KemPharm Receives FDA Clearance to Initiate KP879 Clinical Program for the Treatment of Stimulant Use Disorder

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Financial Restructuring and Nasdaq Re-Listing Process Completed

CELEBRATION, Fla., Jan. 27, 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 completed its review of the Investigational New Drug (IND) application for KP879 (KP879 IND), concluding that the Company may proceed with its planned clinical investigation of the product candidate. KemPharm expects to initiate the clinical program for KP879 in 2021. In addition, the Company reported that it has completed its multi-phase process to regain its Nasdaq listing and to restructure its balance sheet.

KP879 is being developed as an extended-duration, agonist replacement therapy for the treatment of Stimulant Use Disorder (SUD), a condition for which there are no FDA-approved medications. KP879 utilizes serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate. SDX is also the primary active pharmaceutical ingredient (API) of KP415 and KP484, the Company's product candidates which are intended for the treatment of attention-deficit/hyperactivity disorder (ADHD). It is anticipated that certain data from previously completed research may be leveraged for KP879, which KemPharm believes could potentially streamline the development timeline of KP879.

"We are pleased that the FDA has accepted the KP879 IND, enabling us to initiate the clinical program for KP879 currently planned to begin mid-year 2021," said Travis C. Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "KP879 showcases the potential of SDX as a platform technology. In addition to KP879, SDX is the primary API for KP415, our lead product candidate for the treatment of ADHD, which is currently under review with the FDA with an expected PDUFA date of March 2, 2021."

Per the definitive collaboration and license agreement with an affiliate of Gurnet Point Capital (GPC) dated September 3, 2019, GPC holds an option to negotiate the terms of a new license agreement with KemPharm for the rights to develop and commercialize KP879 once the Company has established clinical proof-of-concept.

Multi-Phase Financial Restructure Process Completed

Over the last several weeks, KemPharm has completed a series of transactions as part of its long-term initiative to restructure its balance sheet and fundamentally improve the Company's financial position in order to pursue its ongoing goal of creating shareholder value. Starting with debt of $93.1 million, net of discounts, as of March 31, 2018, the Company began a long-term process to address its debt, entering into a variety of debt exchanges and other transactions that have steadily reduced, and now provided the means to completely eliminate, its outstanding debt. In addition, the Company has regained its listing on The Nasdaq Capital Market.

In December 2019, the Company completed the first phase of its financial restructuring process entering into certain amendments to its debt agreements to extend the debt maturity dates to March 31, 2021, as well as entering into a debt exchange agreement with Deerfield, allowing for the conversion of approximately $18.7 million of nominal debt into a combination of preferred and common shares, which was completed on August 7, 2020. After receiving shareholder authorization for the Company's Board to effect a reverse stock split, the Company entered the second phase of its financial restructuring process. The following provides a brief summary of the transactions recently completed:

- On December 20, 2020, the Company entered into the December 2020 Exchange Agreement with the Deerfield Lenders, which provided that upon completion of an equity offering of at least $40 million, the Deerfield Lenders would exchange additional debt into equity. In addition, the maturity date for the remainder of the debt would be extended to March 31, 2023. Subsequently, on December 28, 2020, the Company reported that its other lenders, Delaware Street Capital and Kingdon Capital (together with Deerfield, the Lenders) had joined the December 2020 Exchange Agreement.

- On December 23, 2020, a reverse stock split of 1-for-16 shares was made effective as a preparatory step to potentially qualify for re-listing on The Nasdaq Capital Market.

- On January 8, 2021, the Company announced pricing of a follow-on equity offering of $50 million, at a price of $6.50 per share, with an issuance of a combination of common shares and pre-funded warrants to purchase 7,692,307 common shares, as well as the issuance of warrants to purchase an additional 7,692,307 at an exercise price of $6.50 per share (the Offering Warrants). This transaction closed on January 12, 2021, with net proceeds to the Company of approximately $46.4 million after underwriting discounts and commissions.

- On January 8, 2021, shares of the Company's common stock were re-listed and began trading on The Nasdaq Capital Market.

- On January 12, 2021, pursuant to the December 2020 Exchange Agreement, the Company made a cash debt repayment of $30.3 million to the Lenders and completed the exchange of approximately $31.5 million of debt into preferred shares, leaving a remainder debt amount of approximately $7.6 million with a maturity date of March 31, 2023.

- Yesterday, January 26, 2021, the Company announced a warrant exchange and inducement transaction with certain of holders of the Offering Warrants, whereby such holders agreed to exercise for cash the Offering Warrants to purchase 6,620,358 shares of the Company's common stock in exchange for the Company's agreement to issue new warrants (the Inducement Warrants) to purchase up to 7,944,430 shares of the Company's common stock, which is equal to 120% of the number of shares of the Company's common stock issued upon exercise of the Offering Warrants. As a result of this transaction, the Company will receive gross proceeds of approximately $44.0 million.

- We intend to use approximately $8.0 million of the proceeds from the warrant exchange and the inducement transaction to repay the remaining debt, including the related prepayment premium.

"The successful completion of this series of transactions, culminating in aggregate gross proceeds of approximately $94 million, has allowed the Company to regain its listing on The Nasdaq Capital Market, created the opportunity to eliminate all of the Company's debt, and has provided a substantial amount of new capital to propel the Company's efforts to create shareholder value," said LaDuane Clifton, KemPharm's Chief Financial Officer. "We are now positioned with a solid balance sheet and a significantly extended cash runway that provides greater operating flexibility as we look forward to the KP415 PDUFA date on March 2, 2021," Mr. Clifton concluded.

About Stimulant Use Disorder (SUD):

Stimulant Use Disorders include those marked by abuse/misuse of cocaine, methamphetamines, prescription stimulant products that contain methylphenidate or amphetamine, and numerous designer stimulants including, for example, 3,4-methylenedioxypyrovalerone (MDPV) and 4-methylmethcathinone (mephedrone) ("bath salts"). According to the Substance Abuse and Mental Health Services Administration (SAMHSA), in 2018, approximately 2.6 million Americans over 12 years of age had a SUD attributed to their use of methamphetamine (1,100,000), cocaine (977,000), or prescription stimulants (561,000). To date, there are no FDA-approved medications for the treatment of SUD.

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, and stimulant use disorder. KemPharm's co-lead clinical development candidates for the treatment of ADHD, KP415 and KP484, are both based on a prodrug of d-methylphenidate, but have differing duration/effect profiles. 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, including the timing of potential initiation of the clinical program for KP879, the ability to use data from previously completed research for KP879 and the potential to streamline the development timeline of KP879, the potential clinical benefits of KP879, or any of KemPharm's other product candidates, the expected PDUFA date for KP415, the potential of SDX as a platform technology, the potential cash runway for KemPharm's operating forecast and the potential repayment of its remaining outstanding debt. 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 KemPharm's Annual Report on Form 10-K for the year ended December 31, 2019, and KemPharm's other Periodic and Current Reports filed 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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