NEW PUBLICATION SUPPORTS THE USE
OF CALDOLOR® IN NEWBORN PEDIATRIC PATIENTS

NASHVILLE, Tenn. (June 26, 2023) - Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX), a specialty pharmaceutical company, today announced the publication of positive results from a clinical study investigating the safety and pharmacokinetics of Caldolor® in newborn infants, published in the journal *Pediatric Drugs*[1]. Caldolor (*ibuprofen*) injection, is an intravenous non-steroidal anti-inflammatory drug (NSAID) approved by the FDA for the treatment of pain and fever in adults and children. The results of this published study supported the recent FDA approval of Caldolor in infants 3 to 6 months of age[2].

"We're excited to publish the results of this study highlighting the safety and the drug exposure profile of Caldolor in infants 1 to 6 months of age," said senior author Dr. John Zhong, Associate Professor of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, Children's Health of Dallas. "Caldolor provides an important new weapon in the armamentarium of clinicians treating this pediatric population for fever and pain. Treating pain synergistically with other non-opioid regimens can potentially lower narcotic consumption in this most vulnerable age group."

The clinical study evaluated the safety and drug exposure profile of Caldolor in 24 hospitalized infants between the ages of 1 and 6 months who required treatment for pain or fever. Of the 24 patients included in the study, three were under 3 months of age, and the remaining 21 patients were 3 to 6 months of age. Twenty patients received a single dose, and four patients received multiple doses. In this study, single and multiple 10 mg/kg doses of Caldolor® are reported safe, with no drug-related adverse events or renal concerns. Drug exposure following a single dose of Caldolor in infants 1 to 6 months of age was similar to what was previously reported in older children[3].

Administration of oral medications for the treatment of pain and fever in hospitalized pediatric patients can be challenging. Moreover, pain in pediatric populations is often poorly assessed and undertreated or mismanaged, leading to adverse patient outcomes (both long- and short-term) and increased healthcare expenditures. The results of this study support the growing body of evidence which demonstrate Caldolor is a safe therapeutic option available to practitioners for the treatment of fever and pain in children.

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

1. Glover CD et al. A Multi-Center Evaluation of the Pharmacokinetics and Safety of Intravenous Ibuprofen in Infants 1-6 Months of Age. *Pediatric Drugs.* 9 June 2023.
2. https://investor.cumberlandpharma.com/news-releases/news-release-details/caldolorr-now-fda-approved-treatment-fever-pain-infants
3. Khalil SN et al. A multicenter, randomized, open-label, active-comparator trial to determine the efficacy, safety, and pharmacokinetics of intravenous ibuprofen for treatment of fever in hospitalized pediatric patients. *BMC Pediatr*. 2017 Feb 1;17(1):42.

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.
- **Sancuso®** (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment.

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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