Alkermes to Present New Clinical Data for ALKS 2680 at SLEEP 2024

May 28, 2024

– Late-Breaking Abstracts Containing Data From the Full Narcolepsy Type 1 Cohort From the ALKS 2680 Phase 1b Study and Vibrance-1 Phase 2 Study Design Accepted for Poster Presentations –

– Findings From In-Depth Qualitative Patient Interviews on the Burden of Narcolepsy Will Also Be Presented –

DUBLIN, May 28, 2024 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced plans to present three posters related to ALKS 2680 at SLEEP 2024, the 38th annual meeting of the Associated Professional Sleep Societies (APSS), taking place June 1-5, 2024 in Houston. ALKS 2680 is the company's novel, investigational, oral orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy.

The company will present two posters during a late-breaking abstract session:

- Data from the full cohort (n=10)[1] of patients with narcolepsy type 1 (NT1) from the phase 1b, proof-of-concept study evaluating single dose oral administration of ALKS 2680. Safety results and pharmacodynamic efficacy assessments evaluating objective (Maintenance of Wakefulness Test [MWT]) and subjective patient-reported (Karolinska Sleepiness Scale [KSS]) measures of sleepiness will be presented.
- Study design and methods for the Vibrance-1 study, a recently initiated phase 2 clinical trial evaluating the safety and efficacy of ALKS 2680 compared to placebo in patients with NT1.

In addition, findings from in-depth, qualitative interviews with patients with NT1 (n=12) and narcolepsy type 2 (NT2) (n=10) will be presented. During the 60-minute interviews, participants described the impact and burden of disease on many facets of their lives, including work and school activities, mental health, activities of daily living and relationships.

"We have made significant progress in the ALKS 2680 program in the last year, including generating proof-of-concept data that validated our design hypothesis and enabled us to initiate our Vibrance-1 phase 2 study in patients with narcolepsy type 1," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President, Research & Development at Alkermes. "We are excited to present data from the full narcolepsy type 1 cohort from our phase 1b study and qualitative findings that bring to light new insights from patients that demonstrate the breadth of impacts narcolepsy can have on patients' lives. We look forward to engaging with the sleep community at this important scientific meeting."

Details of Alkermes' presentations at SLEEP 2024 are as follows:

"Safety and Pharmacodynamic Effects of the Orexin 2 Receptor Agonist ALKS 2680 in Patients with Narcolepsy Type 1: A First-in-Human Phase 1 Study"

- **Abstract ID:** 1323
- **Poster Board Number:** 423
- **Presenter:** Ron Grunstein, M.D., Ph.D., Head of Sleep and Circadian Research at the Woolcock Institute of Medical Research
- **Presentation Date:** The poster will be presented on Tuesday, June 4, 2024 from 10:00–10:45 a.m. CT, during session P-31.

"Vibrance-1: Study Design and Methods for a Phase 2, Randomized, Placebo-Controlled, Parallel Group Study Evaluating the Safety and Efficacy of ALKS 2680 in Patients With Narcolepsy Type 1"

- **Abstract ID:** 1363
- **Poster Board Number:** 462
- **Presenter:** David T. Plante, M.D., Ph.D., Associate Professor of Psychiatry at the University of Wisconsin-Madison
- **Presentation Date:** The poster will be presented on Tuesday, June 4, 2024 from 11:00–11:45 a.m. CT, during session P-31.

"The Burden of Living with Narcolepsy: Patient Perspectives from In-Depth Qualitative Interviews"

- **Abstract ID:** 673
- **Poster Board Number:** 302
- **Presenter:** Michael J. Doane, Ph.D., Alkermes
- **Presentation Date:** The poster will be presented on Wednesday, June 5, 2024 from 11:00–11:45 a.m. CT, during session P-42.

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.[2] 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 and is currently being evaluated in a phase 2 study in patients with narcolepsy type 1.

About the Vibrance-1 Study

Vibrance-1 is a phase 2, randomized, double-blind, dose-range-finding study evaluating the safety and efficacy of ALKS 2680 compared to placebo in patients with narcolepsy type 1. More information can be found at www.clinicaltrials.gov (identifier: NCT06358950) and 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.

[1] Data from the first four patients with NT1 in this phase 1b study were previously presented at the 2023 World Sleep Congress.

[2] 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.

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