



Alkermes Expands ALKS 7290 Development Program With Initiation of Phase 2 Study for the Adjunctive Treatment of Major Depressive Disorder (MDD)

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— Proof-of-Concept Study to Evaluate Effects of Orexin 2 Receptor Agonist on Symptoms of Depression in Adults With and Without Excessive Daytime Sleepiness —

DUBLIN--(BUSINESS WIRE)--Oct. 30, 2026-- [Alkermes plc](#) (Nasdaq: ALKS) today announced the initiation of a phase 2 study evaluating the safety and efficacy of ALKS 7290 as an adjunctive therapy to antidepressants in adult participants with major depressive disorder (MDD). ALKS 7290 is the company's investigational orexin 2 receptor (OX2R) agonist in development for the treatment of attention-deficit hyperactivity disorder (ADHD) and for the adjunctive treatment of MDD.

"Orexin biology represents a compelling area of scientific exploration in neuropsychiatry, given its central role in regulating wakefulness and its broad connections to neural circuits relevant to attention, cognition and mood. Through this phase 2, proof-of-concept study, we aim to assess whether activation of the orexin system may offer a novel approach to addressing symptoms of major depressive disorder," said Craig Hopkinson, M.D. (MBChB), Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "The initiation of this study marks another important milestone in the rapid advancement of our portfolio of orexin 2 receptor agonists and reflects our commitment to maintaining a leadership position in the development of orexin-based therapies across multiple neuropsychiatric indications."

The phase 2, randomized, double-blind, placebo-controlled study will evaluate the safety and efficacy of ALKS 7290 as an adjunctive treatment to standard antidepressants in adults with MDD, including those with and without excessive daytime sleepiness. Participants will be randomized to receive ALKS 7290 or placebo, along with antidepressant therapy (ADT), for six weeks. The study's primary objective is to evaluate the safety and tolerability of ALKS 7290. The secondary objective is to evaluate whether participants taking ALKS 7290 plus ADT experience an improvement in severity of MDD symptoms compared to participants taking placebo plus ADT, as measured by a change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS) and on the Clinical Global Impressions-Severity Scale (CGI-S) at week six.

The study is expected to enroll approximately 180 adult participants with MDD. More information can be found at www.clinicaltrials.gov (NCT07901179).

About ALKS 7290

ALKS 7290 is a novel, investigational, oral orexin 2 receptor (OX2R) agonist in development for the treatment of attention-deficit hyperactivity disorder (ADHD) and as an adjunctive therapy to antidepressants in major depressive disorder (MDD). Orexin, a neuropeptide produced in the lateral hypothalamus, plays a crucial role in regulating wakefulness, and engages multiple downstream pathways and neural circuits relevant to attention, cognition and mood.¹ By targeting the orexin system, ALKS 7290 has the potential to address symptoms relevant to a broad range of disorders characterized by impairments in these domains. ALKS 7290 has been evaluated in a phase 1 study in healthy volunteers and adults living with ADHD, and is currently being evaluated in phase 2 studies in adults with ADHD and adults with MDD.

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 has established a leadership position in orexin biology and is advancing a portfolio of investigational orexin 2 receptor agonists for narcolepsy, idiopathic hypersomnia and other psychiatric and neurological disorders, including attention-deficit hyperactivity disorder (ADHD), major depressive disorder (MDD) 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 ALKS 7290 and the company's other investigational orexin 2 receptor agonists. 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 may not be predictive of results of future stages of ongoing clinical studies, future clinical studies or real-world results; clinical studies may not be initiated or completed on expected timelines or at all; the company's investigational products may be shown to be ineffective or unsafe; the U.S. Food and Drug Administration (FDA) may not agree with the company's regulatory strategies or components of its development program for its investigational products, including clinical trial designs, conduct and methodologies; potential changes in the cost, scope and duration of the company's development programs; 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 Katzman MA, Katzman MP. Neurobiology of the Orexin System and Its Potential Role in the Regulation of Hedonic Tone. *Brain Sciences*. 2022; 12(2):150. <https://doi.org/10.3390/brainsci12020150>

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