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Cumberland Pharmaceuticals Reports Clinical And Regulatory Milestones

- Initial Hepatoren® Phase II study results
- sNDA filed with pediatric data for Caldolor®
- Phase II Boxaban™ trial underway

NASHVILLE, Tenn., March 3, 2015 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care and gastroenterology, today announced achievement of several clinical and regulatory milestones. These developments include top-line results from the Company's Hepatoren Phase II study, submission of a supplemental New Drug Application (sNDA) with pediatric data for Caldolor and initiation of patient enrollment in the Boxaban Phase II clinical trial.



"The sNDA for Caldolor represents a key milestone following the conclusion of a series of important Phase IV studies for the product. We look forward to working with the FDA with the goal of adding pediatric information to the Caldolor label," said A.J. Kazimi, Cumberland's Chief Executive Officer. "The progress with Hepatoren and Boxaban reflect our strategy to expand our product portfolio through a pipeline of innovative products addressing unmet medical needs."

Hepatoren® (ifetroban) Injection

Cumberland completed enrollment in the first of two patient cohorts of its Phase II study of Hepatoren in patients with Hepatorenal Syndrome (HRS). The Phase II double-blind, multi-center, randomized, controlled study evaluated the pharmacokinetics, safety and tolerability of ifetroban administered as daily intravenous doses in HRS patients. Patients were stratified based upon disease type, either Type I or Type II HRS diagnosis - with four dosing cohorts per disease type. Enrollment for Type II HRS patients was completed at the end of 2014.

Top line results from the Type II patient cohort indicate that ifetroban was overall well tolerated with no safety concerns noted. Furthermore, the patients receiving the higher dose levels of ifetroban were more likely to experience increases in urine output, a signal of improvement in kidney function, compared to patients who received placebo. Based on these results, Cumberland will proceed with clinical development of this product candidate.

Caldolor® (ibuprofen) Injection

Cumberland recently completed a series of Phase IV studies for Caldolor in more than 1,000 patients in over 30 leading medical centers across the U.S. These studies included evaluation of the product in both children and adults. Following the completion of these Phase IV studies, the Company submitted a sNDA to the FDA for the product. This submission requested changes to the package insert to include pediatric data from the Company's post-marketing pediatric development program. In addition, the results from two Caldolor Phase IV adult studies were recently published and are currently available as manuscripts in the journal *Clinical Therapeutics*.

Boxaban® (ifetroban) Oral Capsule

Cumberland recently announced an expansion of its pipeline with a new Phase II development program. The Company has begun the clinical development of Boxaban for the treatment of aspirin-exacerbated respiratory disease (AERD). AERD is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin. It is characterized by sharp increases in inflammatory mediators and platelet activity within the respiratory system. Ifetroban, an active thromboxane receptor antagonist, may interfere with these pathways to modify the disease and provide symptomatic relief.

Cumberland has completed manufacturing of Boxaban oral capsules and received clearance from the U.S. Food and Drug Administration (FDA) for its investigational new drug (IND) submission and Phase II study associated with the product. The

study has now been initiated with patient enrollment underway.

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's five marketed products include Acetate[®] (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor[®] (*ibuprofen*) Injection, for treatment of pain and fever, Kristalose[®] (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol[®] (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak[®] for the treatment of *H. pylori* and duodenal ulcer disease.

Cumberland is developing Hepatoren[®] (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome and Boxaban[®] (*ifetroban*) Oral Capsule for treatment of aspirin-exacerbated respiratory disease. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

About Caldolor[®] (*ibuprofen*) Injection

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever in adults. It was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticarial, or allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of Cumberland's operations are subject to factors outside of its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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