



April 27, 2016

Cumberland Pharmaceuticals Announces New Program To Develop Vasculan™ For Systemic Sclerosis

- FDA clears investigational new drug submission**
- Phase II Clinical Study initiated**

NASHVILLE, Tenn., April 27, 2016 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on the development of innovative treatments for underserved patient populations, announced today the addition of **VASCULAN™** to its pipeline. Cumberland has initiated the clinical development of Vasculan™ (ifetroban) oral capsule for the treatment of systemic sclerosis. The U.S. Food and Drug Administration (FDA) has cleared Cumberland's investigational new drug application (IND) for Phase II clinical program for Vasculan in patients with systemic sclerosis.



"Cumberland is committed to developing products that address unmet medical needs," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. Following the exciting preclinical results demonstrating the potential of ifetroban to impact fibrosis, we are now ready to build on those findings by moving directly to a Phase II patient study."

Systemic sclerosis (SSc), also called scleroderma, is a rare autoimmune disorder that affects the skin and internal organs. It is characterized by vasculopathy, inflammation, and fibrosis. SSc affects 2.5 million people worldwide and does not yet have a proven curative therapy. This disease has a high morbidity and the highest case-specific mortality of any rheumatic disorder with 50% of patients dying or developing major internal organ complications within 3 years of diagnosis. Although several medications are used to treat the skin disease associated with SSc, there is no universally effective treatment to improve the function of affected internal organs such as the lungs, heart, and gastrointestinal tract, hence the treatment of SSc remains an unmet need.

"I am excited to investigate ifetroban as a potential therapeutic for scleroderma patients given the significant unmet medical need these patients face," said Dr. Evan Brittain of the Department of Cardiovascular Medicine at the Vanderbilt University Medical Center and lead investigator for the trial. "Cardiac involvement and pulmonary arterial hypertension are major causes of morbidity and mortality in patients with scleroderma. In preclinical work, ifetroban prevents cardiac fibrosis in a model of pulmonary arterial hypertension. Evaluating a treatment that may delay or inhibit tissue fibrosis could significantly improve the quality of life for these patients. We are hopeful that ifetroban will prove to be an effective therapeutic for patients suffering from systemic sclerosis or scleroderma with or without pulmonary arterial hypertension."

In 2011, Cumberland announced the acquisition of the ifetroban program in collaboration with Vanderbilt University and Cumberland Emerging Technologies (CET). Last year, Cumberland initiated the clinical development of Boxaban® (ifetroban) oral capsule with a Phase II study for patients with aspirin-exacerbated respiratory disease (AERD), a respiratory disease affecting nearly a million patients in the U.S. Cumberland is also developing an injectable formulation, Hepatoren® (ifetroban) in patients with Hepatorenal Syndrome (HRS), a life-threatening condition involving progressive kidney failure. Cumberland completed initial Phase II studies for both Boxaban and Hepatoren in 2015.

About Ifetroban

Ifetroban is a potent and selective thromboxane-prostanoid receptor (TP_r) antagonist. Ifetroban exhibits high-affinity for TP_r on platelets, vascular and airway smooth muscle and certain other cell types and lacks agonistic activity. Ifetroban also displays anti-platelet, antivasospastic and antibronchospastic activities and is effective in certain preclinical models of vasospasm, thrombosis, reperfusion injury and endothelial dysfunction, including models that are insensitive to aspirin.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on improving patients' lives through the acquisition, development and commercialization of high-quality meaningful products that address unmet medical needs. 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 providing innovative products that improve the quality of care for patients. For more information on Cumberland Pharmaceuticals Inc., please visit www.cumberlandpharma.com.

About Cumberland Emerging Technologies

Cumberland Emerging Technologies Inc. ("CET") is a joint initiative between Vanderbilt University, Cumberland Pharmaceuticals Inc., the state of Tennessee's Launch TN, and China's Gloria Pharmaceuticals. The mission of CET is to advance biomedical technologies and products conceived at academic research centers towards the commercial marketplace. CET manages the development and commercialization process for select projects, and provides expertise on intellectual property, regulatory, manufacturing, and market issues that are critical to successful new biomedical products.

CET has sponsored Middle Tennessee's first life sciences incubator located in downtown Nashville adjacent to the Union Station Hotel and the Frist Visual Arts Center. This Life Sciences Center provides laboratory space, equipment and other support to a growing number of tenants who specialize in medical products and research advancements. For more information, visit www.CET-Fund.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.

Logo - <http://photos.prnewswire.com/prnh/20140505/84325>

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/cumberland-pharmaceuticals-announces-new-program-to-develop-vasculan-for-systemic-sclerosis-300257430.html>

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media