AZSTARYS®, An Innovative ADHD Treatment Developed by KemPharm, to be Featured in a Poster Presentation at the 2021 Psych Congress

October 27, 2021

Pharmacokinetic data from two clinical studies of AZSTARYS demonstrated its rapid onset of action and long duration of effect

CELEBRATION, Fla., Oct. 27, 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® is being featured in a poster presentation during the 2021 Psych Congress being held both virtually and in-person in San Antonio, Texas, from October 29 through November 1, 2021. The presentation highlights data from clinical studies assessing the relative bioavailability and the steady-state pharmacokinetics (PK) of AZSTARYS.

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 (GPC), is commercializing AZSTARYS in the U.S.

The poster, titled, "Steady-State Pharmacokinetics and Relative Bioavailability of Serdexmethylphenidate/d-Methylphenidate, a Treatment for Attention-Deficit/Hyperactivity Disorder, Containing a Novel Prodrug of d-Methylphenidate," detailed data from two separate pharmacokinetic studies. The first study compared the amount of d-MPH that reached systemic circulation (relative bioavailability) in 30 patients administered a single dose of AZSTARYS and a single dose of extended-release d-MPH hydrochloride (HCl). Data in the poster revealed that following a single dose of AZSTARYS (SDX/d-MPH capsules), d-MPH plasma concentrations increased rapidly and were sustained through late-day time points. This extended-duration exposure profile is governed by the unique properties of the prodrug, SDX, which is gradually converted to active d-MPH after reaching the intestinal tract.

The second study in the poster presentation highlighted data demonstrating that AZSTARYS administered once daily over a four-day period achieved steady-state d-MPH plasma concentration before the third daily dose of AZSTARYS. Steady-state pharmacokinetics is a metric used to determine the time it takes for drug levels to remain consistent in the body when administered continuously.

"We are pleased that data highlighting AZSTARYS were accepted for scientific presentation during the 2021 Psych Congress," said Travis Mickle, Ph.D., President and CEO of KemPharm. "The results of the studies show the unique PK profile of AZSTARYS that accounts for its rapid onset and extended duration of effect. The research being presented at the 2021 Psych Congress highlights key attributes of AZSTARYS that could be potentially attractive to prescribers who are seeking innovative treatments for controlling ADHD symptoms."

The studies presented at the 2021 Psych Congress were 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] An estimated 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. Corium, Inc. is commercializing 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. 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