Newly Published Literature Supports Use Of Caldolor® For Postoperative Pain And Reduction Of Opioid Use

August 18, 2020

NASHVILLE, Tenn., Aug. 18, 2020 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company, today announced the results of a new review of clinical studies evaluating Caldolor® (*ibuprofen*) Injection, which was published in the journal *Clinical Therapeutics*. The manuscript continues an updated integrated safety analysis of Caldolor first presented in 2015[1]. It provides an analysis of nine additional published clinical studies of the product evaluating efficacy, concurrent opioid use, tolerability, pharmacokinetic properties, stress response and postoperative recovery. Results demonstrated Caldolor reaches a higher plasma concentration more quickly than oral ibuprofen, improves post-surgery recovery, decreases surgical stress, and reduces the use of opioids and over-the-counter medication.

The comprehensive review involved 1,062 adult patients, with 757 receiving Caldolor and 305 receiving placebo or a comparator medication. The authors concluded the rapid administration (5-7 minutes) and preemptive use of Caldolor should be considered in *Enhanced Recovery After Surgery* (ERAS) protocols for the management of postoperative pain including that of traumatic origin[2]. When administered in a rapid infusion immediately prior to surgery, patients given Caldolor experienced less postoperative pain and decreased opioid use.

"Before the pandemic began, healthcare systems across the country were in the midst of a public health mission to decrease opioid consumption," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals Inc. "We are proud to see the continued support for the use of Caldolor in postoperative care, with the resulting reduction of opioid use. We feel confident that this newly published narrative provides additional insights into how intravenous ibuprofen can help healthcare professionals and patients as elective surgeries resume."

References:

1. Southworth SR, Woodward EJ, Peng A, et al. An Integrated Safety Analysis of Intravenous Ibuprofen (Caldolor®) in Adults. J Pain Res. 2015;8:753-765
2. Southworth SR, Sellers JA. Narrative Summary of Recently Published Literature on Intravenous Ibuprofen. Clinical Therapeutics, Vol 42, Number 7 July 2020 Open Access (In Press)

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").

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:http://www.prnewswire.com/news-releases/newly-published-literature-supports-use-of-caldolor-for-postoperative-pain-and-reduction-of-opioid-use-301113912.html

SOURCE Cumberland Pharmaceuticals Inc.

Investor Contact - Erin Gull, Corporate Relations, (615) 255-0068; Media Contacts - Jeff Bradford, the Bradford Group, (615) 515-4880 office, (615) 337-0964 mobile, or Molly Aggas, the Bradford Group, (615) 515-4882 office, (704) 641-6641 mobile