Caldolor® Now FDA Approved For Pre-Operative Administration

November 29, 2021

Dosed prior to surgery, Caldolor® demonstrated significant reduction in pain intensity

NASHVILLE, Tenn., Nov. 29, 2021 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company today announced 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 pre-operative administration. The non-narcotic pain reliever may now be administered just prior to surgery to enable patients to wake up from their procedure in significantly less pain.

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 pregnant women, children and other populations.

Supporting this expanded use of Caldolor, a study of orthopedic surgical pain confirmed the significant pain reduction when the product was administered every six hours (started pre-operatively) with supplemental morphine available on an as needed basis. A total of 185 patients were randomized and treated with either Caldolor® 800 mg or placebo administered every six hours (started pre-operatively) and morphine provided on an as needed basis. Efficacy was demonstrated as a statistically significant greater reduction in pain intensity over 24 hours post-operatively for patients treated with Caldolor® as compared to those receiving placebo.

Dr. Stephen Southworth, an orthopedic surgeon at the Orthopedic Institute of North Mississippi concluded that "Caldolor® administered pre-operatively should be considered in *Enhanced Recovery After Surgery* (ERAS) protocols for the management of postoperative pain including that of traumatic origin. When administered immediately prior to surgery, patients given Caldolor experience less postoperative pain and a decrease in their opioid use."

"Before the pandemic began, healthcare systems across the country were in the midst of a public health mission to control surgical pain while decreasing opioid consumption," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals Inc. "We are proud to see the continued support for Caldolor's use in surgical care, with the product's approved labeling now including the expanded use of the product prior to surgery. We feel confident that this important development provides additional insights into how intravenous ibuprofen can help healthcare professionals and patients as elective surgeries resume."

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.

For full prescribing information, including boxed warning, visit www.caldolor.com.

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;
- **RediTrex®** *(methotrexate)* Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis; 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/caldolor-now-fda-approved-for-pre-operative-administration-301433207.html

SOURCE Cumberland Pharmaceuticals Inc.

Investor Contact: Shayla Simpson, Cumberland Pharmaceuticals, (615) 255-0068; Media Contact: Molly Aggas, Dalton Agency, (704) 641-6641