



## Cumberland Pharmaceuticals Receives FDA Approval for New Formulation of Acetadote

- Company commences launch of the next generation product
- Product shelf life extended from 24 to 30 months

NASHVILLE, Tenn., Jan. 13, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for a new formulation of Acetadote® (*acetylcysteine*) Injection, the Company's product used to treat acetaminophen poisoning. The proprietary new formulation, which does not contain Ethylene diamine tetracetic acid or any other stabilization and chelating agents and is free of preservatives, will replace the currently marketed product. Cumberland is immediately commencing U.S. launch activities for this next generation Acetadote product and will no longer manufacture the previously approved formulation.

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 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, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

"We are committed to further developing our products, whether to expand into new patient populations or to improve upon an existing formulation, and worked with the FDA to develop this new formulation of Acetadote," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We look forward to introducing this next generation product to the hospital community and the growing number of patients who will benefit from it."

The new formulation of Acetadote is the result of a phase IV commitment Cumberland made to the FDA upon receipt of initial marketing approval of the product. Cumberland initiated a program to develop the new formulation and determined that it could be prepared and scaled in a commercial manufacturing setting without compromising the potency, solubility or stability of the product. The Company obtained approval for an extended shelf life with the new product, up from 24 months for the original formulation to 30 months.

### 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 the only 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® (*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 that reflect Cumberland's current views with respect to 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 operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include, among other things, market conditions, intense competition from existing and new products,

an inability of manufacturers to produce Acetadote on a timely basis or a failure of manufacturers to comply with stringent regulations applicable to drug manufacturers, maintaining and building an effective sales and marketing infrastructure, government regulation, the possibility that marketing exclusivity and patent rights may provide only limited protection from competition, and other factors related to the Company including those under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in Cumberland's Form 10-K filed with the SEC on March 19, 2010. There can be no assurance that the results or developments anticipated by Cumberland will be realized or, if realized, 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. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof.

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