Alkermes Announces Initiation of Phase 3 Brilliance Studies Evaluating Alixorexton for the Treatment of Narcolepsy Type 1 and Type 2

April 1, 2026

DUBLIN--(BUSINESS WIRE)--Apr. 1, 2026-- Alkermes plc (Nasdaq: ALKS) today announced the initiation of the Brilliance Studies, a phase 3 program evaluating the safety and efficacy of alixorexton compared to placebo in adults with narcolepsy type 1 (NT1) and narcolepsy type 2 (NT2). Alixorexton is the company's novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development for the treatment of NT1, NT2 and idiopathic hypersomnia (IH).

The Brilliance Studies program consists of three 12-week, randomized, double-blind, placebo-controlled phase 3 studies evaluating once-daily and split-dose regimens of alixorexton: Brilliance NT1 (Study 302 and Study 304) and Brilliance NT2 (Study 303).

- **Brilliance NT1 Studies (Study 302 and Study 304):** Participants in each Brilliance NT1 study will be randomized to receive one of two dosing regimens of alixorexton or placebo to be taken daily for 12 weeks. The primary endpoint of each study will assess whether participants taking alixorexton experience an increase in wakefulness compared to participants taking placebo, as measured by the change in mean sleep latency on the maintenance of wakefulness test (MWT). Secondary endpoints include change in Epworth Sleepiness Scale (ESS) score, mean weekly cataplexy rate (WCR), patient-reported outcomes related to fatigue, cognition and disease severity, and incidence of adverse events. Each study is expected to enroll approximately 150 patients with NT1 across sites in North America, Asia Pacific and Europe.
- **Brilliance NT2 Study (Study 303):** Participants in the Brilliance NT2 study will be randomized to receive one of three dosing regimens of alixorexton or placebo to be taken daily for 12 weeks. The primary endpoint will assess whether participants taking alixorexton experience an increase in wakefulness compared to participants taking placebo alone, as measured by the change in mean sleep latency on the MWT. Secondary endpoints include change in ESS score, patient-reported outcomes related to fatigue, cognition and disease severity, and incidence of adverse events. The Brilliance NT2 study is expected to enroll approximately 180 patients with NT2 across sites in North America, Asia Pacific and Europe.

"The initiation of the phase 3 Brilliance Studies program marks an exciting and important milestone for alixorexton. Building on the positive findings observed in our large phase 2 program across both narcolepsy type 1 and type 2, we are entering this pivotal stage with confidence. We look forward to evaluating alixorexton in both once-daily and split-dose regimens as we seek to optimize efficacy, safety and dosing flexibility in the development of a potential new treatment option for patients and providers," said Craig Hopkinson, M.D. (MBChB), Chief Medical Officer and Executive Vice President of Research & Development at Alkermes.

Participants who complete one of the Brilliance Studies will be eligible to continue in a long-term, open-label, safety study. More information can be found at www.brilliancestudies.com (for U.S. audiences only) and www.clinicaltrials.gov (Brilliance NT1 – Study 302: NCT07455383; Brilliance NT2: NCT07502443; Brilliance NT1 – Study 304: Coming soon).

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 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 in Vibrance-1 and Vibrance-2, phase 2 studies in patients with NT1 and NT2, respectively. It 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 (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; 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] 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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