Caldolor® Demonstrates Significant Reduction Of Opioid Use In Orthopedic Trauma Patients

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New study shows use of Caldolor® prolongs time to first narcotic administration

NASHVILLE, Tenn., July 20, 2020 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX),** a specialty pharmaceutical company, today announced the results of a Level 1 Trauma Center study recently published in the Journal of Orthopedic Trauma. Results demonstrate Caldolor® (*ibuprofen*) Injection significantly reduces the quantity of opioids required to manage pain after a traumatic injury with fracture. In addition, the time to first narcotic medication was longer in the Caldolor group than with hospital standard of care. Further, pain was managed better in the Caldolor® group compared to standard of care narcotics[1].

This single-center, randomized, double-blind, placebo-controlled study was led by Drs. Russell Weisz, MD and Alexander Fokin at Delray Beach Medical Center in Delray Beach, Florida. The aim of the research was to evaluate the efficacy of Caldolor® administration in the management of acute pain in orthopedic trauma patients and to minimize opioid use. A total of 99 orthopedic trauma patients with fractures of the ribs, face, extremities, and/or pelvis were randomized to receive either 800 mg IV ibuprofen or placebo administered every 6 hours for a total of 8 doses within 48 hours of admission. Both cohorts were given access to the hospital's standard of care medications. Results demonstrated Caldolor® (IV Ibuprofen) statistically significantly reduced opioid consumption compared with placebo plus standard of care medications during the initial 48-hour period. The pain intensity level was also statistically less at 8 hours, and the time to first narcotic medication was significantly longer in the Caldolor® group.

"With at least 75% of patients coming to emergency departments with a chief complaint related to pain, prudent and careful management of pain is of utmost importance," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals Inc. "Pain management has become one of the most common healthcare problems, with annual direct and indirect costs exceeding that of heart disease and cancer.[2] Physicians are often the first people to prescribe an opioid to a patient experiencing severe pain due to trauma. Cumberland is excited to offer these physicians an alternative to opioids, such as Caldolor, available in a ready-to-use bag that requires no dilution."

References:

1. Weisz RD, Fokin AA, Lerner V et al. Intravenous Ibuprofen Reduces Opioid Consumption During the Initial 48 Hours After Injury in Orthopedic Trauma Patients. *Journal of Ortho Trauma*. 2020;34(7): 341 – 347
2. Gaskin DJ, Richard P. Relieving Pain in America: Relieving Pain in America: A Bluprint for Transforming Prevention, Care, Education, and Research. National Academies Press (U.S.) 2011. ISBN-13: 978-309-21484-1

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 treatment with Caldolor.

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 and gastroenterology 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;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **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;
- **RediTrex®** *(methotrexate)* Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

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"), Hepatorenal Syndrome ("HRS") and Portal Hypertension ("PH").

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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