Announcement of Manufacturing and Marketing Approval of Insomnia Treatment QUVIVIQ® in Japan

This material is an English translation of the press release to be issued on September 24, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

September 24, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; President: Naoyuki Mochida, hereinafter “Mochida”) and Nxera Pharma Japan Co., Ltd. (Head Office: Minato-ku, Tokyo; President: Satoshi Tanaka, hereinafter “Nxera Pharma Japan”), a subsidiary of Nxera Pharma Co., Ltd., have been jointly developing the insomnia treatment drug, QUVIVIQ® (development code: ACT-541468; generic name: daridorexant hydrochloride), and today, Nxera Pharma Japan obtained its manufacturing and marketing approval to the Japanese Ministry of Health, Labour and Welfare (MHLW).

QUVIVIQ® is an oral insomnia treatment drug that selectively inhibits bindings of the neuronal peptide (orexin) that promotes wakefulness to the receptors (OX1R and OX2R) and is expected to exert its effects by suppressing excessive wakefulness and transitioning into a sleep state. It is a dual orexin receptor antagonist (DORA).

QUVIVIQ® was approved in the US and Europe in January and April 2022, respectively, and is marketed by Idorsia Pharmaceuticals Ltd. (Head Office: Allschwil, Switzerland; CEO: Jean-Paul Clozel) in these and other approved territories as QUVIVIQ™. For Japan, in December 2019, Mochida and Idorsia Pharmaceuticals Ltd. signed an exclusive license agreement for the supply, co-development, and co-marketing of QUVIVIQ® for insomnia (including related diseases), and under this agreement, Mochida and Nxera Pharma Japan have been jointly developing it.

It is estimated that approximately 20% of adults do not get enough rest through sleep according to the National Health and Nutrition Survey conducted by the Japanese Ministry of Health, Labor and Welfare (MHLW) in 2018. By expanding treatment options with QUVIVIQ®, we hope to contribute further to improving the quality of life of patients.

[References]

Summary of the approval

Brand Name	:	QUVIVIQ® Tablet 25mg QUVIVIQ® Tablet 50mg
Generic Name	:	Daridorexant hydrochloride
Ingredients and Contents	:	Film-coated Tablet 27.02mg Daridorexant hydrochloride per tablet (25mg Daridorexant per tablet) 54.04mg Daridorexant hydrochloride per tablet (50mg Daridorexant per tablet)
Indications	:	Insomnia
Dosage and Administration	:	The normal adult dosage for Daridorexant is 50mg taken orally once daily, immediately before going to bed. The dosage can be decreased to 25 mg at a time, once daily, according to the condition.
Approval Date	:	September 24, 2024