KemPharm Announces FDA Approval of AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate capsules, for oral use, CII), A New Once-Daily Treatment for ADHD

March 3, 2021 4:31 AM EST

Conference Call and Live Audio Webcast Scheduled for Tomorrow, Wednesday, March 3, at 8:30 a.m. ET

CELEBRATION, Fla., March 02, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application for (NDA) AZSTARYS™ (formerly referred to as KP415), a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older. AZSTARYS consists 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), will lead the commercialization of AZSTARYS per the definitive collaboration and license agreement (the "License Agreement") between KemPharm and an affiliate of GPC. Corium expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

"The FDA approval of the AZSTARYS NDA is a transformational event for KemPharm and, we believe, an important advancement in the treatment of ADHD," said Travis C. Mickle, Ph.D., President and CEO of KemPharm. "Today's approval highlights both the value potential of SDX, our prodrug of d-MPH, and the ability of our LAT® platform technology to develop new prodrugs of approved medications that improve one or more of the attributes of the parent drug. We look forward to continuing our support of Corium as they forge ahead with the commercial launch of AZSTARYS."

"Today's approval by the FDA is met with great excitement for this innovative new ADHD therapy and the potential it holds to meet the unmet needs of children, adolescents and adults," said Perry Sternberg, CEO of Corium. "Our team is mobilized to put our commercial plans into action as the approval of the AZSTARYS NDA now enables us to finalize our preparations for commercial launch as early as the second half of this year."

Ann Childress, M.D., President of the Center for Psychiatry and Behavioral Medicine and an investigator in the AZSTARYS clinical trial, commented: "The ADHD industry, and specifically the MPH space, has seen little innovation in recent years, leaving prescribers and patients desiring new treatment options. In my research and practice, three properties are repeatedly cited by patients and their caregivers as being underserved by current ADHD medications: onset of action, duration of effect and consistency of therapy. Having investigated AZSTARYS and directly observed its clinical impact on patients, I believe this product will be an important new tool for physicians to use in providing effective care for patients with ADHD."

As a result of the FDA's approval of the AZSTARYS NDA, KemPharm has earned a regulatory milestone payment following FDA approval as provided under the License Agreement, and KemPharm is working with GPC to evaluate the related provisions and amounts. Under the License Agreement, KemPharm may be eligible for up to $468 million in regulatory and sales milestone payments, as well as tiered royalty payments, on a product-by-product basis for net sales, with potential percentages up to the mid-twenties for U.S. net sales, and up to the mid-single digits of net sales in each country outside of the U.S.

The complete label for AZSTARYS, including prescribing information and important safety information, may be found at www.kempharm.com/pipeline-products/#kp415.

The complete label may also be downloaded in PDF format here: http://ml.globenewswire.com/Resource/Download/4f63af91-9427-40da-b881-82a5e22a0315.

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation tomorrow, Wednesday, March 3, 2021, at 8:30 a.m. ET, to discuss FDA approval of the AZSTARYS NDA. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)
- (678) 509-7538 (international)
- Conference ID: 4272912

An audio webcast with slide presentation will be accessible via the Investor Relations section of the Company's website, http://investors.kempharm.com/. An archive of the webcast and presentation will be available for 90 days beginning tomorrow, March 3, 2021, at approximately 9:30 a.m. ET.

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 ADHD market accounted for approximately $17.9 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 97% 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: http://ml.globenewswire.com/Resource/Download/4f63af91-9427-40da-b881-82a5e22a0315.

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 product portfolio is highlighted by AZSTARYS™, an FDA-approved, once-daily treatment for attention deficit hyperactivity disorder (ADHD) which is based on serdexmethylphenidate, (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH). KemPharm is also advancing several clinical development candidates, including KP484 for the treatment of ADHD and KP879 for the treatment of Stimulant Use Disorder (SUD). AZSTARYS, KP484, and KP879 are all based on SDX. In addition, KemPharm has received FDA approval 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, including without limitation KemPharm's proposed development and commercial timelines, 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 statements about the commercial launch of AZSTARYS, including the timing of launch, the regulatory milestone payment, and the potential clinical benefits of AZSTARYS. 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 the "Risk Factors" sections of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, KemPharm's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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:

Jason Rando/Maureen McEnroe, CFA
Tiberend Strategic Advisors, Inc.
(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