

CUMBERLAND PHARMACEUTICALS REPORTS FDA APPROVAL FOR UPDATED LABELING OF ACETADOTE®

Revised label includes additional safety data from more than 6,500 patients

NASHVILLE, Tenn. (**December 18, 2008**) – Cumberland Pharmaceuticals announced today that the U.S. Food and Drug Administration (FDA) has approved updated labeling for **Acetadote**[®] (**acetylcysteine**) **Injection**, the company's intravenous treatment for acetaminophen overdose. The revised package insert provides new information from a post-marketing safety study reporting a lower incidence of side effects compared to previously reported data.



The FDA decision is based on a recent Canadian study evaluating 4,709 adults and 1,905 children who were treated with IV acetylcysteine for acetaminophen overdose. Data from the multi-center study comprises the largest known database addressing the safety of intravenously administered acetylcysteine. While Acetadote was deemed safe and effective in 2004 upon FDA approval, this new study found the observed overall rate of reactions commonly associated with IV acetylcysteine – such as urticaria (hives), pruritis (itching) and respiratory symptoms – to be 8.4 percent, or approximately one-half of the 17 percent rate reported in a previous study.

"We are pleased to have access to this large patient database and to communicate important new safety information about our product," said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. "As acetaminophen poisoning in adults and children continues to rise¹, we believe this data reinforces the FDA's previous finding that Acetadote offers a valuable treatment option for patients suffering from this overdose occurrence."

About Acetadote

Acetadote is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose, the leading cause of poisonings presenting in emergency departments in the country².

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 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.

Please visit <u>www.acetadote.net</u> for the full Prescribing Information, which also reflects formatting changes to conform to new FDA mandates.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company that develops and markets niche pharmaceutical products for specific physician segments, including hospital acute care and gastroenterology. Cumberland is dedicated to providing high-quality products which fill unmet medical needs. For more information, please visit the Cumberland Pharmaceuticals web site at www.cumberlandpharma.com.

Forward-Looking Statements

This release contains forward-looking statements which reflect management's current views of future events and operations. Forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from these statements. Cumberland does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

Acetadote[®] is a registered trademark of Cumberland Pharmaceuticals Inc.

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^{1,2} National Poison Data System, American Association of Poison Control Centers