



Alkermes to Present New Data on Alixorexton and LUMRYZ® (sodium oxybate) at Sleep Europe 2026, Underscoring Leadership in Sleep Medicine Research

October 13, 2026

— *Data From Vibrance-1 Phase 2 Study Lancet Neurology Publication Evaluating Alixorexton in Narcolepsy Type 1 and Additional Data From Long-Term Extension Study in Narcolepsy Type 1 and Type 2 to be Shared in Oral Presentation* —

— *Detailed Positive Results From REVITALYZSM Phase 3 Study Evaluating LUMRYZ in Adults With Idiopathic Hypersomnia to be Shared in Oral Presentation* —

DUBLIN--(BUSINESS WIRE)--Oct. 13, 2026-- [Alkermes plc](#) (Nasdaq: ALKS) today announced plans to present two oral presentations and six posters from its industry-leading portfolio of sleep medicine research at the European Sleep Research Society's (ESRS) 28th Congress, Sleep Europe 2026, taking place Oct. 20-23, 2026 in Maastricht, the Netherlands. The company will present new data related to LUMRYZ® (sodium oxybate) extended-release oral suspension, now part of Alkermes' sleep portfolio following the acquisition of Avadel Pharmaceuticals plc, and alixorexton, Alkermes' 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).

In an oral presentation, the company will present findings from the Vibrance-1 phase 2 study of alixorexton in adults with NT1, which were recently published in [The Lancet Neurology](#). The presentation will also include data from the open-label, long-term extension study evaluating the safety and durability of effect in participants with NT1 and NT2 who received alixorexton for up to nine months of treatment.

"I am pleased to present results from the Vibrance-1 phase 2 study and long-term extension evaluating alixorexton in patients with narcolepsy type 1 and type 2 at Sleep Europe. Together, these results further characterize the potential of alixorexton in narcolepsy and provide evidence supporting sustained clinical benefit with longer-term treatment," 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 a separate oral presentation and corresponding poster presentation within the "Impactful Clinical Trial" session, the company will share detailed results from the phase 3 REVITALYZ study evaluating the investigational use of LUMRYZ in adults with IH. The Company previously announced positive topline results for this study.

"I am honored to present results from the REVITALYZ phase 3 trial evaluating LUMRYZ in adults with idiopathic hypersomnia, a chronic neurological disorder for which there are limited treatment options. It is an exciting time in sleep medicine, and the research being presented at Sleep Europe 2026 underscores the significant scientific progress we are seeing across narcolepsy and idiopathic hypersomnia," said Richard Bogan, M.D., FCCP, FAASM, Principal of Bogan Sleep Consultants, LLC and Associate Clinical Professor at the University of South Carolina School of Medicine.

Additional highlights to be shared in poster presentations at Sleep Europe 2026 include:

- Results from an interim analysis of the ongoing open-label, long-term extension (LTE) study evaluating the safety and maintenance of effect of alixorexton in adults with NT1 and NT2 at week 24 of the LTE, approximately nine months after the first dose for participants treated with alixorexton in the randomized double-blind period of the Vibrance-1 and Vibrance-2 phase 2 studies;
- Exploratory findings from the Vibrance-2 phase 2 study evaluating the impact of alixorexton compared to placebo on patient-reported measures of cognition and fatigue in adults with NT2;
- Detailed study designs and methods for the Brilliance Studies, a phase 3 clinical trial program evaluating the safety and efficacy of alixorexton compared to placebo in adults with NT1 and NT2; and
- Findings from REFRESH, a prospective multicenter, real-world study in adults with narcolepsy, including patients who switched to LUMRYZ from a twice-nightly oxybate and patients new to oxybate treatment or returning to oxybate treatment after previously discontinuing a twice-nightly oxybate.

"The breadth of data being presented by Alkermes at Sleep Europe 2026 reflects both the strength of our research programs and our leadership in the field of sleep medicine. We look forward to sharing detailed findings from the REVITALYZ phase 3 study of LUMRYZ in patients with idiopathic hypersomnia, as well as initial data from our long-term extension study evaluating the durability of effect of alixorexton in patients with narcolepsy type 1 and type 2," said Craig Hopkinson, M.D. (MBChB), Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "Through our ongoing investment in scientific innovation across narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia, we aim to help advance differentiated treatment approaches and address the diverse needs of people living with these serious neurological conditions."

