Zevra Therapeutics to Present Top-Line Data from the Phase 2 Clinical Trial of KP1077 for Idiopathic Hypersomnia at Sleep Europe 2024

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KP1077 demonstrates clinically meaningful benefits for key IH symptoms

Top-line data provide key information for the design of a Phase 3 study

CELEBRATION, Fla., Sept. 24, 2024 (GLOBE NEWSWIRE) -- Zevra Therapeutics, Inc. (NasdaqGS: ZVRA) (Zevra, or the Company) a commercial-stage rare disease therapeutics company, today announced that Rene Braeckman, Ph.D., Zevra's Senior Vice President of Clinical Development, will present top-line data from the placebo-controlled, double-blind, randomized withdrawal Phase 2 clinical trial (NCT05668754) evaluating the safety and tolerability of KP1077 (serdexmethylphenidate, or SDX) in patients with idiopathic hypersomnia (IH) at Sleep Europe 2024, the 27th Congress of the European Sleep Research Society (ESRS) being held in Seville, Spain, September 24-27, 2024.

Presentation Details

Oral Presentation
Title: Safety and Efficacy of KP1077 in a Phase 2, Placebo-Controlled, Double-Blind, Randomized Withdrawal Study in Patients with Idiopathic Hypersomnia
Date/Time: Friday, September 27, 2024, 8:20 a.m. – 8:30 a.m. CET
Location: Auditorium 1

Poster Presentation
Title: Safety and Efficacy of KP1077 in a Phase 2, Placebo-Controlled, Double-Blind, Randomized Withdrawal Study in Patients with Idiopathic Hypersomnia
Date/Time: Thursday, September 26, 2024, 12:00 noon – 1:30 p.m. CET, and 5:30 p.m. – 6:45 p.m. CET
Category: Neurology
Number: P771

About Sleep Europe 2024

- The biennial congress of the European Sleep Research Society "Sleep Europe" is Europe's leading congress on sleep medicine and sleep research. Every two years, thousands of clinicians, researchers, scientists, students & trainees come together to learn the latest sleep science news and network with their peers. For more information you can access the full program online here: https://esrs.eu/sleep-congress/scientific-programme/

About the KP1077 Phase 2 Trial

The Phase 2 clinical trial (NCT05668754) was a double-blind, placebo-controlled, randomized-withdrawal, dose-optimizing, multi-center study that evaluated the safety and efficacy of KP1077 for the treatment of IH. Part 1 of the trial consisted of a 5-week open-label dose titration phase during which patients were optimized to one of four doses of KP1077 (80, 160, 240, or 320 mg/day). Part 2 of the trial entailed a two-week randomized, double-blind, withdrawal phase, during which two-thirds of the trial participants continued to receive their optimized dose while the remaining one-third received placebo. Participants were assigned into two evenly divided cohorts. The first cohort received a single daily dose just before bedtime, and the second cohort received half the daily dose shortly after awakening and the second half prior to bedtime. Zevra enrolled 66 adult patients with IH in 24 centers in the U.S. into the open-label titration phase of the study and 50 of those patients continued into the double-blind phase.

The primary endpoint was the safety and tolerability of KP1077. The major secondary efficacy endpoint was the change in Epworth Sleepiness Scale (ESS) total score. Additional secondary endpoints included the IH Severity Scale (IHSS), the Sleep Inertia Visual Analog Scale (SIVAS), and a new scale to assess the symptoms and severity of brain fog.

About Idiopathic Hypersomnia

Idiopathic hypersomnia (IH) is a rare sleep disorder characterized by excessive daytime sleepiness (EDS). Patients with IH experience daytime lapses into sleep, or an irrepressible need to sleep that persists even with adequate or prolonged nighttime sleep. Additionally, those with IH have extreme difficulty waking, otherwise known as sleep inertia, severe brain fog, and often fall asleep unintentionally or at inappropriate times. These symptoms of IH often lead to further, even more debilitating problems such as memory lapses, difficulty maintaining focus, and depression. It is estimated, based on claims data, that approximately 37,000 patients in the United States are currently diagnosed with IH, although the total patient population may be much larger due to some patients who have not yet been diagnosed, have been misdiagnosed, or are not currently seeking treatment.

About KP1077

KP1077 (serdexmethylphenidate or SDX) is Zevra's proprietary prodrug of d-methylphenidate (d-MPH) and its sole active pharmaceutical ingredient (API). KP1077 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA), and by the European Commission, for the treatment of IH. The U.S. Drug Enforcement Agency (DEA) has classified SDX, the sole API in KP1077, as a Schedule IV controlled substance based on evidence suggesting SDX has a lower potential for abuse when compared to d-MPH, a Schedule II controlled substance. In addition, KP1077 has intellectual property protection through 2037 and potentially beyond.

About Zevra Therapeutics, Inc.

Zevra Therapeutics, Inc. is a commercial-stage rare disease company combining science, data, and patient needs to create transformational therapies for diseases with limited or no treatment options. Our mission is to bring life-changing therapeutics to people living with rare diseases. With unique, data-driven development and commercialization strategies, the Company is overcoming complex drug development challenges to make new therapies available to the rare disease community.

Expanded access programs are made available by Zevra Therapeutics, Inc. and its affiliates and are subject to the Company's Expanded Access Program (EAP) policy, as published on its website. Participation in these programs is subject to the laws and regulations of each jurisdiction under which each respective program is operated. Eligibility for participation in any such program is at the treating physician's discretion.

For more information, please visit www.zevra.com or follow us on X (formerly Twitter) and LinkedIn.

Cautionary Note Concerning Forward-Looking Statements:

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, and which can be identified by the use of words such as “may,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “assume,” “intend,” “potential,” “continue” or other similar words or the negative of these terms, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation statements regarding anticipated consummation of the proposed offering, market conditions, the satisfaction of customary closing conditions related to the proposed offering, the completion of the offering on the anticipated terms or at all and general economic conditions. Forward-looking statements are based on information currently available to Zevra and its current plans or expectations. They are subject to several known and unknown uncertainties, risks, and other important factors that may cause Zevra’s actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the “Risk Factors” section of Zevra’s Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Quarterly Reports on Form 10-Q, and other filings with the SEC. While Zevra may elect to update such forward-looking statements at some point in the future, except as required by law, Zevra disclaims any obligation to do so, even if subsequent events cause Zevra’s views to change. Although Zevra believes the expectations reflected in such forward-looking statements are reasonable, Zevra cannot assure that such expectations will prove correct. These forward-looking statements should not be relied upon as representing Zevra’s views as of any date after the date of this press release.

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