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Caldolor® Reduces Narcotic Doses In Pediatric Pain Patients

- Study demonstrates Caldolor significantly reduces the number of post-operative narcotic doses

NASHVILLE, Tenn., Sept. 19, 2012 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)** today announced top-line results from a clinical pediatric pain study evaluating the safety and analgesic efficacy of **Caldolor® (*ibuprofen*) Injection** in treating pain in tonsillectomy patients ranging from 6 to 16 years old.

When administered prior to surgery, Caldolor use was associated with a statistically significant reduction in the number of post-operative narcotic doses required in patients in the efficacy evaluable population. There were also consistent trends toward reduction in pain scores and the incidence of nausea and vomiting in patients receiving Caldolor. Importantly, no safety concerns were observed during this study.

"We remain committed to the ongoing development of an approved product, including studies evaluating them in new patient populations," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are pleased to complete the first of our phase IV Caldolor studies."

This study, in combination with the ongoing work to evaluate the treatment of fever in children, will be used to pursue a pediatric indication for Caldolor.

About Caldolor

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever in adults. It is the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

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 marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved 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, visit the Company's website at www.cumberlandpharma.com.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that 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 operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include market conditions, competition from existing and new products, an inability or failure of manufacturers to produce the Company's products on a timely basis or 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 limited protection from competition, and other factors 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 results 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.