KemPharm Announces Research Affirming Serdexmethylphenidate's Lower Potential for Abuse Featured in Peer-Reviewed Publication, Current Medical Research & Opinion

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Three clinical studies demonstrated serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), yielded significantly lower abuse-related effects compared to d-MPH

CELEBRATION, Fla., June 01, 2022 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NasdaqGS: KMPH) (KemPharm, or the Company), a specialty pharmaceutical company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS), neurodegenerative and lysosomal storage diseases, today announced that a manuscript summarizing the results of three clinical studies involving serdexmethylphenidate (SDX), KemPharm's prodrug of dexmethylphenidate (d-MPH), was published in the peer-reviewed journal, *Current Medical Research & Opinion.* The research concluded that SDX has significantly lower potential for abuse and minimal stimulant-like adverse events compared to d-MPH.

SDX is the sole active pharmaceutical ingredient (API) in KP1077, KemPharm's lead clinical product candidate. KemPharm is developing KP1077 as a treatment for idiopathic hypersomnia, a rare neurological sleep disorder, and narcolepsy. SDX is also primary active pharmaceutical ingredient (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. 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.

As described in *Current Medical Research & Opinion,* three Phase 1 randomized, double-blind, placebo- and active-controlled crossover studies were conducted to evaluate the abuse-related effects of SDX compared to d-MPH via oral, intranasal and intravenous routes of administration. The three clinical studies documented that SDX via all three routes of administration yielded statistically significantly lower abuse-related drug effects and stimulant-like adverse effects (AEs) than molar equivalent doses of d-MPH. Further, investigators employed visual analog scale assessments recommended for use in human abuse potential studies that included other "at-the-moment" effects, such as Feeling High, Good Effects, Bad Effects, Any Effects, and Drowsiness/Alertness and retrospectively assessed endpoints that measured the overall balance of drug effects, such as Take Drug Again and Overall Drug Liking. In all three studies, secondary endpoints were generally consistent with the primary endpoint outcomes.

"We are very pleased that this important research demonstrating SDX's significantly lower abuse potential in comparison to d-MPH was published in the peer-reviewed journal, *Current Medical Research & Opinion*," stated Travis C. Mickle, Ph.D., President and CEO of KemPharm. "Lower abuse potential is one of many beneficial properties of SDX that we believe differentiates the technology from other stimulant-based medications, bringing enhanced value potential to any product that utilizes SDX, including KP1077 and AZSTARYS."

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery, development and commercialization of novel treatments for rare central nervous system (CNS), neurodegenerative and lysosomal storage diseases. KemPharm has a diverse product portfolio, combining a clinical-stage development pipeline with revenue-generating NDA-stage and commercial assets. The pipeline includes arimoclomol, an orally-delivered, first-in-class treatment for Niemann-Pick disease type C (NPC), and KP1077, which the company is developing as a treatment for idiopathic hypersomnia (IH), a rare neurological sleep disorder, and narcolepsy. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a once-daily treatment for ADHD in patients aged six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), which is being commercialized by Corium, Inc. in the U.S., and APADAZ®, an immediate-release combination product containing benzhydrocodone, KemPharm's prodrug of hydrocodone, and acetaminophen, which is being commercialized by KVK-Tech, Inc. in the U.S. For more information on KemPharm and its pipeline of product candidates visit www.kempharm.com or connect with us on Twitter, LinkedIn, Facebook and YouTube.

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 timing and results of any clinical trials or readouts, the timing or results of any IND applications, the potential uses or benefits of arimoclomol, KP1077, SDX or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of KemPharm's product candidates, the success or timing of the launch or commercialization of AZSTARYS or any other products or related sales milestones, the sufficiency of cash to fund operations, our plans or ability to seek funding, our plans with respect to our share repurchase program, and our strategic and product development objectives. These forward-looking statements are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of 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 KemPharm's Annual Report on Form 10-K for the year ended December 31, 2021, as updated by the Quarterly Report on Form 10-Q for the three months ended March 31, 2022, and KemPharm's 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 can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

This press release also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk

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