



Cumberland Receives Acetadote® Patent Notice of Allowance

- Patent provides intellectual property protection through 2025

NASHVILLE, Tenn., Feb. 8, 2012 /PRNewswire/ -- [Cumberland Pharmaceuticals Inc.](#) (NASDAQ: CPIX) today announced that it has received a Notice of Allowance from the United States Patent and Trademark Office relating to its new formulation of Acetadote® (*acetylcysteine*) Injection, which is used to treat acetaminophen poisoning. The new formulation was FDA approved in 2011 and listed in the "Orange Book," the FDA's official register of approved pharmaceutical products. Once issued, the patent will expire in August 2025.

This composition of matter patent represents another significant milestone for Cumberland and its Acetadote brand. The proprietary next generation formula does not contain Ethylene diamine tetracetic acid (EDTA) or any other stabilization and chelating agents and is free of preservatives. The formulation also has a longer shelf life of 30 months compared to 24 for the prior formulation. This new formulation was developed as part of a Phase IV commitment by Cumberland in response to a request by the FDA to remove EDTA. Following the approval of the next generation Acetadote product, the Company immediately ceased manufacture of the previous formulation.

"We are very pleased with the patent office's decision and appreciate their thoughtful deliberation and consideration of our application," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Protecting our intellectual property is paramount for our Company and we are excited about the prospects for this potentially life-saving product."

Acetadote is 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.

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.

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.

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 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 11, 2011. 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.

SOURCE Cumberland Pharmaceuticals Inc.

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