Caldolor® Now FDA Approved For Treatment Of Fever & Pain In Infants

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Caldolor® is the only injectable non-opioid approved for treating pain in infants

NASHVILLE, Tenn., May 15, 2023 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved expanded labeling for Caldolor®, an intravenously delivered formulation of ibuprofen, to now include use in infants. The non-narcotic agent may now be administered for the treatment of pain and fever in patients three months to six months of age.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in these young children.

To support this expanded use of Caldolor, Cumberland sponsored a multi-center study in 21 hospitalized infants. All but one patient was treated with a single dose of the product.

The safety and efficacy of Caldolor has now been established for the treatment of pain and fever in pediatric patients aged 3 months and older. Use of Caldolor for these indications is supported by evidence from one adequate and controlled open label study in infants, along with additional safety data from four studies in 164 pediatric patients, supportive pediatric data from other approved ibuprofen products, and evidence from adequate and well-controlled studies in adults.

Importantly with this newly approved labeling, Caldolor is the only non-opioid product approved to treat pain in infants that is delivered through injection. Ketorolac and meloxicam are not approved for use in children, as the safety and efficacy of those drugs have not been established for pediatric patients. Acetaminophen injection is not approved for treating pain in children less than 2 years of age, as the safety and efficacy of that drug has not been established for treating pain in those pediatric patients.

"We are delighted to provide Caldolor for these youngest of patients," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals. "We believe that this approval for the product's use in infants speaks to Caldolor's favorable safety profile for use in a growing number of patient populations."

Cumberland previously announced FDA approval for use in pre-operative administration. The non-narcotic pain reliever may be administered just prior to surgery, which enables patients to wake up from their procedures in significantly less pain. Caldolor presents a potentially safer alternative to opioids for controlling pain, as the FDA has recently required new safety warnings on the use of opioids.

In addition, the Company recently reported that it expects Caldolor will be eligible for special Medicare reimbursement under the *Non-Opioids Prevent Addiction in the Nation Act* (the "NOPAIN Act"), which was enacted as part of the Consolidated Appropriations Act of 2023.

The NOPAIN Act requires Medicare to provide separate reimbursement for non-opioid products that are used to manage pain during surgeries conducted in outpatient hospital departments or in ambulatory surgical centers. The methodology for reimbursement for non-opioid pain alternatives under the NOPAIN Act will apply to those products that are furnished between January 1, 2025 and January 1, 2028. It is anticipated that in 2024, the Centers for Medicare & Medicaid Services (CMS) will issue regulations implementing the NOPAIN Act and detailing the conditions for, and amount of, the separate reimbursement.

Caldolor is now approved by the U.S. Food and Drug Administration (FDA) for use in adults and pediatric patients three months and older, for the management of mild to moderate pain as a sole therapy, and for the management of moderate to severe pain as an adjunct to an opioid. A series of published clinical studies have demonstrated that Caldolor significantly reduces patient pain, while also significantly reducing patients' need for opioids.

Full prescribing and safety information can be found at the brand's website www.caldolor.com.

About Caldolor®

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 for 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 product treatment.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. The Company develops, acquires, and commercializes brands for the hospital acute care, gastroenterology and rheumatology market segments. The Company's portfolio of FDA-approved brands includes:

- **Acetadote®** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **Vibativ®** (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation; and
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

The Company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidates in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), Systemic Sclerosis ("SSc"), and Aspirin-Exacerbated Respiratory Disease ("AERD").

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, natural disasters, public health epidemics, and other events beyond our control, as more fully discussed in the Company's most recent Form 10-K and subsequent 10-Qs 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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Investor Contact: Shayla Simpson, Cumberland Pharmaceuticals, (615) 255-0068; Media Contact: Julia Motis, Dalton Agency, (615) 515-4894