September 14, 2016

Cumberland Pharmaceuticals Announces New Program To Develop Portaban™ For Portal Hypertension

- FDA clears investigational new drug submission
- Phase II Study initiated for patients with portal hypertension

NASHVILLE, Tenn., Sept. 14, 2016 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ:CPIX), today announced the initiation of a new Phase II clinical program of Portaban™ for patients with portal hypertension associated with liver disease. The U.S. Food and Drug Administration (FDA) has cleared Cumberland's investigational new drug application (IND) for a multicenter, randomized, double-blind, placebo-controlled Phase II clinical study.

Portaban™ is an oral formulation of ifetroban and the fourth development candidate in Cumberland's pipeline. Preclinical studies have shown ifetroban can reduce portal pressure, necrosis, inflammation, and fibrosis in multiple models of liver injury.

"We are very encouraged by the preclinical findings supporting the use of Portaban™ and its potential as a new therapy for liver cyrossis patients," said A.J. Kazimi, Cumberland's Chief Executive Officer. "We remain focused on developing products that address unmet medical needs."

"I am excited to investigate a drug candidate with the potential to induce a clinically meaningful reduction in severe portal hypertension over a relatively short time frame." said Dr. Don Rockey, lead investigator at the Medical Center of South Carolina. "Portal hypertension is largely responsible for events of hepatic decompensation including variceal bleeding, ascites, and encephalopathy, which contribute substantially to morbidity and mortality in these patients. By lowering elevated portal pressures, Portaban™ has the potential to decrease the risk of hepatic decompensation in liver cirrhosis patients over the short term, and may improve both liver function and structure over the long term through anti-inflammatory and anti-fibrotic effects."

Cumberland previously completed an initial Phase II study for Boxaban® (ifetroban) for patients with aspirin-exacerbated respiratory disease (AERD), a disease involving chronic asthma that is worsened by aspirin. The Company has also completed an initial Phase II study for Hepatoren® (ifetroban) in patients with Hepatorenal Syndrome (HRS), a life-threatening condition involving progressive kidney failure.

Earlier this year, Cumberland announced the start of another Phase II clinical program with Vasculan™ (ifetroban) for the treatment of systemic sclerosis, a rare and life-threatening autoimmune disorder that affects the skin and internal organs.

About Portal Hypertension

Portal hypertension, a complication of liver cirrhosis, is an increase in the blood pressure within a system of veins called the portal venous system. Veins coming from the stomach, intestine, spleen, and pancreas merge into the portal vein, which then branches into smaller vessels and travels through the liver. If the vessels in the liver are blocked due to liver damage, blood cannot flow properly through the liver. As a result, high pressure in the portal system develops. This increased pressure in the portal vein may lead to the development of large, swollen veins (varices) within the esophagus, stomach, rectum, or umbilical area (belly button). Varices can rupture and bleed, resulting in potentially life-threatening complications.

About Ifetroban

Ifetroban is a potent and selective thromboxane-prostanoid receptor (TPr) antagonist. Ifetroban exhibits high-affinity for TPr on platelets, vascular and airway smooth muscle and several other cell types and lacks agonistic activity. Ifetroban is effective at preventing hepatic necrosis and inflammation as well as attenuating established liver injury, inflammation and

fibrotic changes in certain preclinical models of liver disease.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on acquisition, development, and commercialization of high-quality products that improve the quality of care for patients. The Company has a diverse product portfolio with a focus in the areas of hospital acute care and gastroenterology.

Cumberland's marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, 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 dedicated to also developing innovative products that address unmet medical needs. The Company's product candidates in clinical development include: Hepatoren® (*ifetroban*) Injection for the treatment of hepatorenal syndrome, Boxaban ® (*ifetroban*) Oral Capsule for patients suffering from aspirin exacerbated respiratory disease, and Vasculan™ *(ifetroban*) Oral Capsule for the treatment of systemic sclerosis. For more information on Cumberland Pharmaceuticals Inc., please visit www.cumberlandpharma.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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