Press release
Valby, Denmark, 23 July 2026

Lundbeck receives FDA Fast Track designation for Lu AH69593, an investigational orexin 2 receptor agonist for narcolepsy

- The U.S. FDA has granted Fast Track designation to Lu AH69593, an oral orexin 2 receptor agonist, for the treatment of patients with narcolepsy
- The orexin 2 receptor is critically located in the main biological pathway involved in wakefulness and sleep-wake regulation
- Lu AH69593 is currently in Phase 1b development for patients with narcolepsy
- The designation marks an important regulatory milestone as Lundbeck advances a portfolio of programs for people living with sleep-wake disorders

Valby, Denmark, 23 July 2026 – Lundbeck today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Lu AH69593, the company's lead oral orexin 2 receptor agonist and one of several investigational compounds in Lundbeck's development portfolio for sleep-wake disorders. Lu AH69593 was discovered by Lundbeck and it is presently in phase 1b development for the treatment of patients with narcolepsy.

Narcolepsy is a chronic neurological disorder that disrupts the brain's ability to regulate sleep and wakefulness. People living with narcolepsy may experience excessive daytime sleepiness, sudden sleep attacks, fragmented nighttime sleep, sleep paralysis and hallucinations. In narcolepsy type 1, symptoms also include cataplexy, a sudden loss of muscle tone often triggered by emotions. These symptoms can affect daily functioning, education, work, social life and quality of life.[1-5]

Orexin is a wake-promoting neuropeptide that plays a key role in stabilizing sleep and wakefulness. Orexin-producing neurons are located in the lateral hypothalamus and project broadly across the brain to regions involved in arousal, wakefulness and REM sleep regulation. Orexin signals through the orexin 1 and orexin 2 receptors, of which the orexin 2 receptor, or OX2R, is considered central to wake-promoting signaling and sleep-wake regulation. Disruption of orexin signaling is therefore a highly relevant therapeutic target in narcolepsy and other disorders characterized by excessive daytime sleepiness.[1,3,6-8]

Lu AH69593 is designed with the ambition of achieving a best-in-class compound to activate the OX2R and enhance wake-promoting signaling through the orexin pathway. By targeting a pathway directly linked to wakefulness biology, Lu AH69593 is intended to restore wakefulness and sleep-wake regulation in people living with narcolepsy, where current treatments can help manage symptoms, but significant disease burden remains for many patients.[1,3,6]

"Fast Track designation is an important milestone for Lu AH69593 and for our ambition to translate compelling orexin biology into a new treatment approach for narcolepsy and other sleep-wake disorders," said Johan Luthman, Executive Vice President R&D, Lundbeck. "For people living with narcolepsy, the ability to sustain wakefulness can shape almost every part of daily life. Fast Track designation underscores the urgent need for innovative therapies for narcolepsy and recognizes the potential of Lu AH69593. This program is a good example of

Lundbeck's transformation of the R&D pipeline into breakthrough neurology, neuroendocrine and rare indication programs, with potential for regulatory designations facilitating development. We are encouraged by the opportunity to work closely with the FDA as we advance Lu AH69593."

Fast Track designation is an FDA process designed to facilitate development and expedite review of medicines intended to treat serious conditions and address unmet medical needs.[9,10]

About Lu AH69593

Lu AH69593 is an investigational small-molecule orexin 2 receptor agonist being developed by Lundbeck for narcolepsy. Orexin, also known as hypocretin, is a neuropeptide involved in arousal, wakefulness and sleep-wake stability. Lu AH69593 is designed with the ambition of achieving a best-in-class compound to activate OX2R, a receptor involved in wake-promoting orexin signaling. Lu AH69593 is currently being evaluated in a Phase 1b clinical program, with Lundbeck continuing to assess its safety, tolerability, pharmacokinetic and pharmacodynamic profile.

Lu AH69593 is an investigational compound that is not approved for marketing by any regulatory authority worldwide, and the efficacy and safety of Lu AH69593 have not been established.

About narcolepsy

Narcolepsy is a chronic neurological sleep-wake disorder characterized by excessive daytime sleepiness and disrupted regulation of sleep and wakefulness. Symptoms may include sleep attacks, fragmented nighttime sleep, sleep paralysis, hallucinations and, in narcolepsy type 1, cataplexy. [1-4] In narcolepsy type 1, low levels of hypocretin, also known as orexin, are a key biological feature.[1,3,4] Current treatments can help manage symptoms, but many people living with narcolepsy continue to experience meaningful effects on daily functioning, education, work and quality of life.[3-5]

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About H. Lundbeck A/S

Lundbeck is a biopharmaceutical company focusing exclusively on brain health. With more than 70 years of experience in neuroscience, we are committed to improving the lives of people with neurological and psychiatric diseases.

Brain disorders affect a large part of the world's population, and the effects are felt throughout society. With the rapidly improving understanding of the biology of the brain, we hold ourselves accountable for advancing brain health by curiously exploring new opportunities for treatments.

As a focused innovator, we strive for our research and development programs to tackle some of the most complex neurological challenges. We develop transformative medicines targeting people for whom there are few or no treatments available, expanding into neuro-specialty and neuro-rare from our strong legacy within psychiatry and neurology.

We are committed to fighting stigma and we act to improve health equity. We strive to create long term value for our shareholders by making a positive contribution to patients, their families and society as a whole.

Lundbeck has more than 5,000 employees in more than 20 countries and our products are available in more than 80 countries. For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us via LinkedIn.

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