KemPharm, Inc. Announces Positive Results from Phase 1 Trial of KP106 for ADHD

-Data Establish Proof of Concept for KP106 and Validate LAT Prodrug Approach-

North Liberty, IA – January 11, 2009 – KemPharm, Inc. today announced positive results from a Phase 1 clinical trial of KP106, its novel prodrug for attention-deficit hyperactivity disorder (ADHD). KP106, a new chemical entity (NCE) composed of the active pharmaceutical compound *d*-amphetamine and a ligand, was created using KemPharm's proprietary Ligand Activated Therapy (LAT) prodrug approach. The pharmacokinetic (PK) profile of *d*-amphetamine released from KP106 is modified versus the profile observed with Vyvanse®, a currently marketed amphetamine-based stimulant for ADHD. These results suggest that KP106 may have an improved side effect profile and a lower propensity for drug abuse. Most significantly, the data reported from the trial proved that KP106 is cleaved and *d*-amphetamine is released as predicted in humans; therefore establishing proof of concept for KP106.

"The results of our first trial of KP106 reinforce our belief that this will be the next-generation ADHD treatment. The human PK data are highly consistent with our expectations and predict that KP106 will deliver the efficacy of current amphetamine-based ADHD treatments with the additional benefit of reduced potential for abuse. Based on these findings, KemPharm will pursue a path to further define the extent of abuse deterrence achievable with KP106," stated Sven Guenther, Ph.D., Vice President of Research at KemPharm. "Additionally, KP106 is highly water soluble and this should enable us to develop the first ever thin film dosage form for ADHD which we believe will increase compliance, particularly in the pediatric population."

The Phase 1 trial was a single-dose, crossover study in which twenty-four healthy volunteers received KP106 25 mg or Vyvanse® 30 mg orally. The objectives of the study included evaluation of the pharmacokinetics of intact KP106, intact Vyvanse and the active pharmaceutical compound, *d*-amphetamine, released from both KP106 and Vyvanse®, as well as safety and tolerability. Similar to previous preclinical data on KP106, the plasma *d*-amphetamine levels demonstrate that KP106 has a PK profile that is differentiated from Vyvanse®, which may result in an improved side effect profile. Furthermore, following KP106 dosing, plasma *d*-amphetamine exposure extended beyond 12 hours consistent with KP106 being a once a day product. Just as important, the data indicate that KP106 behaved predictably, resulting only in plasma levels of *d*-amphetamine, with no quantifiable levels of intact prodrug in the plasma. More specifically, the plasma levels of intact KP106 prodrug were below the limit of quantitation at all time points, whereas intact Vyvanse® levels were detectable and similar to previous reports. Subjects who received KP106 had no adverse events beyond those reported with Vyvanse®.

"KemPharm continues to deliver on our aggressive development timelines with the announcement of these clinical data less than two years after the initiation of the KP106 program. We believe that these results demonstrate unequivocal proof of concept for KP106", commented Travis Mickle, Ph.D., President and Chief Scientific Officer at KemPharm. "Further, due to the streamlined regulatory approach available for prodrugs such as KP106, we are preparing to begin the registration trial for KP106 towards the end of 2010."

About KP106

KP106, KemPharm's lead prodrug candidate for the treatment of ADHD, is composed of *d*-amphetamine and a ligand. In preclinical studies, KP106 demonstrated unique abuse deterrent properties along with pharmacokinetics indicative of an attenuated amphetamine exposure as compared to Vyvanse®. These data predict that patients receiving KP106 may experience decreased side effects and decreased risk of abuse typically associated with stimulants. Importantly, KemPharm is positioning KP106 to be the first ever thin film dosage form for ADHD to address compliance issues, in particular, for the pediatric patient population. KemPharm projects the filing of a new drug application (NDA) for KP106 by the end of 2012.

About KemPharm, Inc.

KemPharm, Inc. is focused on the discovery and development of NCEs to treat serious medical conditions through its proprietary and broadly applicable LAT prodrug approach. KemPharm utilizes its LAT prodrug technology to generate improved versions of FDA-approved drugs. The resulting NCEs enable the creation of 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 NDAs. The Company's business strategy includes seeking strategic development partners following rapid clinical proof of concept demonstration in a Phase 1 trial. 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, "will," "should," "expect," "plan," "predict," "believe," "may" and "project." Such statements, including statements relating to developments, progress, plans of our clinical and preclinical programs, and potential benefits of KemPharm Inc.'s product candidates, 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, results that are inconsistent with preclinical results, unexpected adverse side effects, or inadequate therapeutic efficacy of the product candidates. The forward-looking statements in this release speak only as of this

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Contacts:

KemPharm, Inc.

Kate Holt

319-665-2575

E-mail: info@kempharm.com

MacDougall Biomedical Communications

Chris Erdman

781-235-3060

E-mail: cerdman@macbiocom.com