KemPharm Announces Research Involving Serdexmethylphenidate to be Featured in Two Poster Presentations at the APSARD 2022 Annual Conference

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Data highlight key pharmacokinetic properties of serdexmethylphenidate that are instrumental to its consistent and smooth release of d-MPH

CELEBRATION, Fla., Jan. 11, 2022 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NasdaqGS: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, announced today that research involving serdexmethylphenidate (SDX), the company's proprietary prodrug of d-methylphenidate (d-MPH), will be featured in two poster presentations during the American Professional Society of ADHD and Related Disorders 2022 Annual Conference (APSARD 2022) being held virtually January 13-16, 2022. Both posters will be presented by Rene A. Braeckman, Ph.D., Vice President, Clinical Development for KemPharm and will be accessible to registered meeting attendees beginning January 13th.

SDX is the primary active pharmaceutical ingredient in AZSTARYS®, a once-daily product for the treatment of ADHD in patients aged six years and older, approved by the U.S. Food and Drug Administration in March 2021, and being commercialized by Corium, Inc. SDX is also the basis of several other development-stage products being developed by KemPharm, including KP879 (Stimulant Use Disorder) and KP1077 (Idiopathic Hypersomnia). The U.S. Drug Enforcement Agency (DEA) has classified SDX as a Schedule IV controlled substance, which is a lower schedule than all other currently available methylphenidate-based products.

The first poster, titled, “Mass Balance and Metabolic Pathway Following Oral Administration of [^{14}C]-Serdexmethylphenidate, a Novel Prodrug of d-Methylphenidate,” reported data from an open-label, single radiolabeled–dose, nonrandomized study in eight healthy adult male subjects which evaluated the absorption, metabolism, and excretion of SDX following oral administration of radiolabeled 60 mg [^{14}C]-SDX Cl (molar equivalent to 30 mg d-MPH HCl). Results from the study demonstrated that mass balance was achieved following administration of SDX, which was converted to d-MPH without forming novel major metabolites. The research also affirmed that conversion of SDX to d-MPH likely occurs within the lower gastrointestinal tract.

The second poster, titled, “Dose Proportionality and Effects of Food on the Pharmacokinetics of Single-Entity Serdexmethylphenidate (SDX),” reported on two studies involving SDX, which examined the dose proportionality of SDX-derived d-MPH after single doses of 20, 40, or 60 mg of SDX Cl and the effects of food on the pharmacokinetics (PK) of SDX-derived d-MPH after administration of 60-mg SDX Cl capsules. Results from the studies concluded that key PK measures of SDX appeared to increase in a dose-proportional manner with an increase in SDX dose and that food did not impede the production or absorption of SDX-derived d-MPH.

“The research being presented at APSARD 2022 highlights important PK properties of SDX that are believed to be instrumental in the prodrug’s ability to enable a consistent and smooth release of d-MPH,” said Travis Mickle, Ph.D., President and CEO of KemPharm. “The results of these studies suggest that SDX produces a dose-proportionate effect, is not impacted by the presence or lack of food, and is fully absorbed, metabolized and excreted following oral administration. For prescribers, these attributes are recognized as key factors in converting patients to AZSTARYS.”

The studies to be presented at APSARD 2022 were sponsored by KemPharm. The posters will be available for viewing via the conference’s “e-poster” platform on January 13th and viewing will remain open until 30 days post-meeting. Following the conference, the posters will be added to “Publications & Posters” in the News & Publications section of the Company’s website at http://www.kempharm.com.

About AZSTARYS®:

AZSTARYS is an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years or older. AZSTARYS consists of SDX, KemPharm’s prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH. Corium, Inc., a portfolio company of Gurnet Point Capital, is leading all commercialization efforts for AZSTARYS in the U.S.

The complete approved prescribing information for AZSTARYS may be downloaded in PDF format here:
https://kempharm.com/wp-content/uploads/2021/03/AZSTARYS-Master-Label-Final_20210302.pdf

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, and the recipient of the 2021 David J. Gury Company of the Year award presented by BioFlorida. 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, stimulant use disorder (SUD) and CNS rare diseases, including idiopathic hypersomnia (IH). In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a new once-daily treatment for ADHD in patents age six years and older containing KemPharm’s prodrug, serdexmethylphenidate (SDX), and APADAZ ®, an immediate-release combination product containing benzhydrocodone, KemPharm’s 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, include the ongoing commercialization of AZSTARYS®, and the potential benefits of other KemPharm product candidates. 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 uncertainties and risks that could significantly affect current plans, including market conditions and the possibility that the share repurchase program may be suspended or discontinued at any time. Risks concerning KemPharm’s business are described in detail in KemPharm’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and KemPharm’s other filings 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.

KemPharm Contacts:

Tiberend Strategic Advisors, Inc.
Jason Rando/Maureen McEnroe, CFA
(212) 375-2665 / 2664
jrando@tiberend.com
mmcenroe@tiberend.com

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