



March 3, 2014

## **Cumberland Pharmaceuticals Acquires Vaprisol® from Astellas Pharma US, Inc.**

NASHVILLE, Tenn., March 3, 2014 /PRNewswire/ -- [Cumberland Pharmaceuticals Inc.](#) (NASDAQ:CPIX) today announced the acquisition of Vaprisol® from Astellas Pharma US, Inc.

Vaprisol® is a patented, prescription brand indicated to raise serum sodium levels in hospitalized patients with hyponatremia. The product was developed and registered by Astellas and was commercially launched in 2006. It is one of two branded prescription products indicated for the treatment of hyponatremia.

Hyponatremia is an electrolyte disturbance in which sodium ion concentration in blood plasma is lower than normal. This can be associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia.

"Hyponatremia has been recently recognized to be a significant electrolyte disturbance associated with both acute and long-term consequences, even in cases that would have been previously been considered mild," said Theresa Human, Pharm.D, BCPS, Neuroscience Clinical Specialist, Barnes-Jewish Hospital-St. Louis, Washington University. "It is exciting to have a pharmaceutical company committed to support the education of this underemphasized electrolyte disorder and the therapeutic options available to effectively treat these patients."

Under the terms of the agreement, Cumberland will assume full responsibility for the product including its marketing, distribution and manufacture. Cumberland will promote Vaprisol across the United States through its hospital sales force, which also features its Caldolor® and Acetadote® brands.

"We believe Vaprisol is an excellent strategic fit with our focus on hospital acute care," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Our immediate plan for Vaprisol is to ensure a smooth transition of the product supply and medical support to current users of the brand. We will then launch our hospital promotion support and are very optimistic about the opportunity that Vaprisol will offer Cumberland."

### **About Vaprisol®**

Vaprisol an intravenous treatment for hyponatremia used in the critical care setting. Hyponatremia is an electrolyte disturbance in which sodium ion concentration in blood plasma is lower than normal. This can be associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia. The product is a vasopressin receptor antagonist that raises serum sodium levels and promotes free water secretion. Vaprisol does not require dilution and has a well-defined daily dose of 10 mg, 20 mg, or 40 mg. The product is a vasopressin receptor antagonist that raises serum sodium levels and promotes free water secretion. Vaprisol was approved by the U.S. Food and Drug Administration in 2005 for euvolemic hyponatremia and in 2007 for hypervolemic hyponatremia. For full prescribing information, visit [www.vaprisol.com](http://www.vaprisol.com).

### **About Acetadote**

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma or where there is a history of bronchospasm. The total volume administered should be adjusted for patients weighing less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure and death. For full prescribing information, visit [www.acetadote.com](http://www.acetadote.com).

### **About Caldolor**

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](http://www.caldolor.com).

### **About Cumberland Pharmaceuticals Inc.**

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 product portfolio includes Acetadote<sup>®</sup> (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning; Caldolor<sup>®</sup> (*ibuprofen*) Injection, the first injectable treatment for pain and fever available in the United States; and Kristalose<sup>®</sup> (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients.

For more information, please visit the company website at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

### **Important Note Regarding 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.

SOURCE Cumberland Pharmaceuticals Inc.

News Provided by Acquire Media