



KemPharm, Inc. Expands ADHD Pipeline with Discovery of KP415

First Ever Prodrug of Methylphenidate Developed Using KemPharm's Ligand Activated Therapy (LAT) Platform

North Liberty, IA – August 30, 2011 – KemPharm, Inc. (“KemPharm”) today announced it plans to initiate development of its recently identified lead compound KP415, a first-in-class prodrug of methylphenidate, which is a commonly used medication for the treatment of attention-deficit hyperactivity disorder (ADHD). KP415 was identified using KemPharm’s Ligand Activated Therapy (LAT) approach. KP415 is the second product candidate in KemPharm’s ADHD portfolio, which also includes KP106, a prodrug of *d*-amphetamine that has successfully completed a clinical proof-of-concept trial against Vyvanse®. KemPharm is actively seeking a pharmaceutical partner for late-stage clinical development and commercialization of its novel ADHD franchise.

“We are excited about our discovery of KP415 because it expands and diversifies our ADHD franchise by addressing the needs of patients that do not respond well to amphetamines,” commented Travis Mickle, Ph.D., President and Chief Executive Officer at KemPharm. “This first-in-class prodrug of methylphenidate may offer specific pharmacokinetic and compliance advantages over current therapies, which could have a positive impact on treatment outcomes in this large and primarily pediatric patient population.”

KemPharm is currently developing KP106 in an oral film dosage form with MonoSol Rx, LLC (“MonoSol Rx”), the developer of PharmFilm® technology, through an exclusive technology and manufacturing collaboration agreement. The companies plan to develop KP415 in an oral film dosage form pursuant to this same collaboration.

“We look forward to applying our PharmFilm technology to KP415 and developing this exciting new molecule into a dosage form that is ideally suited for treating ADHD,” commented A. Mark Schobel, President and Chief Executive Officer, MonoSol Rx. “With KP415 and KP106, our partner KemPharm is addressing unmet needs of this disorder and we believe combination with PharmFilm adds significant value to these already differentiated products.”

In preclinical studies, KP415 exhibited superior pharmacological characteristics that may suggest an improved stimulant-associated side effect profile compared to currently marketed methylphenidate products, potentially reducing symptoms such as loss of appetite and insomnia. Additionally, KP415 has improved physicochemical properties, which may allow the development of more patient-friendly dosage forms when compared to currently approved methylphenidate products.

About KP415

KP415, KemPharm's preclinical candidate for the treatment of ADHD, is composed of methylphenidate and a ligand. In preclinical studies, KP415 demonstrated an improved pharmacokinetic profile, with the potential to lower the therapeutic dose of methylphenidate and possibly reduce the side effects consistent with stimulants such as loss of appetite and insomnia. Additionally, KemPharm has filed a provisional patent application covering key aspects of KP415.

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 that KP106 may reduce the potential for 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

KemPharm 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. KemPharm'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 and other central nervous system disorders. www.kempharm.com

About MonoSol Rx

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

For press releases and other company information visit www.monosolrx.com

Forward Looking Statements and Information

This release contains forward-looking statements which are not necessarily 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’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 such statement to reflect the occurrence of events or circumstances after the date hereof.

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