KemPharm Announces Amendment to Licensing Agreement with Gurnet Point Capital Affiliate Following FDA Approval of AZSTARYS ™

April 8, 2021

Amendment Increases Total Potential Regulatory and Sales Milestone Payments to $590 Million, and Adds a New Top-Level Tier for Royalties on U.S. Net Sales

Conference Call and Live Audio Webcast Scheduled for Today, Thursday, April 8, at 4:30 p.m. ET

CELEBRATION, Fla., April 08, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced an amendment to the definitive collaboration and license agreement (the License Agreement) with an affiliate of Gurnet Point Capital (GPC), a private investment firm focused on the life sciences and medical technology sectors. The License Agreement provides for an exclusive worldwide license to develop, manufacture and commercialize KemPharm's product candidates containing serdexmethylphenidate (SDX) and d-methylphenidate (d-MPH), including 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 was approved by the U.S. Food and Drug Administration (FDA) on March 2, 2021.

Under the terms of the amended License Agreement, KemPharm is now eligible to receive a total of up to $590 million in future regulatory and sales milestone payments for AZSTARYS, as well as tiered royalty payments on a product-by-product basis for net sales. Royalty rates range, on a product-by-product basis, from a percentage in the high single digits up to the mid-twenties for U.S. net sales, and a percentage in the low to mid-single digits of net sales in each country outside of the U.S. Under the original terms of the License Agreement, KemPharm was eligible to receive up to $468 million in regulatory and sales milestones, having already received $15 million from previously achieved milestones.

Per the amended terms, KemPharm will receive a regulatory milestone payment of $10 million for the FDA approval of AZSTARYS which is due five (5) calendar days after the effective date of the amendment. In addition, KemPharm is eligible to receive an additional regulatory milestone payment of $10 million within thirty (30) days following the scheduling determination of SDX, the prodrug component of AZSTARYS, by the U.S. Drug Enforcement Administration (DEA). The DEA action is expected to be completed on or around June 2, 2021. Other changes include the addition of four new sales milestone tiers, including three lower-level sales tiers and a new top level sales tier. Potential sales milestones available under the amended License Agreement total $550 million, as compared to $420 million in the original agreement. Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital (GPC), is leading the commercialization of AZSTARYS and expects to make AZSTARYS commercially available in the U.S. as early as the second half of 2021.

"The last few weeks since AZSTARYS was approved have been an exciting and busy time as we have worked with our partners at GPC and Corium to re-evaluate the commercial potential of AZSTARYS based on the final approved label, and negotiated adjustments to the economics of our License Agreement to optimize investment in the commercial launch and, ultimately, long-term value creation. The outcome is that more resources will be invested during the initial phases of the commercial timeline for AZSTARYS which we believe could lead to greater market share and potentially accelerate the ramp to peak, as compared to our original forecasts, if successful," said Travis C. Mickle, Ph.D., President and CEO of KemPharm.

Dr. Mickle continued, "Our recently completed financial restructuring, by which we eliminated all of our debt and built a cash reserve of more than $77 million, has provided KemPharm with the financial flexibility to work with GPC to re-allocate a portion of the original regulatory milestone amounts associated with FDA approval of AZSTARYS to the commercialization efforts underway at Corium. In exchange for re-allocating of a portion of the original regulatory milestone payments, the amended License Agreement now has a greater total value in terms of total regulatory and sales milestones, and increased royalty rates throughout the life of the patents that cover AZSTARYS, which extend to 2037."

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

Conference Call Information:

KemPharm will host a conference call and live audio webcast with slide presentation today, Thursday, April 8, 2021, at 4:30 p.m. ET, to discuss the amendments to the License Agreement. Interested participants and investors may access the conference call by dialing either:

- (866) 395-2480 (U.S.)

- (678) 509-7538 (international)
- Conference ID: 3593808

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 today, April 8, 2021, at approximately 5:30 p.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: 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.

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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

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 the timing of the potential commercial launch of AZSTARYS, the potential greater market share and ramp to commercial peak, potential regulatory and sales milestone and royalty payments pursuant to the License Agreement, and the potential clinical benefits of AZSTARYS or any of the Company's product candidates 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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