



CORRECTION – KemPharm Announces Corporate Name Change to Zevra Therapeutics

February 22, 2023

New name, Greek for “zebra,” is the internationally-recognized symbol for the rare disease community

Branding reflects Company’s commitment to making rare disease therapies available through its research, development, and commercialization efforts

The Company’s common shares will trade on The Nasdaq Global Select Market under the new ticker symbol “ZVRA” starting on or about March 1, 2023

CELEBRATION, Fla., Feb. 22, 2023 (GLOBE NEWSWIRE) -- We are issuing a corrected version of the KemPharm release originally issued this morning at 7:30 am ET. The corrected release follows.

KemPharm, Inc. (NasdaqGS: KMPH) (“KemPharm,” or the “Company”), announced today that it changed its name to Zevra Therapeutics, Inc. (“Zevra”). This name change reflects the Company’s intensified focus and dedication to developing transformational, patient-focused therapies for rare diseases with limited or no treatment options. In conjunction with the name change, the Company will begin trading under the new ticker symbol “ZVRA” on The Nasdaq Global Market on or about March 1, 2023.

“The adoption of the name Zevra, the Greek word for zebra, is an important step in our journey to become a leading rare disease company since the zebra is the recognized symbol of the rare disease community around the world,” said Richard W. Pascoe, Chief Executive Officer of Zevra. “With the launch of our new company name in anticipation of Rare Disease Day next week, we renew our unwavering commitment to stand with this important community as we pursue our primary mission to deliver life-changing treatments to people with rare conditions, their families and caregivers who desperately need better options.”

In May 2022, Zevra, then KemPharm, acquired arimoclomol, an orally-delivered, first-in-class investigational product candidate for the treatment of Niemann-Pick type C disease (“NPC”), from Orphazyme A/S as part of the Company’s long-term vision to evolve into a commercially-driven rare disease therapeutics company. Through the acquisition, Zevra welcomed key new team members with years of valuable rare disease therapeutic research and development experience, maintained the ongoing early access programs and relationships with treatment centers in the U.S. and Europe, and continues to build upon longstanding partnerships within the NPC patient community. NPC, a rare disease with no currently approved treatments in the U.S., primarily affects children and is often fatal, causing progressive loss of brain, nerve, liver, spleen, bone marrow, and lung functions. The U.S. Food and Drug Administration (“FDA”) has granted arimoclomol orphan drug designation, Fast Track designation, and rare pediatric disease designation for treating NPC.

In addition to arimoclomol, Zevra is advancing KP1077, a product candidate based on Zevra’s prodrug of d-methylphenidate, serdexmethylphenidate (“SDX”), which is currently being evaluated in a Phase 2 trial for the treatment of idiopathic hypersomnia (“IH”), a rare sleep disorder. Pending the results from that trial, the Company plans to conduct a pivotal phase 3 study in IH, with the potential to study an expanded indication in narcolepsy.

“The launch of the Zevra brand today marks the next key step in our evolution into a commercially-focused rare disease therapeutics company. People with rare diseases are desperately awaiting treatments, and even one drug that doesn’t reach them is one drug too many,” said Matthew R. Plooster, Chairman of the Zevra Board of Directors. “The Zevra team is actively leveraging their deep scientific and clinical expertise and strategic approach to overcome drug development and regulatory barriers to advance much-needed solutions to the people who need them. Moreover, we have the leadership team and financial resources to get our promising rare disease drug candidates over the regulatory approval finish line and into the U.S. market, which the Board firmly believes will be a key value-driver for patients and shareholders alike.”

Zevra looks ahead to key milestones in 2023, including the resubmission of arimoclomol New Drug Application (“NDA”) to the FDA as early as Q3 2023, an interim and final data readout for KP1077 in IH, and the potential achievement of certain commercial sales milestones for our partnered asset, AZSTARYS®.

Along with the new name, the Company has a new logo and website. Visit zevra.com to learn more.

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 Neimann-Pick type C ("NPC"), has been granted orphan drug designation, Fast Track designation and rare pediatric disease designation for NPC by the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA").

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, including without limitation, 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 statements regarding: 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 timing or results of any Investigational New Drug ("IND") applications and New Drug Application ("NDA") submissions for arimoclomol, KP1077, or any other product candidates for any specific disease indication or at any dosage, and our strategic and product development objectives. These 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 KemPharm) Annual Report on Form 10-K for the year ended December 31, 2021, as updated by Zevra's (formerly KemPharm) Quarterly Report on Form 10-Q for the three months ended September 30, 2022, and Zevra's (formerly KemPharm) 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.

Contacts:

Nichol Ochsner
+1 (732) 754-2545
nochsner@zevra.com

Jennifer Arcure
+1 (917) 603-0681
Jennifer.arcure@evokegroup.com



Source: KemPharm