



November 23, 2015

Caldolor Approved For Use In Pediatric Patients

Caldolor® (ibuprofen) Injection Approved in Pediatric Patients Six Months and Older for Management of Pain and Reduction of Fever

NASHVILLE, Tenn., Nov. 23, 2015 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (**NASDAQ: CPIX**), a specialty pharmaceutical company focused on hospital acute care and gastroenterology announced the approval of Caldolor® (ibuprofen) Injection for pediatric patients six months of age and older. The approval was based on data submitted to the U.S. Food and Drug Administration (FDA) as part of a post-marketing commitment following approval of Caldolor in adults in 2009. Caldolor is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for use in pediatric patients.



Caldolor's pediatric approval came after the FDA's review of safety and efficacy data from clinical trials in hospitalized febrile children and in children undergoing tonsillectomy surgery. The pivotal fever study demonstrated a statistically significant greater reduction in temperature for the primary endpoint, an area under the curve analyses of temperature versus time for the first two hours, as well as over the entire dosing interval, as compared to acetaminophen. Seventy-four percent of Caldolor treated patients became afebrile by the end of first dosing interval. A total of 143 pediatric patients, ages six months and older, have received Caldolor in controlled clinical trials. The most common adverse reactions (incidence greater than or equal to 2%) in pediatric patients treated with Caldolor were infusion site pain, vomiting, nausea, anemia and headache.

The recommended dosing for pediatric patients ages six months to twelve years of age is 10 mg/kg up to a maximum single dose of 400 mg Caldolor every four to six hours as necessary. For patients ages twelve to seventeen years of age, the recommended dosing is 400 mg of Caldolor every four to six hours as necessary for management of pain and/or reduction of fever. The product is diluted and administered intravenously over a ten minute infusion and the maximum daily dose in pediatric patients is 2,400 mg.

A.J. Kazimi, CEO – Cumberland Pharmaceuticals said: "FDA's approval of Caldolor for children represents another milestone in Cumberland's mission to provide effective treatment options, particularly for hospitalized patients."

About Cumberland Pharmaceuticals Inc.

Cumberland Pharmaceuticals Inc. is a 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, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information on Cumberland, please visit the Company's website www.cumberlandpharma.com.

About Caldolor® (ibuprofen) Injection

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with a history of asthma or other 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.

Important Note Regarding 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 of 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 failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. There can be no assurance that results anticipated by the Company will be realized or 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. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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