway.

Insomnia, characterised by difficulties in sleep onset and/or sleep maintenance, is highly prevalent in Japan, affecting about 20% of Japanese adults according to the MHLW, and is recognized as an important national issue impacting both physical and mental health.

The approval of QUVIVIQ by the MHLW is supported by positive results of a randomised, double-blind, placebo-controlled Phase 3 study in Japan to investigate the efficacy and safety of daridorexant. The study met all primary and secondary efficacy endpoints.

QUVIVIQ (daridorexant) is a dual orexin receptor antagonist 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 a New Drug Application was submitted in Japan in October 2023. Daridorexant is approved in the US and Europe and marketed in these territories under the brand name QUVIVIQ by Idorsia Pharmaceuticals.

Nxera Pharma has the Japanese and APAC (ex-China) rights for daridorexant following its acquisition of Idorsia Pharmaceuticals Japan Ltd and Idorsia Pharmaceuticals Korea Co., Ltd in 2023. QUVIVIQ was co-developed in Japan by NPJ and Mochida Pharmaceutical Co.