Alkermes to Present Detailed Positive Results From Vibrance-1 Phase 2 Study Evaluating Alixorexton in Patients With Narcolepsy Type 1 at World Sleep 2025

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– Results From Vibrance-1 to Be Shared in Three Oral Presentations, Including Primary and Secondary Efficacy and Safety Measures, and Exploratory Patient-Reported Outcomes Related to Disease Severity, Fatigue and Cognition –

– Company to Host Investor Webcast on Monday, Sept. 8 at 8:00 a.m. ET –

DUBLIN, Aug. 25, 2025 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced plans to present detailed results from its Vibrance-1 phase 2 study evaluating alixorexton in patients with narcolepsy type 1 (NT1) at World Sleep Congress, taking place Sept. 5-10, 2025 in Singapore, and in an investor webcast presentation hosted by the company. Alixorexton, formerly referred to as ALKS 2680, is the company's novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in phase 2 development as a once-daily treatment for NT1, narcolepsy type 2 (NT2) and idiopathic hypersomnia (IH).

"We are honored to welcome leading researchers and clinicians from the global sleep medicine community to World Sleep Singapore 2025 Congress, where groundbreaking research in narcolepsy will be presented," said Raffaele Ferri, M.D., President of World Sleep Society. "We are looking forward to the presentation of new datasets on orexin 2 receptor agonists in development, as well as other innovative updates across the field of sleep medicine. I am encouraged by the continued interest and commitment from the global research community to improve the standard of care for people living with central disorders of hypersomnolence."

Following the recent announcement of positive topline results from Vibrance-1, the company plans to present additional details from this phase 2 study in three oral presentations. In addition, the company will present a poster outlining the study design and methods for Vibrance-3, a phase 2 clinical study evaluating the safety and efficacy of alixorexton compared to placebo in patients with IH.

"Substantial new datasets from the leading orexin 2 receptor agonists in development will be presented at this year's World Sleep Congress, representing an important milestone in understanding the broad implications of orexin biology as we seek to transform the treatment of narcolepsy," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "We look forward to sharing detailed data from our Vibrance-1 phase 2 study with clinicians at World Sleep. Along with important new findings related to improvements in fatigue and cognitive impairment – disruptive symptoms that impact patients' day-to-day lives – the efficacy, tolerability and safety data from Vibrance-1 will be presented, providing an overview of the differentiating features of once-daily alixorexton across a range of doses in patients with narcolepsy type 1."

Oral presentations

The following presentations will take place during the *Targeting the orexin pathway: Emerging pharmacotherapies for narcolepsy type 1* session taking place on Monday, Sept. 8, 2025 (3:15– 4:46 p.m. SGT; 3:15– 4:46 a.m. ET):

Vibrance-1: A Randomized Phase 2 Study Evaluating Safety and Efficacy of the Orexin 2 Receptor Agonist Alixorexton (ALKS 2680) in Patients with Narcolepsy Type 1

- **Presenter:** 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.

Improvement in the Severity of Narcolepsy Symptoms and Fatigue in Patients with Narcolepsy Type 1 Treated with the Orexin 2 Receptor Agonist Alixorexton (ALKS 2680)

- **Presenter:** Yves Dauvilliers, M.D., Ph.D., Director, Sleep-Wake Disorders Center, Department of Neurology, Gui de Chauliac Hospital, Montpellier, France.

Improvement in Patient-reported Cognitive Functioning in Patients with Narcolepsy Type 1 Treated with the Orexin 2 Receptor Agonist Alixorexton (ALKS 2680)

- **Presenter:** 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.

Poster Presentation

A Phase 2, Randomized, Placebo-Controlled, Parallel-Group Study Evaluating the Safety and Efficacy of ALKS 2680 in Patients With Idiopathic Hypersomnia: Study Design and Methods for Vibrance-3

- **Poster Board Number:** 169
- **Presenter:** Marcus Yountz, M.D., Alkermes
- **Presentation Date:** The poster will be presented on Tuesday, Sept. 9, 2025 from 4:45 – 5:45 p.m. SGT as part of poster abstract group 3.

Conference Call and Webcast
Alkermes will host a webcast presentation and conference call with accompanying slides for analysts and investors on Monday, Sept. 8, 2025, at 8:00 a.m. ET (8:00 p.m. SGT) to discuss these data. The webcast player may be accessed on the Investors section of Alkermes' website at www.alkermes.com. To participate in the question-and-answer session, please also dial in to the conference call, which may be accessed by dialing +1 877-407-2988 for U.S. callers and +1 201-389-0923 for international callers. A replay of the webcast will be archived on the company's website for 30 days following the presentation.

About the Vibrance-1 Phase 2 Study (NCT06358950)
Vibrance-1 is a phase 2, randomized, double-blind, dose-range-finding, placebo-controlled study evaluating the safety and efficacy of alixorexton (formerly referred to as ALKS 2680) 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 6 and mean weekly cataplexy rate (WCR) at weeks five and six, 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 as a once-daily treatment for 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.[1] Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease.[2] Once-daily oral administration of alixorexton was previously evaluated in a phase 1 study in healthy volunteers and patients with NT1, NT2 and IH, and is currently being evaluated in the phase 2 Vibrance-1, Vibrance-2 and Vibrance-3 studies in patients with NT1, NT2 and IH, respectively.

About Alkermes plc
Alkermes plc (Nasdaq: ALKS) is a mid-cap growth and value equity 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 and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy and idiopathic hypersomnia. 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 (formerly referred to as ALKS 2680). 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: whether initial clinical results for alixorexton will be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; whether ongoing or future clinical studies for alixorexton will be initiated or completed on expected timelines or at all; whether alixorexton could be shown to be ineffective or unsafe; 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, 2024 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] Buysse, D. Diagnosis and assessment of sleep and circadian rhythm disorders. *Journal of Psychiatric Practice*. 2005; 11(2):102-115

[2] 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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