Details of Alkermes' presentations at Sleep Europe 2026 are as follows:

REVITALYZ: A Phase 3, Double-Blind, Placebo-Controlled, Randomised Withdrawal Trial of Extended-Release Sodium Oxybate for Idiopathic Hypersomnia

- **Presenter:** Richard Bogan, M.D., FCCP, FAASM, Principal of Bogan Sleep Consultants, LLC and Associate Clinical

Professor at the University of South Carolina School of Medicine

- **Presentation Date:** The oral presentation is scheduled to occur on Friday, Oct. 23, 2026 from 12:10–12:30 CEST as part of the “Impactful Clinical Trial Session 1.” The corresponding poster (F314) will be presented on Friday, Oct. 23, 2026 from 12:30–13:30 CEST.

Phase 2 and Long-term Extension Results from Treatment With the Orexin 2 Receptor Agonist Alixorexton Demonstrated Clinically Meaningful Improvements in Symptoms of Narcolepsy Type 1 and 2

- **Presenter:** Giuseppe Plazzi, M.D., Ph.D., Head of the Sleep Center at the Institute of Neurological Sciences of Bologna, Italy and Chair of Child Neurology at the University of Modena and Reggio Emilia
- **Presentation Date:** The oral presentation is scheduled to occur on Friday, Oct. 23, 2026 from 15:55–16:15 CEST as part of the “Hot Topics in Sleep Science and Medicine” session.

Long-Term Safety, Tolerability, and Durability of Alixorexton: Interim Results from a Phase 2/3 Extension Study in Narcolepsy

- **Poster ID:** F304
- **Presenter:** Yves Dauvilliers, M.D., Ph.D., Professor of Neurology and Physiology, and Director of the Sleep-Wake Disorders Center at the University of Montpellier, France, and Coordinator of the French National Reference Center for Rare Diseases dedicated to narcolepsy and hypersomnia
- **Presentation Date:** The poster will be presented on Friday, Oct. 23, 2026 from 12:30–13:30 CEST.

Participant-Reported Cognitive Functioning and Fatigue in Participants with Narcolepsy Type 2 Treated With Alixorexton, an Orexin 2 Receptor Agonist, in the Vibrance-2 Study

- **Poster ID:** W339
- **Presenter:** Richard Bogan, M.D., FCCP, FAASM, Principal of Bogan Sleep Consultants, LLC and Associate Clinical Professor at the University of South Carolina School of Medicine
- **Presentation Date:** The poster will be presented on Wednesday, Oct. 21, 2026 from 12:30–13:30 CEST.

Study Design for 2 Phase 3, Randomised, Double-Blind, Placebo-Controlled Studies Evaluating Alixorexton in Patients With Narcolepsy Type 1: The Brilliance NT1 Studies

- **Poster ID:** W338
- **Presenter:** Julie Himes, M.D., Alkermes
- **Presentation Date:** The poster will be presented on Wednesday, Oct. 21, 2026 from 12:30–13:30 CEST.

Study Design for a Phase 3, Randomised, Double-Blind, Placebo-Controlled Study Evaluating Alixorexton in Patients With Narcolepsy Type 2: The Brilliance NT2 Study

- **Poster ID:** W337
- **Presenter:** Juan Chavez, M.D., Alkermes
- **Presentation Date:** The poster will be presented on Wednesday, Oct. 21, 2026 from 12:30–13:30 CEST.

Real-World Experience of Once-Nightly Sodium Oxybate Treatment in People With Narcolepsy: Final Results From REFRESH

- **Poster ID:** T340
- **Presenter:** Jeremy McConnell, M.D., Florida Sleep Specialists
- **Presentation Date:** The poster will be presented on Thursday, Oct. 22, 2026 from 12:30–13:30 CEST.

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.¹ Targeting the orexin system may address excessive daytime sleepiness across hypersomnolence disorders, whether or not orexin deficiency 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 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. 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 LUMRYZ® (sodium oxybate) for extended-release oral suspension

LUMRYZ (sodium oxybate) for extended-release oral suspension is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. LUMRYZ is not currently approved by regulatory authorities for the treatment of idiopathic hypersomnia (IH). Pursuant to the terms of a previously disclosed settlement and license agreement, Alkermes may not market, offer for sale, take orders for, distribute, promote, or provide patient support services with respect to LUMRYZ for IH before March 1, 2028,

even if LUMRYZ were to receive FDA approval for IH prior to that date.

