KemPharm's KP415 and Serdexmethylphenidate (SDX) Prodrug to be Featured in Multiple Sessions at the 2021 APSARD Virtual Conference

January 14, 2021

Combination of Oral and Poster Presentations Scheduled for January 15, 2021

CELEBRATION, Fla., Jan. 14, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that research involving KP415 and serdexmethylphenidate (SDX) will be featured in an oral symposium and three poster presentations during the 2021 American Professional Society of ADHD and Related Disorders (APSARD) Virtual Conference. The 2021 APSARD Virtual Conference (APSARD 2021) is being be held January 15-17, 2021.

KP415 is KemPharm's investigational product candidate for the treatment of attention deficit hyperactivity disorder (ADHD). Serdexmethylphenidate (SDX) is KemPharm's prodrug of d-methylphenidate (d-MPH). KP415 consists of SDX co-formulated with immediate-release d-MPH. A New Drug Application (NDA) for KP415 is currently under review with the U.S. Food and Drug Administration (FDA) with an anticipated PDUFA date of March 2, 2021.

"We are pleased KP415 and the potentially advantageous properties of SDX will be featured in an oral symposium and three posters during APSARD 2021," said Travis Mickle, Ph.D., President and CEO of KemPharm. "As the regulatory review of KP415 advances towards its PDUFA date of March 2, 2021, we believe the research presented at APSARD 2021 highlights important data on the potential for KP415 to address unmet needs for treating patients with ADHD, including the observed safety and efficacy of KP415 and the observed lower abuse potential of SDX."

The oral symposium, "Novel Pharmacology and Technology Approaches to the Non-Medical Use of Stimulants," is scheduled for Friday, January 15, 2021, from 3:30 p.m. to 5:00 p.m., ET, and will feature multiple speakers who will address issues related to the non-medical use of stimulants, as well as products in development that are designed to reduce the risk of abuse. During the symposium, Megan Shram, Ph.D., Adjunct Professor, University of Toronto, will highlight the oral, intranasal, and intravenous abuse potential of SDX, including research demonstrating SDX has a lower intrinsic abuse potential than d-MPH when administered via the most common routes of abuse for other MPH products currently available.

The three poster presentations involving KP415 and SDX will also be featured on January 15th. The first presentation, "Efficacy and Safety of KP415 (Serdexmethylphenidate and d-Methylphenidate) Capsules in Children with ADHD: A Randomized, Double-Blind, Placebo-Controlled Laboratory Classroom Study," details the multicenter, double-blind, randomized, placebo-controlled, laboratory classroom study of KP415 to investigate the efficacy, safety, and tolerability of once-daily KP415 capsules vs. placebo in children age 6 to 12 years with ADHD. To be presented by Scott H. Kollins, Ph.D., Professor, Department of Psychiatry and Behavioral Sciences; Director, Duke ADHD Program, Duke University School of Medicine, the clinical study concluded that KP415 was efficacious and generally well tolerated for treating ADHD in children 6 to 12 years of age.

The second poster presentation, "Safety and Tolerability of KP415 (Serdexmethylphenidate and d-Methylphenidate) Capsules in Children with ADHD: A 12-month, Open-Label Safety Study," provides an analysis of the multicenter, dose-optimized, open-label safety study of KP415 to investigate the safety and tolerability of once-daily KP415 capsules in children (6 to 12 years of age) with ADHD treated for up to 12 months. To be presented by Ann Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine, the research determined that KP415 was generally well tolerated and demonstrated sustained efficacy in children with ADHD treated for up to one year.

The third poster presentation titled, "In Vitro Tampering Assessment of Serdexmethylphenidate, a Novel Prodrug of d-Methylphenidate," highlights in vitro studies designed to assess the extent to which SDX can be physically or chemically manipulated to yield immediately available d-MPH for potential abuse. Submitted by Sven Guenther, Ph.D., KemPharm's Executive Vice President, Research and Development, the research concluded that SDX is stable under a broad range of experimental conditions and cannot readily be converted to d-MPH in vitro.

About KemPharm:

KemPharm is a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs to treat serious medical conditions through its proprietary LAT® (Ligand Activated Therapy) technology. KemPharm utilizes its proprietary LAT® technology to generate improved prodrug versions of FDA-approved drugs as well as to generate prodrug versions of existing compounds that may have applications for new disease indications. KemPharm's prodrug product candidate pipeline is focused on the high need areas of attention deficit hyperactivity disorder, or ADHD, and stimulant use disorder. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of

d-methylphenidate, but have differing duration/effect profiles. In addition, KemPharm has received FDA approval for APADAZ®, an immediate-release combination product containing benzhydrocodone, a prodrug of hydrocodone, and acetaminophen. For more information on KemPharm and its pipeline of prodrug 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 made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements, including the timing of the PDUFA date and potential approval of the KP415 NDA, or the potential clinical benefits of KP415 and/or SDX, are based on information currently available to KemPharm and its current plans or expectations and are subject to a number of uncertainties and risks that could significantly affect current plans. Risks concerning KemPharm's business are described in detail in KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, KemPharm's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and KemPharm's other Periodic and Current Reports filed with the Securities and Exchange Commission. KemPharm is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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