KemPharm Announces AZSTARYS® Clinical Data to be Featured in Poster Presentation at the 2021 Virtual International Conference on ADHD

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Data demonstrate efficacy of AZSTARYS in children, including 30-minute onset of action and 13-hour duration of effect

Corium Continues Commercialization Effort in U.S.

CELEBRATION, Fla., Nov. 05, 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® will be featured in a poster presentation during the 2021 Virtual International Conference on ADHD, co-hosted by Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) with the ADHD Coaches Organization (ACO), and the Attention Deficit Disorder Association (ADDA), taking place November 4-6, 2021.

The poster, titled, "Serdexmethylphenidate/d-Methylphenidate Capsules for Children With ADHD: Effects on SKAMP-C Evaluated Over 13 Hours in a Randomized, Double-blind, Placebo-controlled Laboratory Classroom Study," detailed a multicenter, pivotal study that assessed the efficacy and safety of AZSTARYS in 150 children aged 6 to 12 years with a diagnosis of ADHD. Results indicated that the trial's primary endpoint was met, demonstrating significantly greater improvements from baseline on the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) scale in subjects treated with AZSTARYS versus a placebo ($p<0.001$). Results also showed the onset of treatment effect began 30 minutes after dosing with AZSTARYS and continued for 13 hours post dosing. Lastly, AZSTARYS was generally well-tolerated with adverse events (AEs) typical of stimulant therapy.

"We are very pleased that data from the pivotal clinical trial of AZSTARYS were accepted for presentation during the 2021 Virtual International Conference on ADHD," said Travis Mickle, Ph.D., President and CEO of KemPharm. "These efficacy results formed the backbone of the New Drug Application that was approved by the FDA and is now reflected in the product label for AZSTARYS. No other FDA-approved ADHD drug offers such immediate and long-lasting effect, which, when combined with its additional attributes, makes AZSTARYS, in our view, the first truly differentiated ADHD drug to be introduced in decades."

Approved by the U.S. Food and Drug Administration (FDA) in March 2021, AZSTARYS is a once-daily product for the treatment of ADHD in patients aged six years and older consisting of serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH. Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital, is commercializing AZSTARYS in the U.S.

The data presented at the 2021 Virtual International Conference on ADHD is from a study sponsored by KemPharm. The poster can be viewed via the conference's virtual platform and is also available under "Publications & Posters" in the News & Publications section of the Company's website at http://www.kempharm.com.

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] It is estimated that 8.4% of children and 2.5% of adults have ADHD.[2, 3]

The U.S. ADHD market accounted for approximately $17.7 billion of revenue in 2020 with a year-over-year prescription growth rate of approximately one percent (1%). Within this, the branded portion of the ADHD market was approximately $7.6 billion in 2020, with extended-release products representing more than 98% of the branded prescriptions. In 2020, the methylphenidate segment of the ADHD market accounted for approximately 19 million prescriptions and $4.5 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.

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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