



## **Cumberland Pharmaceuticals Announces New Product Addition With Hepatoren™ (ifetroban) Injection**

- Company acquires new hospital acute care product**
- FDA clears investigational new drug submission**
- Phase II clinical development program and manufacturing underway**

NASHVILLE, Tenn., April 19, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX), a specialty pharmaceutical company focused on hospital acute care and gastroenterology markets, today announced that it has entered into an agreement to acquire the rights to ifetroban, a new Phase II development product. The Company has initiated clinical development under the brand name Hepatoren™ (ifetroban) Injection and is evaluating the product for the treatment of critically ill hospitalized patients suffering from Hepatorenal Syndrome (HRS). Cumberland also has commenced manufacturing and received clearance from the U.S. Food and Drug Administration (FDA) for its investigational new drug (IND) submission associated with the product.

Hepatorenal Syndrome is a life-threatening condition involving progressive kidney failure. Approximately 450,000 patients in the United States suffer from medical conditions that make them susceptible to cirrhosis and a subset of these patients develop HRS every year. Decrease in kidney function causes nitrogen-containing waste products to build up in the bloodstream and ifetroban may improve renal function in HRS patients by increasing low renal blood flow. There is currently no drug approved for the treatment of HRS in the United States.

Cumberland's acquisition of the ifetroban program includes rights to an extensive clinical database and non-clinical data package as well as manufacturing processes, know-how and intellectual property related to the product. Ifetroban, an active thromboxane receptor antagonist, was initially developed by Bristol-Myers Squibb (BMS) for significant cardiovascular indications. BMS conducted extensive preclinical and clinical studies, including seven Phase II trials for its own target indications, and eventually donated the entire program to Vanderbilt University. Researchers at Vanderbilt's Department of Clinical Pharmacology identified ifetroban as a potentially valuable compound in treating patients for several niche indications.

Cumberland Pharmaceuticals acquired the ifetroban program from Vanderbilt through its majority-owned subsidiary, Cumberland Emerging Technologies (CET), assuming responsibility for development and commercialization of the product. CET facilitated the program transfer, which included product development activities at CET laboratories.

"This new product is an excellent strategic fit for our company given our established presence in hospital acute care," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "CET was created in conjunction with Vanderbilt University to serve as a source of innovative new biopharmaceutical products, and the ifetroban program represents a milestone for that organization. Cumberland Pharmaceuticals is extremely pleased to have another opportunity to provide a potential new solution to address an unmet medical need for critically ill patients."

Cumberland plans to develop ifetroban for a series of indications, initially focusing on the treatment of HRS for the hospital acute care market. In addition to commencing manufacturing, the Company has initiated a Phase II clinical study for the product. Cumberland intends to develop Hepatoren as an Orphan Drug for which the Company would pursue seven years of marketing exclusivity. Patent applications have also been filed to protect certain intellectual property related to the product.

### **About Ifetroban**

Ifetroban is a pharmacological antagonist of the thromboxane A<sub>2</sub> / prostaglandin endoperoxide receptor (TPR). Ifetroban exhibits high-affinity for TPRs on platelets, vascular smooth muscle and certain other cell types and lacks agonistic activity. Ifetroban also displays anti-platelet and antivasospastic 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 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, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing

innovative products that improve quality of care for patients. For more information on Cumberland, please visit the Company's website at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

### **About Cumberland Emerging Technologies**

Cumberland Emerging Technologies, Inc. (CET) is a joint initiative between Vanderbilt University, Cumberland Pharmaceuticals Inc. and the Tennessee Technology Development Corporation. The mission of CET is to bring biomedical technologies and products conceived at research centers to the commercial marketplace. CET helps manage the development and commercialization process for select projects and provides expertise on intellectual property, regulatory, manufacturing and marketing issues that are critical to successful new biomedical products. CET's Life Sciences Center, located in Nashville, Tennessee, provides laboratory space, equipment and infrastructure for its own product development activities as well as for other early-stage life sciences companies.

### **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 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 a 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 2010 Annual Report on Form 10-K filed with the SEC on March 11, 2011. 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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