KemPharm Inc. Focuses on Advanced Pain Management Franchise

Provides Business and Development Program Update

North Liberty, IA – May 22, 2012 – KemPharm, Inc. ("KemPharm"), a clinical-stage biopharmaceutical company focused on the discovery and development of new, safer therapies to treat pain, today provided an update on its business and development stage programs. The Company plans to leverage its deep pipeline of new chemical entities (NCEs) designed to improve the safety of opioid-based pain therapies by reducing the potential for drug abuse and diversion as well as reducing or eliminating the side effect of opioid-induced constipation (OIC). KemPharm is currently seeking a development and commercialization partner for its lead product, KP201, which is on track to file for FDA-approval in mid-2013.

"2012 is shaping up to be a transformative year for KemPharm," said Travis Mickle, Ph.D., President and Chief Executive Officer at KemPharm. "We are pleased to announce final resolution of our litigation with Shire LLC, which enables us to focus our full effort on advancing our pipeline of novel opioid drug candidates. Our strategy is to select the most promising lead compounds that have improved properties as compared to the marketed drug, and then demonstrate clinical proof-of-concept in a Phase 1 study. We expect the full value of our drug candidates to be realized through strategic partnerships with industry-leading biopharma companies. Our lead product KP201, a prodrug of hydrocodone, has successfully demonstrated clinical proof-of-concept and exhibited compelling preclinical results suggesting a prevention of OIC."

Continued Dr. Mickle, "Opioid abuse has been a serious public health concern for decades, yet despite the efforts of drug companies and various government agencies, the danger and heartbreak associated with 'pain-killers' continues to devastate families worldwide. In recent months, there has been a significant resurgence in activism to curb opioid abuse, with experts and advocates calling for new legislature and tighter controls over prescription opioids. We view this as a very positive step and a significant opportunity for KemPharm to bring safer drugs with reduced abuse potential into the growing market for abuse-deterrent opioids."

All of KemPharm's product candidates were discovered using the Company's proprietary Ligand Activated Therapy (LAT) prodrug technology. By chemically linking a ligand to FDA-approved drugs, KemPharm is able to improve certain characteristics while providing an accelerated path to market.

KP201

KemPharm's most advanced opioid-based drug candidate, KP201, is composed of hydrocodone chemically bound to a ligand. The Company previously reported positive Phase 1 clinical data, which confirmed that KP201 is cleaved in man as predicted, releasing

hydrocodone into the bloodstream at amounts equivalent to the reference listed drug, Norco®. This data supports a 505(b)(2) regulatory pathway for KP201 in combination with acetaminophen.

KP201 has unique physicochemical and pharmacological attributes that may deliver additional patient benefits, including reduced potential for abuse and reduction or elimination of OIC. Importantly, intact KP201 could not be detected in systemic circulation, perhaps indicating that minimal additional studies are warranted to determine the impact of KP201 exposure in the body.

KemPharm has worked diligently with its manufacturing partner, Johnson Matthey, to successfully and efficiently scale up KP201 active pharmaceutical ingredient (API) in anticipation of a commercial launch. KP201 is on track for a new drug application (NDA) submission to the FDA in mid-2013. KemPharm is actively seeking a strategic development partner with the expertise to take KP201 through regulatory review and commercialization.

KP511

KP511 is the second product candidate in KemPharm's pain therapy portfolio. It is a first-in-class oral prodrug of hydromorphone that has exhibited superior pharmacological characteristics in preclinical studies. These studies suggest a vastly improved safety profile compared to currently marketed hydromorphone products, as well as possibly reducing or preventing symptoms of OIC.

KP511 also features tamper resistant properties that make it difficult to extract hydromorphone from the prodrug, which is not active until cleaved in the body. KP511 is currently being evaluated in additional preclinical studies. The company expects to file an IND mid-2013 with Phase 1 clinical proof-of-concept expected later that year, and potentially file an NDA for KP511 in late 2014.

Early-Stage Candidates

KemPharm is leveraging its LAT technology to identify additional drug candidates for the treatment of pain and related therapeutic areas where abuse or safety is a key potential improvement. Like lead compounds KP201 and KP511, these earlier-stage compounds will be based on other commonly prescribed opioid analgesics, including oxycodone, morphine, codeine, oxymorphone, and fentanyl. The Company is also using its LAT approach to create extended-release candidates based on oxycodone and hydromorphone. This deep pipeline of NCE opioid assets with potentially improved characteristics may enable KemPharm to capture a large share of the prescription opioid market over the coming years.

Final Resolution of Shire Case

Recently, Shire LLC (a subsidiary of Shire plc), Dr. Mickle and KemPharm dismissed with prejudice all pending claims and counterclaims against one another in the legal action brought by Shire LLC against KemPharm and Dr. Mickle in the United States District Court for the Western District of Virginia, Roanoke Division, captioned *Shire LLC v. Travis C. Mickle PhD et. al.*, No. 7:10-cv-00434 (SGW) (PMS) (W.D. Va.). The dismissal of these claims and counterclaims effectively brings final resolution to the forgoing litigation.

About KemPharm

KemPharm 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. 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 primarily focused on developing candidates for pain and other central nervous system disorders. www.kempharm.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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