



Alkermes to Present First Clinical Data for Orexin 2 Receptor Agonist ALKS 2680 at World Sleep Congress

October 10, 2023

— Oral Presentation to Include Initial Clinical Proof-of-Concept Data in Patients With Narcolepsy Type 1 for ALKS 2680, the Company's Investigational Orexin 2 Receptor Agonist —

DUBLIN, Oct. 10, 2023 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced plans to present new data related to ALKS 2680, the company's novel, investigational orexin 2 receptor (OX2R) agonist in development for the treatment of narcolepsy, at World Sleep Congress, taking place Oct. 20-25, 2023, in Rio de Janeiro. In an oral presentation, the company will present initial data from its ongoing phase 1 study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of ALKS 2680 in healthy volunteers and patients with narcolepsy or idiopathic hypersomnia. This presentation will include initial clinical proof-of-concept data from the first cohort of four patients with narcolepsy type 1.

In a separate oral presentation, the company will share results from a preclinical study evaluating the effect of ALKS 2680 (RDC-264177) on wakefulness and cataplexy in a mouse model of narcolepsy type 1. In a poster presentation, the company will also share findings from recently completed structured interviews evaluating the diagnosis journey and symptoms of people living with narcolepsy type 1 and type 2.

"The design and development of ALKS 2680 is grounded in Alkermes' strong medicinal chemistry capabilities coupled with a strong biological rationale for the use of orexin agonists in the treatment of narcolepsy," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "As a leader in the field of neuroscience, Alkermes is excited to leverage its expertise in pursuit of the development of a potential new treatment option for narcolepsy. We look forward to presenting data at the World Sleep Congress, including our first clinical data for ALKS 2680 in patients with narcolepsy."

Details of the presentations are as follows:

Oral presentations

- **Abstract:** #1600
- **Title:** Preliminary Results from a Phase 1 Study of ALKS 2680, an Orexin 2 Receptor Agonist, in Healthy Participants and Patients with Narcolepsy or Idiopathic Hypersomnia
- **Presenter:** Brendon Yee, Ph.D., Woolcock Institute for Medical Research
- **Presentation Date/Time:** The oral presentation is scheduled to occur on Oct. 23, 2023 during the *Evidence-based approaches for optimizing pharmacologic treatment for narcolepsy* session (9:13 – 9:26 a.m. BRT).

- **Abstract:** #1337
- **Title:** Evaluation of a Novel, Orally Available Orexin 2 Receptor Agonist, on Wakefulness and Cataplexy in a Mouse Model of Type 1 Narcolepsy
- **Presenter:** Brian Raymer, Ph.D., Alkermes
- **Presentation Date/Time:** The oral presentation is scheduled to occur on Oct. 25, 2023 during the *Risk factors for impact on brain function and patient-reported consequences of narcolepsy* session (9:00 – 9:13 a.m. BRT).

Poster presentation

- **Abstract:** #1329
- **Title:** Diagnosis and Symptoms of Narcolepsy from the Patient Perspective: Results from In-Depth Qualitative Interviews
- **Presenter:** Bhaskar Rege, Ph.D., Alkermes
- **Presentation Date/Time:** The poster presentation is scheduled to occur on Oct. 23, 2023 during poster abstract group 2 (6:00 – 7:00 p.m. BRT).

About ALKS 2680

ALKS 2680 is a novel, investigational, oral, selective orexin 2 receptor (OX2R) agonist in development for the treatment of 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 is currently being evaluated in a phase 1 study in healthy volunteers and people living with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia.

About Alkermes

Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder,

and a pipeline of product candidates in development for neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes has a research and development (R&D) 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.

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.

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