Zevra Therapeutics Presents Design of Phase 2 Clinical Trial Investigating KP1077 for the Treatment of Idiopathic Hypersomnia (IH) at Beyond Sleepy 2023

June 3, 2023

Zevra is a corporate sponsor of the Hypersomnia Foundation and Beyond Sleepy Conference

CELEBRATION, Fla., June 03, 2023 (GLOBE NEWSWIRE) -- Zevra Therapeutics, Inc. (NasdaqGS: ZVRA) (Zevra, or the Company, formerly Zevra.), a rare disease therapeutics company, today announced that an oral presentation featuring the Phase 2 clinical trial design evaluating KP1077 as a treatment for idiopathic hypersomnia (IH), a rare neurological sleep disorder, will be presented at the Hypersomnia Foundation's 2023 Beyond Sleepy Conference being held June 2 - 4, 2023, in Indianapolis, IN, for people living with IH, narcolepsy and Kleine-Levin syndrome and their supporters. Zevra is a corporate sponsor of the Hypersomnia Foundation and the Beyond Sleep program.

"We are proud to sponsor the Hypersomnia Foundation and the Beyond Sleepy program as part of Zevra's commitment to support the patients and caregivers dealing with rare sleep disorders. We believe the design of the Phase 2 study will allow us to evaluate KP1077's effect on several unmet needs associated with IH, including excessive daytime sleepiness, extreme difficulty waking, and severe brain fog," said Christal Mickle, President, interim Chief Executive Officer and Chief Development Officer of Zevra. "We expect to report interim data from the Phase 2 trial exploring the optimal SDX dose range and regimen as early as Q3 2023."

KP1077 is comprised solely of serdexmethylphenidate (SDX), Zevra's proprietary prodrug of d-methylphenidate. SDX was recently granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of IH. Zevra has also opened an IND to study KP1077 for the treatment of narcolepsy.

Details of Zevra's oral presentation are as follows:

Title:	A Clinical Study with KP1077 in Adults with Idiopathic Hypersomnia
Oral Presentation:	Sunday, June 4, 2023, 10:20 AM – 10:50 AM ET
Speaker:	Rene Braeckman, Ph.D., Sr. Vice President of Clinical Development, Zevra, Orlando, FL USA and Christopher Drake, PhD, FAASM, DBSM, Director of Sleep Research, Henry Ford Health, Detroit, MI
Location:	Fletcher Place

The Company will also attend SLEEP 2023, the 37th annual meeting of the Associated Professional Sleep Societies (APSS), being held in Indianapolis, IN, June 3-7, 2023, and will host booth number 233.

It is estimated that 37,000 patients are currently diagnosed with IH and seeking treatment in the U.S., although the total population may be much larger due to patients not seeking treatment, undiagnosed or misdiagnosed.

About SDX and KP1077:

Serdexmethylphenidate (SDX) is Zevra's proprietary prodrug of d-methylphenidate (d-MPH) and the sole active pharmaceutical ingredient (API) in KP1077, Zevra's lead clinical candidate being developed as a treatment for idiopathic hypersomnia (IH) and narcolepsy. Zevra is currently enrolling a multicenter, dose-optimizing, double-blind, placebo-controlled, randomized-withdrawal Phase 2 clinical trial to evaluate safety and efficacy of KP1077 as a treatment for IH. For more information regarding the Phase 2 trial, visit www.clinicaltrials.gov.

SDX is also the primary API in AZSTARYS®, a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients ages six and older being commercialized in the U.S. by Corium, Inc.

KP1077 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of IH, and 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.

About Zevra:

Zevra Therapeutics is a rare disease company melding science, data, and patient need to create transformational therapies for diseases with limited or no treatment options. With unique, data-driven clinical, regulatory, and commercialization strategies, the Company is overcoming complex drug development challenges to bring much-needed therapies to patients.

Arimoclomol, Zevra's orally-delivered, first-in-class investigational product candidate for the treatment of Niemann-Pick disease type C (NPC), has been granted orphan drug designation, Fast Track designation, Breakthrough Therapy designation and rare pediatric disease designation for NPC by the U.S. Food and Drug Administration (FDA), and orphan medicinal product designation for the treatment of NPC by the European Medicines Agency (EMA). The arimoclomol New Drug Application (NDA) is currently being prepared for a resubmission to the FDA.

KP1077 is Zevra's lead clinical candidate being developed to treat idiopathic hypersomnia (IH) and narcolepsy. KP1077 is comprised solely of serdexmethylphenidate (SDX), Zevra's proprietary prodrug of d-methylphenidate ("d-MPH"). The FDA has granted KP1077 orphan drug designation for the treatment of IH, and the U.S. Drug Enforcement Agency (DEA) has classified SDX 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.

Early access programs are made available by Zevra Therapeutics, Inc. and its affiliates and are subject to the Company's Early Access Program (EAP) policy as published on its website at zevra.com. 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.

Caution 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," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "could," "intend," "target," "predict," or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include without limitation statements regarding our strategic and product development objectives, the promise and potential impact of our preclinical or clinical trial data, including without limitation the initiation, timing and results of any clinical trials or readouts, the number of patients who may be diagnosed with any specific disease or condition, the content, timing or results of any Investigational New Drug ("IND") applications and New Drug Application ("NDA") submissions or resubmissions for arimoclomol, KP1077, or any other product candidates for any specific disease indication or at any dosage, and our strategic and product development objectives, including with respect to becoming a leading, commercially-focused rare disease company. 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 our 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 (formerly Zevra) Annual Report on Form 10-K for the year ended December 31, 2022, as updated in Zevra's (formerly Zevra) Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and Zevra's (formerly Zevra) other filings with the Securities and Exchange Commission. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we cannot assure that such expectations will prove correct. These forward-looking statements should not be relied upon as representing our views as of any date after the date of this press release.

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