New Study Compares Caldolor® (ibuprofen injection) to ketorolac

– *Real World Study Compared Over 150,000 Adult & Pediatric Patients* –

– *Caldolor Associated with Fewer Adverse Drug Reactions* –

– *Caldolor also Improved Healthcare Utilization* –

NASHVILLE, Tenn. (November 5, 2024) – Specialty pharmaceutical company Cumberland Pharmaceuticals (Nasdaq: CPIX) today announced the publication of new real-world outcomes research demonstrating the safety and healthcare resource advantages of its Caldolor (*ibuprofen*) injection over ketorolac in both adult and pediatric populations. The study, published in *Frontiers of Pain Research*, provides compelling evidence that Caldolor is associated with a significantly reduced incidence of adverse drug reactions (ADRs) and improved healthcare utilizations when compared to ketorolac.

This extensive, retrospective, payer database analysis evaluated the records of over 17 million patients who had received either ketorolac or Caldolor. Ultimately, 31,046 Caldolor and 124,184 ketorolac adult patients were selected and compared for ADRs and subsequent healthcare resource utilization, which includes inpatient, outpatient and emergency department visits as well as all procedures and prescriptions during the follow up time of 29 days. An additional 5,579 pediatric patients were identified in each arm and compared in a separate claims analysis.

Key findings reveal that, in adults, Caldolor was associated with a 45% reduction in renal dysfunction ($p<0.001$) and a 78% decrease in hematuria rates ($p<0.001$) when compared to ketorolac. Notably, patients also experienced fewer gastrointestinal complications as well as reduced headaches, nausea and abdominal pain. Among pediatric patients, the results showed Caldolor was associated with a 51-65% lower rate of ADRs, including headache and nausea, with 95% confidence intervals supporting clinical significance.

Caldolor also demonstrated a positive impact on healthcare resource utilization (HCRU) when compared to ketorolac, with decreased emergency room and outpatient visits, as well as a shortened hospital length of stay for both adults and children.

“These findings underscore Caldolor’s potential to improve patient care by reducing their treatment complications, while also delivering potential saving for healthcare systems through decreased hospital readmissions and shortened treatment times,” said A.J. Kazimi, CEO of Cumberland Pharmaceuticals.

About Caldolor® (ibuprofen) Injection

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

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on providing unique products that improve the quality of patient care. The company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and oncology 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*) oral, a prescription laxative, for the treatment of constipation;
- **Sancuso®** (*granisetron)* transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol®** (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **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.

The company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy, Systemic Sclerosis and Idiopathic Pulmonary Fibrosis.

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

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.

SOURCE: Cumberland Pharmaceuticals Inc.

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