KemPharm Advances KP201 Clinical and Commercial Program with Completion of Tablet Registration Activities

April 16, 2014 4:36 PM ET

Company Targets Second Quarter of 2014 to File NDA As Development Activities Accelerate

North Liberty, IA – April 16, 2013 – KemPharm, Inc., a clinical stage biopharmaceutical company focused on the discovery and development of new, safer therapies to treat pain, announced today that it has completed tablet manufacturing activities as part of the clinical and commercial development program for KP201. The manufactured tablets are a fixed-dose combination of KemPharm's proprietary, non-toxic ligand attached to hydrocodone and 325 mg of acetaminophen.

KP201 is KemPharm's lead clinical candidate in development for the treatment of acute moderate to moderately severe pain. KP201, which was recently designated by the USAN council as benzhydrocodone, offers unique physicochemical and pharmacological attributes that may deliver additional patient benefits, including reduced potential for abuse and reduction or elimination of opioid-induced constipation (OIC). KemPharm anticipates submitting a new drug application (NDA) for KP201 to the FDA in the second quarter of 2014.

Travis C. Mickle, Ph.D., president and CEO of KemPharm, commented, "Completing the tablet registration process for KP201 is an important event as it signifies that the drug is optimally designed for continued clinical and commercial advancement. As we continue toward an NDA filing in 2014, the next milestone for KP201 is the completion of several pivotal pharmacokinetic studies this summer. Our expectation is this data will be the foundation of our submission to the FDA and will provide the basis upon which the safety, efficacy and abuse-deterrent properties of KP201 will be evaluated. KemPharm's goal is to develop KP201 as a first-in-class opioid-based drug that possesses the ability to reduce abuse potential and opioid-induced constipation."

About KemPharm

KemPharm is a biopharmaceutical company 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) approach. The company utilizes its LAT technology to generate improved prodrug versions of FDA approved drugs in the high needs areas of pain, ADHD and other CNS diseases. KemPharm's lead clinical candidate, KP201, is in development for the treatment of acute moderate to moderately severe pain with a new drug application (NDA) expected to be filed in the second quarter of 2014. Composed of hydrocodone chemically bound to a ligand, KP201 offers unique physicochemical and pharmacological attributes that may deliver additional patient benefits, including reduced potential for abuse and reduction or elimination of opioid-induced constipation (OIC). KemPharm's pipeline is also highlighted by KP511, its hydromorphone prodrug for pain, and KP415, a prodrug of methylphenidate for the treatment of ADHD. For more information on KemPharm, please visit the company's website at www.kempharm.com

###