KemPharm Completes KP1077 Pre-IND Meeting Process with FDA

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KemPharm Positioned to Submit IND Application for KP1077 for Idiopathic Hypersomnia by Mid-2022

CELEBRATION, Fla., Feb. 23, 2022 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NasdaqGS: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced the successful completion of its pre-IND (Investigational New Drug) meeting process with the U.S. Food and Drug Administration (FDA) for KP1077. KemPharm is developing KP1077 as a treatment for idiopathic hypersomnia (IH), a rare neurological sleep disorder whose symptoms include excessive daytime sleepiness (EDS), extreme difficulty waking (sleep inertia), severe brain fog, and falling asleep unintentionally or at inappropriate times (narcolepsy).

Per recent interactions with the FDA, KemPharm has confirmed that it may proceed with the submission of an IND application for KP1077, which the company expects to submit by mid-year 2022. As part of those interactions, the FDA provided collaborative feedback including that additional non-clinical studies will not be needed for the initiation of the KP1077 clinical development program given the data already available for serdexmethylphenidate (SDX). SDX is KemPharm's proprietary prodrug of d-methylphenidate (d-MPH) and the sole active pharmaceutical ingredient (API) for KP1077.

"The successful completion of the pre-IND meeting process with the FDA for KP1077 affirms our plan to submit the IND application by mid-year 2022 and, following that, potentially initiate a Phase 2 trial of KP1077 in IH as early as the third quarter of 2022," stated Travis Mickle, Ph.D., President and Chief Executive Officer of KemPharm. "Noteworthy in our interactions with the FDA was confirmation that we will be able to utilize certain non-clinical studies from the KP415, now known as AZSTARYS®, and KP879 development programs as part of the data package for KP1077 due to both drugs being developed from SDX, our prodrug of d-MPH. This should allow us to realize meaningful cost and time savings, which may expedite the KP1077 program and, ultimately, the potential future filing of a New Drug Application (NDA)."

Dr. Mickle continued, "The ability to rapidly develop novel, high-value treatments in areas of unmet need has been a cornerstone of the KemPharm approach. With KP1077, we are now advancing a novel product candidate designed to address the most debilitating effects of IH and provide patients with a solution that has the potential to improve upon currently available treatment options."

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) platform technology. KemPharm utilizes its proprietary LAT® platform 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 idiopathic hypersomnia (IH) and other CNS/rare diseases. In addition, the U.S. Food and Drug Administration (FDA) has approved AZSTARYS®, a new once-daily treatment for ADHD in patents age six years and older containing KemPharm's prodrug, serdexmethylphenidate (SDX), and APADAZ ®, an immediate-release combination product containing benzhydrocodone, KemPharm's 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation and which can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue," "could," "intend," "target," "predict," or the negative versions of those words or other comparable words or expressions, although not all forward-looking statements contain these identifying words or expressions. Forward-looking statements are not guarantees of future actions or performance. These forward-looking statements include statements regarding KemPharm's pipeline of product candidates including the clinical development of KP1077, and the potential timing and/or ultimate filing of an IND application or an NDA, upcoming milestones, including without limitation the commencement of a Phase 2 trial for KP1077 and the timing and results of any clinical trials or readouts. 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 known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of KemPharm's Annual Report on Form 10-K for the year ended December 31, 2020, KemPharm's Quarterly Report for the quarter ended September 30, 2021, and KemPharm's other filings with the U.S. Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

This press release also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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