The Lancet Neurology Publishes Data From Alkermes' Positive Vibrance-1 Phase 2 Study of Alixorexton in Adults With Narcolepsy Type 1

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– Alixorexton Demonstrated Statistically Significant and Clinically Meaningful Improvements in Wakefulness and Cataplexy –

– At All Doses Tested, Alixorexton Demonstrated Clinically Meaningful Improvements in Patient-Reported Outcomes Related to Disease Severity, Fatigue, Cognition and Health-Related Quality of Life –

– Alixorexton Was Generally Well Tolerated at All Doses Tested –

DUBLIN--(BUSINESS WIRE)--Aug. 24, 2026-- Alkermes plc (Nasdaq: ALKS) today announced the publication of data from the Vibrance-1 phase 2 study of alixorexton in adults with narcolepsy type 1 (NT1) in *The Lancet Neurology*. Alixorexton is a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development for the treatment of NT1, narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH). Based on the positive results demonstrated by alixorexton in the phase 2 Vibrance Studies in NT1 and NT2, Alkermes has initiated the Brilliance Studies, a global phase 3 program evaluating once-daily and split dose regimens of alixorexton in adults with NT1 and NT2.

The phase 2 Vibrance-1 study was conducted in 92 adults with NT1 and included a six-week, randomized, placebo-controlled, double-blind period followed by an optional seven-week open-label extension. As previously announced, treatment with once-daily alixorexton led to statistically significant improvements from baseline versus placebo in both objective and subjective measures of excessive daytime sleepiness, as measured by the Maintenance of Wakefulness Test (MWT) and Epworth Sleepiness Scale (ESS)[1], respectively. All dose groups (4 mg, 6 mg and 8 mg) achieved mean sleep latency values within the normative range on the MWT (i.e., ≥20 minutes) and ESS (a score of ≤10) at week six. Weekly cataplexy rate[2] was significantly decreased versus placebo in the 6 mg alixorexton group. Alixorexton also demonstrated clinically meaningful improvements on exploratory patient-reported endpoints assessing overall disease severity, fatigue, cognition and health-related quality of life. Alixorexton treatment was generally well tolerated, with most treatment-emergent adverse events (TEAEs) being mild to moderate in severity, and no serious TEAEs.

"The data published in *The Lancet Neurology* highlight the robust efficacy of once-daily doses of alixorexton in patients with narcolepsy type 1 across measures of wakefulness and excessive daytime sleepiness. Along with a generally well-tolerated profile, alixorexton demonstrated improvements across a broad range of symptoms that affect daily functioning, including cataplexy, overall disease severity, cognition and fatigue. These data are a substantial contribution to the evidence base supporting the potential of orexin 2 receptor agonists to transform the treatment of narcolepsy and the utility of a range of doses to address the individual needs of people living with NT1," said Giuseppe Plazzi, M.D., Ph.D., Neurologist, Director of the Narcolepsy Center at the IRCCS of the Neurological Sciences of Bologna and Professor of Childhood Neuropsychiatry at the University of Modena and Reggio Emilia.

"In the Vibrance-1 study, alixorexton demonstrated substantial and clinically meaningful benefits across multiple dimensions of narcolepsy type 1," said Craig Hopkinson, M.D. (MBChB), Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "The totality of evidence generated across the Vibrance phase 2 program in narcolepsy has reinforced our confidence in alixorexton's potential to meaningfully impact the lives of people living with narcolepsy type 1 and type 2. These findings highlight the potential of alixorexton to address a broad range of symptoms that continue to burden patients despite currently available therapies. With the global Brilliance phase 3 program now underway in both narcolepsy type 1 and type 2, we are excited to continue advancing alixorexton in this next stage of development."

About the Vibrance-1 Phase 2 Study (NCT06358950)

Vibrance-1 was a phase 2, randomized, double-blind, dose-range-finding, placebo-controlled study evaluating the safety and efficacy of alixorexton in adults with narcolepsy type 1 (NT1). Participants (n=92) were randomized to receive one of three doses of alixorexton (4 mg, 6 mg or 8 mg) or placebo to be taken once-daily for six weeks. The primary endpoint assessed whether participants taking alixorexton experienced an improvement in wakefulness compared to participants taking placebo, as measured by the change from baseline in mean sleep latency on the Maintenance of Wakefulness Test (MWT) at week six. Secondary endpoints included change from baseline in Epworth Sleepiness Scale (ESS) score at week six, mean weekly cataplexy rate (WCR) at week six[2], and incidence of adverse events. The study also included a number of exploratory patient-reported outcome measures, which evaluated the effect of alixorexton on participants' disease severity, fatigue and cognition. All participants in the double-blind portion of the study were eligible to continue to a seven-week open-label safety extension portion of the study, followed by a long-term safety study.

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.[3] Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease.[4] 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. 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: clinical study results for alixorexton may not be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; 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.

[1] ESS: 8-item self-administered questionnaire that measures severity of excessive daytime sleepiness across multiple conditions over the past 7 days (≤10 = normative).

[2] Weekly cataplexy rate was derived at Week 6 from patients' cataplexy diaries over Weeks 5 and 6.

[3] Buysse, D. Diagnosis and assessment of sleep and circadian rhythm disorders. *Journal of Psychiatric Practice*. 2005; 11(2):102-115

[4] Ten-Blanco M, Flores A, Cristino L, Pereda-Perez I. Targeting the orexin/hypocretin system for the treatment of neuropsychiatric and neurodegenerative diseases: From animal to clinical studies. Frontiers in Neuroendocrinology. 2023;69(101066). https://www.sciencedirect.com/science/article/pii/S0091302223000146

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Alkermes Contacts:
For Investors: Sandy Coombs, +1 781 609 6377
For Media: Gretchen Murphy, +1 781 609 6419

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