



## **KemPharm, Inc. Announces Plans to Launch KP106 as First Oral Film Dosage Form for ADHD**

*KemPharm Enters Collaboration with MonoSol Rx to Co-Develop and Commercialize KP106*

**North Liberty, IA --** April 25, 2011 – KemPharm, Inc. today announced that KP106, its clinical candidate for Attention Deficit/Hyperactivity Disorder (ADHD), will be formulated and developed in an oral film dosage form pursuant to an exclusive collaboration agreement with MonoSol Rx relating to the development, commercialization and manufacture of KP106.

KP106 is a new chemical entity (NCE) comprised of *d*-amphetamine, and was identified utilizing KemPharm's proprietary ligand activated therapy (LAT) approach. Phase 1 human clinical trial results demonstrated pharmacokinetics that predict a superior safety profile for KP106 as compared to Vyvanse®, a currently marketed amphetamine stimulant for ADHD. In addition, preclinical studies suggest that the prodrug properties of KP106 may offer unique abuse deterrent properties as compared with current amphetamine-based treatments for ADHD.

Under the terms of the exclusive collaboration agreement, MonoSol Rx, the developer of PharmFilm® technology and a drug delivery company specializing in rapid dissolving prescription film pharmaceutical products, has acquired the exclusive manufacturing rights for KP106. In exchange for these manufacturing rights and a right to receive a share of any royalties or other value associated with KP106, MonoSol Rx will be responsible for the majority of formulation costs and the manufacturing costs through commercial launch. KemPharm will retain controlling ownership of the commercial rights for KP106, while intellectual property rights created during the joint-development program will be shared by both companies.

“We are enthusiastic about the synergies that will result from this collaboration. Due to its abuse deterrent properties combined with its compliance film dosage form to address issues plaguing existing pediatric pill dosage forms, KP106 is poised to become the next generation ADHD therapy,” commented Travis Mickle, Ph.D., President and Chief Executive Officer, KemPharm.

“This collaboration is a natural strategic fit for MonoSol Rx and our PharmFilm® technology,” commented A. Mark Schobel, President and Chief Executive Officer, MonoSol Rx. “KemPharm is a true pharmaceutical innovator, and through the combination of KP106 and PharmFilm®, there is the potential to introduce a novel ADHD product that could represent a safer, more convenient treatment option for ADHD patients. We look forward to working together to maximize the commercial potential of KP106 through this partnership.”

### **About KP106**

KP106, KemPharm's lead prodrug candidate for the treatment of ADHD, is composed of *d*-amphetamine and a ligand. In clinical studies, KP106 demonstrated pharmacokinetics indicative of an attenuated amphetamine exposure as compared to Vyvanse®. These data suggest that patients

receiving KP106 may experience decreased side effects and decreased risk of abuse typically associated with stimulants. In addition, KemPharm is positioning KP106 to be the first ever proprietary oral film dosage form for ADHD. KemPharm projects the filing of a new drug application (NDA) for KP106 in 1H2013.

### **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 LAT prodrug approach. KemPharm utilizes its LAT prodrug technology to generate improved versions of FDA-approved drugs. 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. KemPharm is developing candidates for ADHD, pain, other central nervous system disorders. [www.kempharm.com](http://www.kempharm.com)

### **About MonoSol Rx**

MonoSol Rx is a specialty pharmaceutical company leveraging its proprietary PharmFilm<sup>®</sup> technology to deliver drugs in films. PharmFilm<sup>®</sup> is designed to benefit patients by improving the convenience, efficacy, and compliance of new and currently marketed drugs. The Company's leadership in film drug delivery is supported by strong intellectual property, a portfolio of commercialized prescription and over-the-counter (OTC) drug products, a pipeline of prescription formulations based on PharmFilm<sup>®</sup> technology, and two recent FDA approvals - Zuplenz<sup>®</sup>, the first approved prescription oral soluble film for the prevention of chemotherapy-induced, radiotherapy-induced, and postoperative nausea and vomiting, and Suboxone<sup>®</sup> sublingual film, the first combination sublingual film product for the treatment of opioid dependence.

MonoSol Rx's commercialization strategy for all PharmFilm<sup>®</sup> products is to partner with the innovator, other specialty pharma or leading consumer products companies that can sell-in and manage product sales and marketing. For existing and future partners, PharmFilm<sup>®</sup> formulations represent revenue-life cycle extensions for products with patent lives that have expired or are approaching expiration. PharmFilm<sup>®</sup> is also a tool to help sales and marketing partners differentiate in competitive markets while offering unique advantages over drugs dosed by traditional tablets, capsules and orally disintegrating tablets (ODTs). For press releases and other company information visit [www.monosolrx.com](http://www.monosolrx.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," "anticipate," "plan," "predict," "believe," "may" and "project." Such statements, including statements relating to developments, progress, timelines, 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 date, and KemPharm disclaims any obligation to update publicly any forward-looking statement to reflect the occurrence of events or circumstances after the date hereof.

**Contacts:**

**KemPharm, Inc.**

Kate Holt, Ph.D.

319-665-2575

E-mail: [info@kempharm.com](mailto:info@kempharm.com)

**The Ruth Group (on behalf of KemPharm)**

Jason Rando/Eric Reiss (media)

(646) 536-7025/7032

[jrando@theruthgroup.com/ereiss@theruthgroup.com](mailto:jrando@theruthgroup.com/ereiss@theruthgroup.com)

Joshua Drumm (investors)

(646) 536-7006

[jdrumm@theruthgroup.com](mailto:jdrumm@theruthgroup.com)