



Alkermes to Present Additional Data From Vibrance-1 Phase 2 Study of Alixorexton in Patients with Narcolepsy Type 1 at the American Academy of Neurology (AAN) 2026 Annual Meeting

April 16, 2026

— Alixorexton Data From Seven-Week Open-Label Extension Period Demonstrated Sustained Improvements in Patient-Reported Disease Severity, Cognitive Functioning and Fatigue—

— Alixorexton Was Generally Well Tolerated at All Doses Tested —

— Phase 3 Brilliance NT1 Study of Alixorexton in Patients With Narcolepsy Type 1s Ongoing —

DUBLIN--(BUSINESS WIRE)--Apr. 16, 2026-- [Alkermes plc](#) (Nasdaq: ALKS) today announced plans to present new data from the Vibrance-1 phase 2 study evaluating alixorexton in patients with narcolepsy type 1 (NT1) at the American Academy of Neurology (AAN) 2026 Annual Meeting, taking place April 18-22, 2026 in Chicago. 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).

Vibrance-1, a randomized, placebo-controlled, double-blind phase 2 study conducted in 92 patients with NT1, demonstrated clinically meaningful and statistically significant improvements from baseline compared to placebo in wakefulness, cognition, and fatigue. New data to be presented at AAN augment the detailed positive results from the six-week, randomized double-blind treatment (RDBT) period previously presented at the 2025 World Sleep Congress. The new data demonstrate clinically meaningful improvements from pre-treatment baseline on established measures evaluating excessive daytime sleepiness and cataplexy, as well as participant-reported outcomes, including narcolepsy symptom severity, cognitive functioning and fatigue in patients with NT1 through the seven-week open-label extension. More than 95% (n=88) of participants who entered Vibrance-1 completed treatment in both the six-week double-blind portion of the trial and the seven-week open-label extension for a total of 13 weeks.

"Results from the Vibrance-1 phase 2 study of alixorexton provide a rich and comprehensive dataset that allows us to better understand its treatment effects on core symptoms of narcolepsy type 1. Improvements observed at week 6 across patient-reported measures of disease severity, cognitive functioning and fatigue were sustained through the seven-week open-label extension, supporting the durability of alixorexton's effects," 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. "These patient-reported outcomes highlight clinically relevant dimensions of narcolepsy that are often underrecognized, yet central to patients' daily functioning, and demonstrate alixorexton's potential to make a meaningful impact for people living with narcolepsy type 1."

Exploratory patient-reported outcomes (PROs) in Vibrance-1 included the Narcolepsy Severity Scale-Clinical Trials (NSS-CT)¹, British Columbia Cognitive Complaints Inventory (BC-CCI)², Patient Global Impression of Severity (PGI-S) for Cognition³, PROMIS-Fatigue Short-form 6a (PROMIS-Fatigue)⁴, and PGI-S for Fatigue.³ Clinically meaningful improvements were seen across all PRO measures at week 6 with alixorexton, with improvements sustained through weeks 12-13.⁵

Alixorexton was generally well tolerated across all doses tested throughout the six-week, RDBT period and the seven-week open-label extension period. No serious treatment-emergent adverse events (TEAEs) were reported. Most TEAEs were mild to moderate in severity.

"The breadth and depth of the data generated in the Vibrance-1 study provide strong evidence of alixorexton's potential to meaningfully impact the lives of patients by addressing multiple elements across the spectrum of disease burden of narcolepsy type 1. Importantly, the differentiated profile observed across patient-reported symptom severity, cognition and fatigue highlights alixorexton's potential to offer a distinct and clinically relevant approach for patients with narcolepsy," said Craig Hopkinson, M.D. (MBChB), Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "These data provide a strong foundation for our phase 3 program and reinforce our confidence as we enroll the recently initiated Brilliance Studies in narcolepsy type 1 and type 2. We look forward to further characterizing alixorexton's efficacy and safety profile in these pivotal trials."

Details of the poster presentation are as follows:

Poster Number: 14-002

Title: Improvement in Patient-Reported Disease Severity, Cognitive Functioning, and Fatigue in Patients With Narcolepsy Type 1 Treated With Alixorexton, an Orexin 2 Receptor Agonist, in the Vibrance-1 Phase 2 Study

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

Presentation Date: Monday, April 20, 2026 from 5:00 – 6:00 p.m. CT during Poster Session 6

[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 six⁶, 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.⁷ Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not deficient orexin signaling is the underlying cause of disease.⁸ 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 in Vibrance-1 and Vibrance-2, phase 2 studies in patients with NT1 and NT2, respectively. 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. Alixorexton has received Breakthrough Therapy designation for the treatment of NT1 from the U.S. Food and Drug Administration (FDA).

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: 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; 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 NSS-CT: 15-item self-administered questionnaire (score: 0-57) that assesses the severity and consequences of five major narcolepsy symptoms over the past 7 days: daytime sleepiness, cataplexy, hallucinations, sleep paralysis, and disturbed nighttime sleep.

² BC-CCI: 6-item self-administered questionnaire (score: 0-18) assessing perceived problems with concentration, memory, expressing thoughts, word finding, slow thinking, and difficulty solving problems over the past 7 days (≤ 4 = normative).

³ PGI-S for Cognition, Fatigue: Self-administered, single items assessing cognitive impairment as well as fatigue, over the past 7 days on a 5-point scale (none, mild, moderate, severe or very severe).

⁴ PROMIS-Fatigue: 6-item self-administered questionnaire assessing the severity of a patient's fatigue over the past 7 days. Items are scored and transformed to T-scores (< 55 = normative).

⁵ Per protocol, select PROs were administered at week 12 (NSS-CT, BC-CCI) while others were administered at week 13.

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

⁷ Buysse, D. Diagnosis and assessment of sleep and circadian rhythm disorders. *Journal of Psychiatric Practice*. 2005; 11(2):102-115

⁸ 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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