Alkermes Announces Orphan Drug Designations for Alixorexton in the U.S. and Europe

June 15, 2026

DUBLIN--(BUSINESS WIRE)--Jun. 15, 2026-- Alkermes plc (Nasdaq: ALKS) today announced that alixorexton, a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development for the treatment of narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH), was recently granted orphan drug designations (ODD) from leading regulatory bodies in the U.S. and Europe. The U.S. Food and Drug Administration (FDA) has granted ODD to alixorexton for the treatment of IH, and the European Commission has granted ODD to alixorexton for the treatment of narcolepsy.

“Narcolepsy and idiopathic hypersomnia are rare, chronic neurological conditions for which significant unmet need remains. These orphan drug designations represent important milestones for the alixorexton program and underscore its potential, if approved, to advance care for the narcolepsy and idiopathic hypersomnia patient communities,” said Craig Hopkinson, M.D., (MBChB), Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. “Alixorexton’s phase 2 clinical trial results in narcolepsy type 1 and type 2 underscore its potential to become a differentiated treatment option. We look forward to continuing our momentum in the alixorexton development program as we enroll the phase 3 Brilliance Studies and work to complete the Vibrance-3 phase 2 study in IH this year.”

Orphan drug designation supports the development of medicines intended to treat rare diseases. In the U.S., orphan drug designation qualifies the drug developer for a variety of development incentives, including tax credits for qualified clinical testing, exemptions from certain FDA application fees, and seven years of market exclusivity, if approved. In the European Union, orphan designation provides incentives that may include protocol assistance, reduced regulatory fees, and up to 10 years of market exclusivity, if approved.

Alixorexton previously received Breakthrough Therapy designation for the treatment of NT1 from the FDA. Alixorexton is currently being evaluated in the phase 3 Brilliance Studies in adults with NT1 and NT2, and in the phase 2 Vibrance-3 study in adults with IH (Brilliance NT1 – Study 302: NCT07455383; Brilliance NT2 – Study 303: NCT07502443; Brilliance NT1 – Study 304: NCT07540897; Vibrance-3: NCT06843590).

About Narcolepsy

Narcolepsy is a rare, chronic, neurological disorder that affects the brain’s ability to regulate the sleep/wake cycle. Excessive daytime sleepiness is the hallmark symptom of narcolepsy; additional symptoms can include sleep paralysis, sleep-related hallucinations and disturbed nighttime sleep.[1] There are two types of narcolepsy: narcolepsy type 1 is characterized by the loss of orexin-producing neurons, and is also associated with cataplexy, a sudden loss of muscle control while a person is awake, often triggered by strong emotions.[2] The underlying neuropathology of narcolepsy type 2 remains to be fully elucidated; however the orexin pathway may play an important role.[3]

About Idiopathic Hypersomnia

Idiopathic hypersomnia (IH) is a rare, chronic, neurological sleep disorder characterized by excessive daytime sleepiness despite normal sleep durations.[4,5] Additional common symptoms can include severe sleep inertia (individuals may feel groggy or disoriented for prolonged periods after waking up), unrefreshing naps, fatigue and cognitive dysfunction.[6,7] The underlying neuropathology of idiopathic hypersomnia is unknown.[4] IH affects an estimated 40,000 people in the U.S.[8]

About Alixorexton

Alixorexton (formerly referred to as ALKS 2680) is a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development for the treatment of narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH). Orexin, a neuropeptide produced in the lateral hypothalamus, is considered to be the master regulator of wakefulness due to its activation of multiple, downstream wake-promoting pathways that project widely throughout the brain.[9] Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease.[10] Alixorexton is currently being evaluated in the phase 3 Brilliance Studies in patients with NT1 and NT2, and in the phase 2 Vibrance-3 study in patients with IH. The U.S. Food and Drug Administration (FDA) has granted alixorexton Breakthrough Therapy designation for the treatment of NT1 and Orphan Drug Designation (ODD) for the treatment of IH. The European Commission has granted ODD to alixorexton for the treatment of narcolepsy.

About Alkermes plc

Alkermes plc (Nasdaq: ALKS), a mid-cap growth and value equity, is a global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. The company has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia, bipolar I disorder and narcolepsy. Alkermes’ pipeline includes late-stage clinical candidates in development for narcolepsy and idiopathic hypersomnia, and orexin 2 receptor agonists in early clinical development for other neurological disorders, including attention-deficit hyperactivity disorder (ADHD) and fatigue associated with multiple sclerosis and Parkinson’s disease. Headquartered in Ireland, Alkermes also has a corporate office and research and development center in Massachusetts and a manufacturing facility in Ohio. For more information, please visit Alkermes’ website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the potential therapeutic and commercial value of alixorexton, its

potential regulatory approval, and timelines for its continued clinical development. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: initial clinical results for alixorexton may not be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; ongoing or future clinical studies for alixorexton may not be initiated or completed on expected timelines or at all; alixorexton may be shown to be ineffective or unsafe; the FDA may not agree with the company's regulatory strategies or components of its development program for alixorexton, including clinical trial designs, conduct and methodologies; potential changes in the cost, scope and duration of the alixorexton development program; and those risks and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2025 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

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