KemPharm, Inc. Announces Orange Book Listing for Six Patents Covering Serdexmethylphenidate (SDX) and Confirmation of NCE Status

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SDX is KemPharm's proprietary prodrug of d-methylphenidate (d-MPH) and the primary active pharmaceutical ingredient (API) in AZSTARYS™

CELEBRATION, Fla., May 26, 2021 (GLOBE NEWSWIRE) -- KemPharm, Inc. (NASDAQ: KMPH), a specialty pharmaceutical company focused on the discovery and development of proprietary prodrugs, today announced that six U.S. patents governing serdexmethylphenidate (SDX), KemPharm's prodrug of d-methylphenidate (d-MPH), and AZSTARYS™, are now listed in the U.S. Food and Drug Administration (FDA) publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." In addition, the Orange Book listing confirms the status of SDX, which is the primary API in AZSTARYS, as a new chemical entity (NCE), which provides at least five years of market exclusivity.

AZSTARYS was conditionally approved by the FDA in March 2021 as a once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years and older. Recently, SDX was classified as a Schedule IV controlled substance by the U.S. Drug Enforcement Administration (DEA) and thereby formally approved for marketing in the U.S. SDX is the primary API in KP484, an investigational ADHD treatment, and the only API in KP879, an investigational treatment for stimulant use disorder (SUD).

"The Orange Book listing of these six patents covering SDX's composition of matter and its method of use is an important step in protecting AZSTARYS and KemPharm's additional SDX-based products from patent infringements," said Travis C. Mickle, Ph.D., President and Chief Executive of KemPharm. "Moreover, this is another significant value-building event for SDX as we advance towards the anticipated commercialization of AZSTARYS and the expected initiation of the clinical program for KP879."

Among the listed patents, U.S. Patent No. 9,079,928, due to expire on July 27, 2032, is a composition of matter patent. The other five patents are all slated to expire on December 9, 2037 and include U.S. Patent No. 10,584,112 and U.S. Patent No. 10,584,113 (composition of matter and method of use patents), U.S. Patent No. 10,759,778 (method of use), U.S. Patent No. 10,858,341 (composition of matter and method of use) and U.S. Patent No. 10,954,213 (composition of matter). All or some of these patents may be subject to patent term extension.

The Orange Book listing confirms that SDX, which is contained within AZSTARYS, is an NCE, which provides five years of market exclusivity that expires on May 7, 2026. During the NCE exclusivity period, the FDA cannot approve a new drug application (NDA), an abbreviated new drug application (ANDA) or a 505(b)(2) application for another product based on the same API, regardless of indication. If another party attempts to rely upon the clinical data for SDX for a generic or other new drug application, which cannot be filed prior to four years post-approval, the patent holder can sue and receive an automatic 30-month stay, which has the practical implication of extending the exclusivity period for up to an additional two and a half years. These market exclusivity periods run parallel to the applicable patent exclusivity period but can provide the benefit of avoiding patent defense costs during the first four years of NCE exclusivity and during the early years of sales and marketing.

Patents listed in the Orange Book cover drugs that the FDA has approved and deemed both safe and effective for the general public's use. Inclusion in the book's list of patents can make it easier for drug makers to monitor for new generic drugs that could potentially arrive on the U.S. market and infringe on their own patents.

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.

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 potential benefits of the NCE exclusivity, and the potential benefits of the patent exclusivity for SDX, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, 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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