Alkermes Announces Initiation of Vibrance-1 Phase 2 Study Evaluating ALKS 2680 for the Treatment of Narcolepsy Type 1

April 24, 2024

DUBLIN, April 24, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced initiation of the Vibrance-1 study, a phase 2 clinical trial evaluating the safety and efficacy of ALKS 2680 compared to placebo in patients with narcolepsy type 1 (NT1). ALKS 2680 is the company's novel, investigational, oral orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy, a chronic, neurological disorder characterized by excessive daytime sleepiness. NT1 is associated with an absence or significant deficiency in orexin levels, and the presence of cataplexy, a sudden loss of muscle tone triggered by strong emotions.

"ALKS 2680 offers the potential to harness the orexin system, the master regulator of wakefulness, by addressing the loss of orexin signaling common in people with narcolepsy type 1. Based on data from our phase 1, proof-of-concept study, we are excited to advance this novel oral compound to phase 2," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "Initiation of the Vibrance-1 study is a significant milestone for the ALKS 2680 development program, and we look forward to further characterizing ALKS 2680's safety and efficacy profile throughout this phase 2 study."

Vibrance-1 is a phase 2, randomized, double-blind, dose-range-finding, placebo-controlled study evaluating the safety and efficacy of ALKS 2680 in people with NT1. Participants will be randomized to receive one of three doses of ALKS 2680 (4 mg, 6 mg or 8 mg) or placebo to be taken once-daily for six weeks. The primary endpoint will assess whether participants taking ALKS 2680 experience a greater decrease in sleepiness compared to participants taking placebo alone, 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) and incidence of adverse events. The study is expected to enroll approximately 80 patients with NT1 across sites in the U.S., Australia and Europe. All participants in the double-blind portion of the study will be eligible to continue in the open-label safety extension portion of the study.

More information can be found at www.clinicaltrials.gov (identifier: NCT06358950) and www.vibrancestudies.com (for U.S. audiences only).

The company expects to initiate Vibrance-2, a planned phase 2 study in patients with narcolepsy type 2, in the second half of 2024.

About ALKS 2680

ALKS 2680 is a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy. Orexin neuropeptides are important regulators of the sleep/wake cycle through OX2R activation, and loss of orexinergic neurons in the brain is associated with excessive daytime sleepiness and cataplexy in narcolepsy.[1] ALKS 2680 was designed to address the underlying pathology of narcolepsy with the goal of improving duration of wakefulness and providing cataplexy control. Once-daily oral administration of ALKS 2680 was previously evaluated in a phase 1 study in healthy volunteers and people living with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia.

About Alkermes plc

Alkermes plc 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 and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders. Headquartered in Dublin, Ireland, Alkermes has a research and development center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, 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 value of ALKS 2680 for the treatment of narcolepsy; and the company's expectations regarding plans and timelines for clinical development activities for ALKS 2680, including study design and initiation of a phase 2 study in patients with narcolepsy type 2. 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 ALKS 2680 could be shown to be ineffective or unsafe; potential changes in the cost, scope and duration of the ALKS 2680 development program; whether preclinical and initial clinical results for ALKS 2680 will be predictive of results of future clinical studies or real-world results; whether future clinical trials or future stages of ongoing clinical trials for ALKS 2680 will be initiated or completed on time or at all; 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, 2023 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] Nagahara T, Saitoh T, Kutsumura N, Irukayama-Tomobe Y, Ogawa Y, Kuroda D, Gouda H, Kumagai H, Fujii H, Yanagisawa M, Nagase H. Design and Synthesis of Non-Peptide, Selective Orexin Receptor 2 Agonists. J Med Chem. 2015 Oct 22;58(20):7931-7. doi: 10.1021/acs.jmedchem.5b00988. Epub 2015 Aug 26. PMID: 26267383.

Alkermes Contacts:
For Investors: Sandy Coombs, +1 781 609 6377
For Media: Gretchen Murphy, +1 781 609 6419

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