KemPharm Confirms Receipt of $10 Million Milestone Payment for FDA Approval of AZSTARYS™ Per License Agreement with Affiliate of Gurnet Point Capital

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Eligible to Receive Additional Near-Term $10 Million Milestone Payment Following DEA Scheduling of SDX

CELEBRATION, Fla., April 21, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company engaged in the discovery and development of proprietary prodrugs, today announced receipt of a regulatory milestone payment of $10 million for the FDA approval of AZSTARYS™ in accordance with the recently amended definitive collaboration and license agreement with Commave Therapeutics, SA, an affiliate of Gurnet Point Capital (the License Agreement).

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. As previously announced, Corium, Inc. (Corium), a portfolio company of Gurnet Point Capital, is leading U.S. commercialization efforts for AZSTARYS.

Corium is led by Perry Sternberg, President and CEO, who is a biotechnology and pharmaceutical industry leader with more than 25 years of commercial experience across a wide range of therapeutic areas in diverse markets. Prior to joining Corium, Mr. Sternberg served a dual role at Shire Plc (Shire) as the Head of U.S. Commercial for seven therapeutic area business units, as well as the Chief Commercial Officer/Head of the Neuroscience Division, before the acquisition of Shire by Takeda Pharmaceutical Corporation Limited in early 2019.

Under the terms of the License Agreement and including the $10 million regulatory milestone payment just received, KemPharm is 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. The next regulatory milestone payment related to AZSTARYS is $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.

"We continue to work collaboratively with Corium in preparation for the commercial launch of AZSTARYS," stated Travis C. Mickle, Ph.D., President and CEO of KemPharm. "Corium is targeting a product launch in the second half of 2021, and we believe the uptake for AZSTARYS could be substantial given the strong and differentiated product characteristics as reflected in the label which directly addresses key prescriber and patient needs not met by currently available methylphenidate treatments for ADHD."

"The Corium team is deep in ADHD commercialization experience and excited about the FDA approval of AZSTARYS. Since approval, we have significantly ramped-up our commercialization activities to prepare for a successful launch," said Perry Sternberg, Corium's President and CEO. "We have seen positive receptivity and reactions from customers due to the potential differentiation that AZSTARYS may provide for patients." Mr. Sternberg concluded, "We are energized and driving forward to optimize the commercial launch later this year."

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 for substantial market uptake of AZSTARYS, potential regulatory and sales milestone and royalty payments pursuant to the License Agreement, the timing of the scheduling determination of SDX by the DEA, and the potential clinical benefits of AZSTARYS, 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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