IMPORTANT SAFETY INFORMATION

WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION and ABUSE AND MISUSE

Central Nervous System Depression

LUMRYZ® (sodium oxybate) is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with LUMRYZ at recommended doses. Many patients who received LUMRYZ during clinical trials in narcolepsy were receiving CNS stimulants.

Abuse and Misuse

LUMRYZ (sodium oxybate) is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma, and death.

Because of the risks of CNS depression and abuse and misuse, LUMRYZ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the LUMRYZ REMS.

CONTRAINDICATIONS

LUMRYZ is contraindicated for use in:

- combination with sedative hypnotics or alcohol
- patients with succinic semialdehyde dehydrogenase deficiency

WARNINGS AND PRECAUTIONS

Central Nervous System Depression

The concurrent use of LUMRYZ with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating antiepileptic drugs, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. If use of these CNS depressants in combination with LUMRYZ is required, dose reduction or discontinuation of one or more CNS depressants (including LUMRYZ) should be considered. In addition, if short-term use of an opioid (eg, post- or perioperative) is required, interruption of treatment with LUMRYZ should be considered.

After first initiating treatment and until certain that LUMRYZ does not affect them adversely (eg, impair judgment, thinking, or motor skills), caution patients against engaging in hazardous activities requiring complete mental alertness or motor coordination such as operating hazardous machinery, including automobiles or airplanes. Also caution patients against engaging in these hazardous activities for at least six (6) hours after taking LUMRYZ. Patients should be queried about CNS depression-related events upon initiation of LUMRYZ therapy and periodically thereafter.

Abuse and Misuse

LUMRYZ is a Schedule III controlled substance. The active ingredient of LUMRYZ, sodium oxybate, is the sodium salt of gamma-hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. The rapid onset of sedation, coupled with the amnesic features of GHB, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim). Physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely.

LUMRYZ REMS

LUMRYZ is available only through a restricted distribution program called the LUMRYZ REMS because of the risks of central nervous system depression and abuse and misuse.

Notable requirements of the LUMRYZ REMS include the following:

- Healthcare providers who prescribe LUMRYZ are specially certified.
- LUMRYZ will be dispensed only by pharmacies that are specially certified.
- LUMRYZ will be dispensed and shipped only to patients who are enrolled in the LUMRYZ REMS with documentation of safe use conditions.

Further information is available at www.LUMRYZREMS.com or by calling 1-877-453-1029.

Respiratory Depression and Sleep-Disordered Breathing

LUMRYZ may impair respiratory drive, especially in patients with compromised respiratory function. In overdoses of oxybate with illicit use of GHB, life-threatening respiratory depression has been reported. Increased apnea and reduced oxygenation may occur with LUMRYZ administration. A significant increase in the number of central apneas and clinically significant oxygen desaturation may occur in patients with obstructive sleep apnea treated with LUMRYZ. Prescribers should be aware that sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women not on hormone replacement therapy, and among patients with narcolepsy.

Depression and Suicidality

Depression, and suicidal ideation and behavior, can occur in patients treated with LUMRYZ. In an adult clinical trial in patients with narcolepsy (n=212), there were no suicide attempts, but one patient with a history of depression and anxiety developed suicidal ideation in the LUMRYZ-treated group. In a clinical trial in pediatric narcolepsy patients administered immediate-release sodium oxybate, one patient experienced suicidal ideation and two patients reported depression. The emergence of depression in patients treated with LUMRYZ requires careful and immediate evaluation. Patients with a previous history of a depressive illness and/or a suicide attempt should be monitored carefully for the emergence of depressive symptoms while taking LUMRYZ.

Other Behavioral or Psychiatric Adverse Reactions

Other behavioral and psychiatric adverse reactions can occur in patients taking LUMRYZ. During adult clinical trials in patients with narcolepsy administered LUMRYZ, 2% of 107 patients treated with LUMRYZ experienced a confusional state. No patients treated with LUMRYZ discontinued treatment because of confusion. Anxiety occurred in 7.5% of 107 patients treated with LUMRYZ in the adult trial in patients with narcolepsy. Other psychiatric reactions reported in adult clinical trials in patients with narcolepsy administered LUMRYZ included irritability, emotional disorder, panic attack, agitation, delirium, and obsessive thoughts. Other neuropsychiatric reactions reported in adult clinical trials in patients with narcolepsy administered immediate-release sodium oxybate and in the postmarketing setting for immediate-release sodium oxybate include hallucinations, paranoia, psychosis, aggression, and agitation. In a clinical trial in pediatric patients administered immediate-release sodium oxybate, neuropsychiatric reactions including acute psychosis, confusion, and anxiety were reported. The emergence or increase in the occurrence of behavioral or psychiatric events in patients taking LUMRYZ should be carefully monitored.

