KemPharm Announces Serdexmethylphenidate (SDX) Has Been Classified as a Schedule IV Controlled Substance by the DEA

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KP879, KemPharm's Lead Product Candidate Based on SDX and Intended for the Treatment of Stimulant Use Disorder (SUD), Could Be Schedule IV, If Approved by the FDA

CELEBRATION, Fla., May 07, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced that serdexmethylphenidate (SDX), KemPharm's proprietary prodrug of d-methylphenidate (d-MPH) and the primary active pharmaceutical ingredient (API) in AZSTARYS™, has been 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), respectively.

According to the "Schedules of Controlled Substances: Placement of Serdexmethylphenidate in Schedule IV," which has been published in the Federal Register (federalregister.gov/d/2021-09738), the DEA concluded that SDX meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the Controlled Substances Act (CSA). This determination was based on an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of SDX by the U.S. Department of Health and Human Services (HHS), which concluded that "SDX is related in action and effect to the schedule IV substance phentermine, and can therefore be expected to have a similar potential for abuse." Notably, in its report, HHS affirmed that "in clinical studies, SDX demonstrated a lower potential for abuse when compared to d-MPH," a Schedule II controlled substance under the CSA.

"We are pleased with the publication of the analysis conducted by HHS and the DEA's decision to classify SDX as a Schedule IV controlled substance, affirming our research which indicated SDX has a lower potential for abuse when compared to d-MPH," stated Travis C. Mickle, Ph.D., President and CEO of KemPharm. "We believe the combination of the AZSTARYS product label received at approval, the Schedule IV designation for SDX and the economic terms of the recently announced amendment to our Licensing Agreement with GPC will provide the opportunity to generate substantial value for KemPharm for many years to come."

"The decision by the DEA further builds our confidence in how parents, healthcare providers and payors will view AZSTARYS as an option to consider for patients living with ADHD," said Perry Sternberg, President and CEO of Corium, Inc., which will commercialize AZSTARYS in the U.S. "We believe the knowledge that SDX, which comprises 70% of the API in AZSTARYS, has been classified as a Schedule IV controlled substance, will be meaningful when considering the potential benefit of SDX's lower abuse potential. We are enthusiastically continuing our commercial launch preparations to bring AZSTARYS to the U.S. market as early as the second half of 2021."

"The DEA's decision may also positively impact the value proposition for KemPharm's lead pipeline product candidate, KP879, and potentially other SDX-based products," Dr. Mickle continued. "KP879, which is intended for the treatment of stimulant use disorder, is based on SDX as the sole API. If approved, KP879 could be a Schedule IV product, and physicians who are treating patients seeking to overcome addictions to cocaine, methamphetamine or other stimulants may be able to prescribe KP879 with the knowledge that the product candidate could have a significantly lower potential for abuse. For a therapeutic area that currently has no approved treatments available, this determination could be a game changer."

Per the License Agreement, as amended, with an affiliate of Gurnet Point Capital (GPC), KemPharm has earned a $10 million milestone payment which is payable within 30 days following the scheduling determination of SDX by the DEA.

About AZSTARYS™:

AZSTARYS™ is an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and 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 timing of the potential commercial launch of AZSTARYS, the potential perception of AZSTARYS by parents and physicians and its potential differentiation from other ADHD medications, the potential clinical benefits and differentiation of KP879, the potential for the approval of KP879, and if approved, the potential that KP879 could be

classified as a schedule IV controlled substance by the DEA, 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 Annual Report on Form 10-K for the year ended December 31, 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.

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