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## Cumberland Pharmaceuticals Reports FDA Approval For Updated Acetadote® Labeling

### - New label revises product's indication and provides new dosing guidelines.

NASHVILLE, Tenn., June 10, 2013 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX) announced today that the U.S. Food and Drug Administration (FDA) has approved updated labeling for Acetadote (acetylcysteine) Injection. The new labeling revises the product's indication and offers new dosing guidance for specific patient populations. Acetadote is free of EDTA or any other stabilization or chelating agents.

The new indication states, "Acetadote is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen." The product's previous indication included the qualifying phrase, "administered intravenously within 8 to 10 hours," which was originally intended to impress the urgency for early treatment. This phrase has been removed due to potential confusion concerning efficacy when administration within that time period is not possible.

Furthermore, specific dosing guidance is now included for patients weighing over 100 kg. New language has also been added to alert health care providers that in certain clinical situations, therapy should be extended for some patients.

"We are committed to the further development of our products and worked with FDA and its Division of Medication Error Prevention and Analysis (DMEPA) to improve the package insert for Acetadote," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are pleased to provide clearer and more extensive dosing guidance to assist health care professionals when treating patients in a time-urgent and life-threatening situation. The label changes reflect our commitment to this patient population, which includes development of the EDTA-free Acetadote formulation."

Acetadote does not contain Ethylene diamine tetraacetic acid (EDTA) or any other stabilization or chelating agents and is free of preservatives. The product's formulation was developed as part of a Phase IV commitment by Cumberland in response to a request by the FDA to evaluate the reduction of EDTA. The formulation also has a longer shelf life of 30 months.

Acetadote, which has been available in the United States since Cumberland's 2004 introduction of the product, is currently used in hospital emergency departments to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many prescription and over-the-counter pain relief and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States.

#### **About Acetadote**

Acetadote is an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen. Used in the emergency department, Acetadote is an injectable product approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. 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.net](http://www.acetadote.net).

#### **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 product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning; Caldolor® (*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).

### **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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