KemPharm Announces Research Involving AZSTARYS® and Serdexmethylphenidate to be Featured in Poster Presentations at Multiple Medical Conferences during ADHD Awareness Month (October)

October 20, 2021 11:30 AM EDT

CELEBRATION, Fla., Oct. 20, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced that research involving AZSTARYS® and serdexmethylphenidate (SDX), the company's proprietary prodrug of d-methylphenidate (d-MPH), will be featured in poster presentations during multiple medical conferences being held in October (ADHD Awareness Month). Presentations will be given at the following conferences:

Event:	American Academy of Child & Adolescent Psychiatry 68th Annual Meeting (AACAP 2021)
Date:	October 18-30, 2021
Title:	Single-Dose Pharmacokinetics of Serdexmethylphenidate/d-Methylphenidate Capsules in Children and Adolescents with ADHD and Healthy Adults: An Evaluation of Age and Body Weight

Event:	Psych Congress
Date:	October 29-November 1, 2021
Title:	Steady-State Pharmacokinetics and Relative Bioavailability of Serdexmethylphenidate/d-Methylphenidate, a Treatment for Attention-Deficit/Hyperactivity Disorder, Containing a Novel Prodrug of d-Methylphenidate

During AACAP 2021, Rene A. Braeckman, Ph.D., Vice President, Clinical Development for KemPharm, will present the poster titled, "Single-Dose Pharmacokinetics of Serdexmethylphenidate/d-Methylphenidate Capsules in Children and Adolescents with ADHD and Healthy Adults: An Evaluation of Age and Body Weight," which highlights data from two Phase 1 clinical trials evaluating the pharmacokinetic (PK) properties of single doses of AZSTARYS administered to children, adolescents, and adults. Researchers demonstrated that the shape of the PK curves in children and adolescents was similar to that in adults. Consistent with published studies of methylphenidate PK, exposure of d-MPH decreased with age due to body weight differences between younger children and adolescents. However, when normalized by dose and body weight, d-MPH exposure levels and PK parameters were comparable between children, adolescents, and adults. Researchers concluded that body weight rather than age is the appropriate scaling factor for d-MPH exposure levels after AZSTARYS dosing in children and adolescents.

"We are pleased that clinical research involving AZSTARYS and SDX have been accepted for poster presentations during multiple medical conferences in October, coinciding with ADHD Awareness Month," said Travis Mickle, Ph.D., President and CEO of KemPharm. "Our goal in developing AZSTARYS was to advance the treatment of ADHD by bringing to market a product that could address several key shortcomings of other commercially available ADHD drugs. The data being presented at these conferences highlights several properties of AZSTARYS and SDX that, we believe, will be attractive to patients and prescribers who have been seeking innovative therapies that address the symptoms of ADHD, while also reducing the side-effects sometimes encountered with stimulant-based medications."

About Attention Deficit Hyperactivity Disorder (ADHD):

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common mental disorders affecting children. ADHD also affects many adults. Symptoms of ADHD include inattention (not being able to keep focus), hyperactivity (excess movement that is not fitting to the setting) and impulsivity (hasty acts that occur in the moment without thought).[1] An estimated 8.4% of children and 2.5% of adults have ADHD.[23]

The U.S. ADHD market accounted for approximately $17.5 billion of revenue in 2019 with a year-over-year prescription growth rate greater than four percent (4%). Within this, the branded portion of the ADHD market was approximately $7.4 billion in 2019, with extended-release products representing more than 95% of the branded prescriptions. In 2019, the methylphenidate segment of the ADHD market accounted for approximately 20 million prescriptions and $4.9 billion in sales.

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.

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. 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). KemPharm's lead clinical development candidate for the treatment of SUD, KP879, is based on its prodrug of d-methylphenidate, known as serdexmethylphenidate (SDX). In addition, KemPharm has received FDA approval for AZSTARYS®, a new once-daily treatment for ADHD in patents age six years and older, and 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 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 Quarterly Report on Form 10-Q for the quarter ended June 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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[1] American Psychiatric Association (https://www.psychiatry.org/patients-families/adhd/what-is-adhd)

[2] Danielson, ML, et al. Prevalence of Parent-Reported ADHD Diagnosis and Associated Treatment Among U.S. Children and Adolescents, 2016. Journal of Clinical Child & Adolescent Psychology, Volume 47, 2018 - Issue 2

[3] Simon V , Czobor P, Bálint S , et al: :Prevalence and correlates of adult attention-deficit hyperactivity disorder: a meta-analysis. Br J Psychiatry194(3):204–211, 2009

Source: KemPharm