KemPharm Announces U.S. Launch of Innovative ADHD Treatment AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate capsules) by Corium, Inc.

July 21, 2021

CELEBRATION, Fla., July 21, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced the U.S. commercial launch of AZSTARYS™, a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older. Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital (GPC), is leading the commercialization of AZSTARYS in the U.S.

AZSTARYS was approved by the U.S. Food and Drug Administration (FDA) in March 2021 and consists of serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH. Subsequent to the approval of AZSTARYS, SDX was classified as a Schedule IV controlled substance by the U.S. Drug Enforcement Administration (DEA). AZSTARYS is classified as a Schedule II controlled substance as it includes a 70:30 mixture of SDX (Schedule IV) and d-MPH (Schedule II).

"The U.S. commercial launch of AZSTARYS is a significant milestone for KemPharm and an important advancement in the treatment of ADHD, a disease indication that has seen little innovation in recent years," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "Since the FDA's approval of AZSTARYS in March, the various teams across Corium have been working diligently to ready AZSTARYS for its U.S. launch. We believe Corium has built a best-in-class commercial organization, and as a result, we expect the market potential for AZSTARYS will be maximized. It is great news that patients living with ADHD will now have a new treatment option with the potential to address previously unmet needs because of AZSTARYS' unique prodrug platform."

"The launch of AZSTARYS provides patients with ADHD, their caregivers, and their clinicians with a first-of-its-kind treatment that offers both rapid and extended ADHD symptom improvement because of the dual action of its formulation using the prodrug SDX with IR d-MPH," said Perry J. Sternberg, President and CEO of Corium. "We believe Corium's extensive ADHD and commercialization expertise will help ensure a successful AZSTARYS launch, and I am incredibly proud of our team for reaching this milestone, a significant inflection point in Corium's journey to become a leader in the CNS space."

Ann Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine and an investigator in the AZSTARYS clinical trial, commented: "My decades of research in the ADHD space and treating patients with the condition has allowed me to be a firsthand witness to the evolution of ADHD drug development and implementation. Based on this perspective, I believe that AZSTARYS represents a true advance in ADHD medicine due to its unique combination of SDX, a prodrug of d-MPH, co-formulated with immediate release d-MPH, which provides both immediate release and consistent benefit throughout the course of the day. As a result, I believe AZSTARYS will soon become a drug of preference for physicians seeking to provide effective care for patients with ADHD."

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 $17.5 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, including the potential benefits of AZSTARYS, the potential commercial success of AZSTARYS, and AZSTARYS becoming a drug of preference for physicians treating patients with ADHD, 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 March 31, 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