Parasomnias

Parasomnias can occur in patients taking LUMRYZ. Sleepwalking, defined as confused behavior occurring at night and at times associated with wandering, was reported in 3% of 107 adult patients with narcolepsy treated with LUMRYZ. No patients treated with LUMRYZ discontinued due to sleepwalking. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered.

Use in Patients Sensitive to High Sodium Intake

LUMRYZ has a high sodium content. In patients sensitive to sodium intake (eg, those with heart failure, hypertension, or renal impairment), consider the amount of daily sodium intake in each dose of LUMRYZ.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (incidence $\geq 5\%$ and greater than placebo) reported for any dose of LUMRYZ in a trial of adults with narcolepsy were nausea, dizziness, enuresis, headache, and vomiting. Similarly, in a trial of pediatric narcolepsy patients receiving immediate-release sodium oxybate, the most commonly observed adverse reactions (incidence $\geq 5\%$) were nausea, enuresis, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.

ADDITIONAL ADVERSE REACTIONS

Additional adverse reactions that occurred in $\geq 2\%$ of adult patients with narcolepsy treated with LUMRYZ and were more frequent in the LUMRYZ treatment group than with placebo were vomiting, nausea, decreased weight, decreased appetite, dizziness, somnolence, headache, enuresis, anxiety, and somnambulism.

DRUG INTERACTIONS

LUMRYZ is contraindicated for use in combination with alcohol or sedative hypnotics. Use of other CNS depressants may potentiate the CNS-depressant effects of LUMRYZ.

PREGNANCY AND LACTATION

There are no adequate data on the developmental risk associated with the use of sodium oxybate in pregnant women. LUMRYZ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. GHB is excreted in human milk after oral administration of sodium oxybate. There is insufficient information on the risk to a breastfed infant, and there is insufficient information on milk production in nursing mothers. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LUMRYZ and any potential adverse effects on the breastfed infant from LUMRYZ or from the underlying maternal condition.

PEDIATRIC USE

LUMRYZ has not been studied in a pediatric clinical trial for narcolepsy. The safety and effectiveness of LUMRYZ in the treatment of cataplexy or excessive daytime sleepiness in pediatric patients 7 years of age and older with narcolepsy is supported by evidence from a double-blind, placebo-controlled, randomized-withdrawal study of immediate-release sodium oxybate. Safety and effectiveness of LUMRYZ in pediatric patients below the age of 7 years have not been established.

GERIATRIC USE

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

HEPATIC IMPAIRMENT

LUMRYZ should not be initiated in patients with hepatic impairment because appropriate dosage adjustments for initiation cannot be made with the available dosage strengths. Patients with hepatic impairment who have been titrated to a maintenance dosage of another oxybate product can be switched to LUMRYZ if the appropriate dosage strength is available.

DEPENDENCE AND TOLERANCE

There have been case reports of withdrawal, ranging from mild to severe, following discontinuation of illicit use of GHB at frequent repeated doses (18 g to 250 g per day) in excess of the recommended dosage range. Signs and symptoms of GHB withdrawal following abrupt discontinuation included insomnia, restlessness, anxiety, psychosis, lethargy, nausea, tremor, sweating, muscle cramps, tachycardia, headache, dizziness, rebound fatigue and sleepiness, confusion, and, particularly in the case of severe withdrawal, visual hallucinations, agitation, and delirium. These symptoms generally abated in three (3) to fourteen (14) days. In cases of severe withdrawal, hospitalization may be required. The discontinuation effects of LUMRYZ have not been systematically evaluated in controlled clinical trials.

Tolerance to LUMRYZ has not been systematically studied in controlled clinical trials. There have been some case reports of symptoms of tolerance developing after illicit use at dosages far in excess of the recommended LUMRYZ dosage regimen.

Please see full [Prescribing Information](#), including **BOXED Warning**.

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 and LUMRYZ. 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 results for alixorexton and LUMRYZ may not be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; alixorexton or LUMRYZ 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 or LUMRYZ in IH, including clinical trial designs, conduct and methodologies; clinical studies for alixorexton may not be initiated or completed on expected timelines or at all; 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.

LUMRYZ® is a registered trademark, and REVITALYZSM is a service mark, of Flamel Ireland Limited, an affiliate of Alkermes plc.

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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