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Cumberland Pharmaceuticals Announces Pipeline Expansion With Boxaban™ (ifetroban) Oral Capsule

- - FDA clears investigational new drug submission
- - Manufacturing completed and Phase II clinical development program underway

NASHVILLE, Tenn., Feb. 11, 2015 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX)** today announced an expansion of its pipeline with a new Phase II development program. The Company has initiated the clinical development of Boxaban™ (ifetroban) oral capsule for the treatment of aspirin-exacerbated respiratory disease (AERD). Cumberland has completed manufacturing 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.

"Physicians and patients alike are eager for viable new treatment options for AERD to help relieve symptoms and restore quality of life. This ifetroban clinical program is a truly exciting development, supported by laboratory findings in animal models of the disease," said Andrew White, M.D., lead investigator for the trial and researcher from Scripps Clinic in San Diego, CA.

Aspirin-exacerbated respiratory disease (AERD), also known as Samter's Triad, is a respiratory disease involving chronic asthma and nasal polyposis that is worsened by aspirin or nonsteroidal anti-inflammatory drugs. Approximately one in 20 asthmatic adults (nearly 1 million patients in the United States) suffer from AERD and the disease awareness is growing within the medical community. AERD 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 symptom relief. Current treatment of AERD remains a challenge, as novel and effective treatment modalities are lacking for this unmet medical need.

"Patients with AERD often have the most severe and difficult to treat form of asthma. The manufacture of the oral capsule formulation and initiation of the AERD clinical development program by Cumberland represents a significant milestone for our collaboration," said John Oates, M.D., the Professor of Medicine and Pharmacology at Vanderbilt University. "Data from this important trial will help us to understand the potential for ifetroban in treating AERD while generating safety information that will allow us to consider ifetroban therapy for other patient populations."

In 2011, Cumberland announced the acquisition of the ifetroban program in collaboration with Vanderbilt University and Cumberland Emerging Technologies (CET). Cumberland is also currently studying ifetroban in an injectable formulation in a Phase II study in patients with Hepatorenal Syndrome (HRS), a life-threatening condition involving progressive kidney failure.

About Ifetroban

Ifetroban is a pharmacological antagonist of the thromboxane A2 / prostaglandin endoperoxide receptor (TPR). Ifetroban exhibits high-affinity for TPRs 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 Tennessee-based 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 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 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., and the state of Tennessee's Launch TN (formerly the Tennessee Technology Development Corporation). 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.

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