



KemPharm, Inc. Announces Initiation of Phase 1 Trial of KP106 for ADHD

-Completes Discovery and All Preclinical Work plus IND Submission in Less Than Two Years-

North Liberty, IA -- October 22, 2009 – KemPharm, Inc. today announced that it has commenced a Phase 1 clinical trial in healthy volunteers of its novel prodrug compound, KP106, which is in development for the treatment of attention-deficit hyperactivity disorder (ADHD). KP106, a new chemical entity (NCE) composed of *d*-amphetamine and a ligand, is the lead investigational candidate from KemPharm's proprietary ligand activated therapy (LAT) platform, which creates improved versions of FDA-approved drugs. KemPharm began the KP106 program in 2007 and has initiated the Phase 1 clinical trial of this candidate in less than 24 months.

“Preclinical studies suggest that the prodrug properties of KP106 may offer an improved side effect profile, including reduced weight loss and cardiovascular effects, and decreased abuse potential compared with current amphetamine-based treatments for ADHD,” said Robert Karr, M.D., Chief Executive Officer of KemPharm. “We are therefore very excited to begin clinical studies of KP106 because, if it continues to demonstrate results similar to the compelling preclinical data, KP106 may provide a valuable new treatment option for patients with ADHD.”

“The extremely rapid progress to Phase 1 in less than two years from program inception is a testament to the inherent strength and efficiency of our LAT platform,” commented Travis Mickle, Ph.D., President and Chief Scientific Officer of KemPharm. “Further, we anticipate continuing the aggressive development timeline for KP106, with the data from this trial expected in early 2010 and the filing of an NDA projected for 2012.”

KemPharm utilizes its LAT platform to generate ligand-activated, prodrug versions of FDA-approved drugs, allowing for potentially shorter development timelines and reduced development costs. The Company is also developing candidates for pain, other central nervous system disorders, cardiovascular disease and cancer. The second candidate generated by the LAT platform, KP201, is in preclinical studies for the treatment of pain.

KemPharm recently closed a \$3.8 million Series B financing round, the proceeds of which will be used to advance KP106 and KP201 through Phase 1 studies. The Company's business strategy is to demonstrate proof-of-concept for its prodrug candidates in Phase 1 clinical trials in an accelerated timeframe, then execute collaboration agreements with strategic development partners to complete the candidates' development and commercialization.

About the KP106 Phase 1 Clinical Trial

The Phase 1 trial is a single dose, crossover study in which twenty-four healthy volunteers will receive KP106 25mg and Vyvanse® 30mg, separated by a seven day washout period. The objectives of the study include evaluation of the pharmacokinetics of KP106, Vyvanse

and *d*-amphetamine, and safety and tolerability, including cardiovascular effects. Vyvanse is a FDA-approved drug indicated for the treatment of ADHD.

About KP106

KP106, KemPharm's lead prodrug candidate for the treatment of ADHD, is composed of *d*-amphetamine and a ligand. In preclinical studies, the pharmacokinetic profile of *d*-amphetamine released from KP106 has a lower C_{max} and delayed T_{max} compared to the profile observed with Adderall XR®, an approved treatment for ADHD. The preclinical studies suggest that KP106 may have an improved side effect profile, including reduced weight loss and cardiovascular effects, and decreased abuse potential. KemPharm projects the filing of an NDA for KP106 by the end of 2012.

About KP201

KP201, KemPharm's prodrug candidate for the treatment of pain, is composed of hydrocodone combined with a ligand. Preclinical studies suggest that KP201 may have reduced abuse potential compared with currently approved narcotic analgesics. KemPharm expects to file an IND for KP201 in the second half of 2010 and may be able to use the 505(b)(2) regulatory pathway for a more rapid development timeline.

About KemPharm, Inc.

KemPharm, Inc. is focused on the discovery and development of new chemical entities (NCEs) to treat serious medical conditions through its proprietary and broadly applicable ligand activated therapy (LAT) prodrug technology. KemPharm utilizes its LAT prodrug technology to generate improved versions of FDA-approved drugs. These NCEs create new composition-based intellectual property, may have shorter development timelines and reduced development costs, and may be eligible for 505(b)(2) regulatory submissions of New Drug Applications (NDAs). The Company's business strategy includes seeking strategic development partners following rapid clinical proof-of-concept demonstration in Phase 1. KemPharm also plans to explore discovery stage alliances with industry leaders, leveraging its prodrug know-how and LAT technology platform. KemPharm is developing candidates for ADHD, pain, other central nervous system disorders, cardiovascular disease and cancer.

www.kempharm.com

Forward Looking Statements and Information

This release contains forward-looking statements which are not based upon historical fact, including, without limitation, statements regarding the development timeline and potential benefits of KemPharm Inc.'s product candidates. Forward-looking statements involve various assumptions, known and unknown risks, and uncertainties which may cause actual results or events to be materially different and adverse from those expressed in or implied by the forward-looking statements. Such assumptions, risks and uncertainties may relate to difficulties or delays in discovery, development, testing, and regulatory approval of the company's product candidates, and unexpected adverse side effects or inadequate therapeutic efficacy of the product candidates. The forward-looking statements in this release speak only as of this date, and KemPharm disclaims any obligation to update publicly any forward-looking statement except as required by law. Additionally, with respect to the pre-clinical

results discussed in this release, there is no certainty that human clinical results will be consistent with pre-clinical results.

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