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Caldolor® Launched For The Treatment Of Pain And Fever In Children

-Follows Recent FDA Approval for Caldolor's Pediatric Indication

NASHVILLE, Tenn., March 24, 2016 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (NASDAQ:CPIX) a specialty pharmaceutical company, today announced the launch of **Caldolor®** (ibuprofen) injection for pediatric patients. This launch follows the U.S. Food and Drug Administration (FDA) approval of Caldolor for the treatment of pain and fever in children six months of age and older. Caldolor is an injectable form of ibuprofen designed primarily for hospitalized patients who are not able to tolerate their pain and fever medications orally. It is the first and only injectable non-steroidal anti-inflammatory drug (NSAID) approved for the treatment of pain and fever in pediatric patients.

Caldolor will be introduced to the pediatric medical community with the support of Cumberland's national hospital marketing and sales organization. The objectives of the launch are to introduce the product for pediatric use, provide its dosing information and ensure the product's appropriate administration.

- The recommended dosing of Caldolor is 10mg/kg for children ages 6 months to 12 years every four to six hours as necessary, with a maximum dose of 400mg.
- For children ages 12 to 17 years of age, the recommend dosing of Caldolor is 400mg every four to six hours as necessary to manage the patient's pain or fever.
- Caldolor is diluted and administered intravenously over a ten minute infusion and the maximum daily dose in pediatric patients is 2,400 mg.

"We are delighted to be able to offer Caldolor as a new treatment for the pain and fever in hospitalized children" said A.J. Kazimi, Cumberland Pharmaceutical's CEO. "This pediatric launch of Caldolor reflects our mission to address poorly met medical needs in under-served patient populations."

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 the first dosing interval. A total of 143 pediatric patients, ages six months and older, have received Cadolor in controlled clinical trials. The most common adverse reactions in pediatric patients treated with Caldolor were infusion site irritation, vomiting, nausea, anemia, and headache.

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 .

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, 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 Pharmaceuticals Inc., please visit 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 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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