# Cumberland Pharmaceuticals Announces Voluntary Recall of Acetadote® Vials

## - Recall is a precautionary measure not based on any adverse events

NASHVILLE, Tenn., Dec. 30, 2010 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) announced today that it has implemented a recall of 6 lots of Acetadote® (acetylcysteine) Injection, the Company's injectable treatment to prevent or lessen liver injury after ingestion of a potentially toxic quantity of acetaminophen. Cumberland informed the U.S. Food and Drug Administration (FDA) of its plans to voluntarily recall these lots of Acetadote as a precautionary measure based on observed particulate matter found in a very small number of vials. The source of the particulate matter was from the glass vial produced by a former supplier. The recall, which is not being undertaken on the basis of any known adverse medical events, affects a limited supply of product.

"We are recalling certain lots manufactured by a previous packaging supplier as a precautionary measure, and believe the risk of any serious adverse medical events to be remote," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "As part of ongoing quality assessment, we switched to a new vial packaging supplier in August of 2009. Patient safety, as always, remains our highest priority, and we are committed to taking the necessary steps to proactively protect patients from the potential of any safety risks."

The product being recalled is Acetadote (acetylcysteine) Injection, 20% solution (200mg/mL) in 30 mL single dose glass vials, NDC 66220-107-30. The lot numbers being recalled are lots 090304 (expiration Feb 2011), 090331 (expiration Feb 2011), 090401 (expiration Mar 2011), 090511 (expiration Apr 2011), 090602 (expiration May 2011) and 090616 (expiration May 2011). This product was distributed to U.S. wholesalers and distributors nationwide.

To report adverse reactions or quality concerns, please contact Cumberland Pharmaceuticals via email at aereport@cumberlandpharma.com, by fax to 866-438-2372 or by phone at 1-877-484-2700. Adverse reactions may also be reported to FDA's MedWatch Program online at www.fda.gov/medwatch, or by mail at MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

### 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® for the treatment of acetaminophen poisoning, Caldolor®, the first injectable treatment for pain and fever approved in the United States, and Kristalose®, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit the Company's website at 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 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 a failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and

marketing infrastructure and other factors set forth 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 results anticipated by the Company will be realized or that they will have the expected effects. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

SOURCE Cumberland Pharmaceuticals Inc.