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

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DUBLIN, Aug. 22, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced initiation of the Vibrance-2 study, a phase 2 clinical trial evaluating the safety and efficacy of ALKS 2680 compared to placebo in adults with narcolepsy type 2 (NT2). ALKS 2680 is the company's novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy, a chronic, neurological disorder characterized by excessive daytime sleepiness.

"We are pleased to initiate Vibrance-2, a phase 2 clinical study for adults with narcolepsy type 2, based on the data from our phase 1, proof-of-concept study in this patient population. ALKS 2680 is the most advanced investigational orexin 2 receptor agonist currently in development for narcolepsy type 2," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "Across narcolepsy type 1 and narcolepsy type 2, significant unmet need remains, and we look forward to further characterizing the efficacy and safety profile of ALKS 2680 in the Vibrance studies in both of these important patient populations."

Vibrance-2 is a phase 2, randomized, double-blind, dose-range-finding, placebo-controlled study evaluating the safety and efficacy of ALKS 2680 in adults with NT2. Participants will be randomized to receive one of three doses of ALKS 2680 (10 mg, 14 mg or 18 mg) or placebo to be taken once-daily for eight 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 and incidence of adverse events. The study is expected to enroll approximately 80 patients with NT2 across sites in the U.S., Australia and Europe. All participants who complete the double-blind portion of the study will be eligible to continue in the open-label safety extension.

More information can be found at www.clinicaltrials.gov (identifier: NCT06555783) and www.vibrancestudies.com (for U.S. audiences only).

Vibrance-1, a phase 2 study evaluating the efficacy and safety of ALKS 2680 in adults with narcolepsy type 1, is currently enrolling.

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, 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 ALKS 2680 was previously evaluated in a phase 1 study in healthy volunteers and patients with narcolepsy type 1 (NT1), narcolepsy type 2 (NT2) and idiopathic hypersomnia, and is currently being evaluated in the phase 2 Vibrance-1 and Vibrance-2 studies in patients with NT1 and NT2, respectively.

About Narcolepsy

Narcolepsy is a chronic, neurological disorder that affects the brain's ability to regulate the sleep/wake cycle. Excessive daytime sleepiness is the hallmark symptom of narcolepsy; additional symptoms can include sleep paralysis, sleep-related hallucinations and disturbed nighttime sleep.[3] There are two types of narcolepsy: narcolepsy type 1 is characterized by the loss of orexin-producing neurons, and is also associated with cataplexy, a sudden loss of muscle control while a person is awake, often trigged by strong emotions.[4] The underlying neuropathology of narcolepsy type 2 remains to be fully elucidated; however the orexin pathway may play an important role.[5] Narcolepsy affects an estimated 200,000 adults in America, with men and women affected equally.[6]

About the Vibrance Studies

The Vibrance Studies are phase 2, randomized, double-blind, dose-range-finding studies evaluating the safety and efficacy of ALKS 2680 compared to placebo in patients with narcolepsy type 1 (Vibrance-1; NCT06358950) and narcolepsy type 2 (Vibrance-2; NCT06555783). More information can be found at www.vibrancestudies.com (for U.S. audiences only).

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, including narcolepsy. 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 value of ALKS 2680 for the treatment of narcolepsy; and the company's expectations regarding clinical development activities for 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 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.

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[6] Global Narcolepsy Drugs Market, Forecast 2019-2025. Allied Market Research.

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