



## **NEW STUDY FINDS CALDOLOR® SAFE AND EFFECTIVE FOR OPIOID-SPARING PAIN MANAGEMENT IN OLDER ADULTS**

**Analysis Shows 23% Reduction in Morphine Use  
with Favorable Safety Profile in Patients 60 Years of Age and Older**

**NASHVILLE, Tenn. (May 27, 2025) - Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX)**, a specialty pharmaceutical company, today announced the publication of its study investigating Caldolor® (intravenous ibuprofen) in older patients. The analysis evaluated the safety and efficacy of Caldolor for the management of pain and fever in patients 60 years of age and older. It marks an important advancement in pain management for older individuals, as it's one of the first studies specifically evaluating Caldolor in this vulnerable population.

Pain management in older patients presents unique challenges due to their increased sensitivity to opioid analgesics and higher risk of side effects. Nearly one-third of all ambulatory surgeries are performed on older patients, yet this population is often underrepresented in clinical trials, highlighting an important medical need addressed in this study.

A post-hoc subgroup analysis was performed using data from four prospective clinical studies in which Caldolor was administered for the treatment of pain and/or fever in hospitalized patients. The efficacy analysis included 591 patients from two placebo-controlled trials, with safety assessed across all 1,041 patients.

"These results provide compelling evidence that intravenous ibuprofen is both safe and effective for managing post-operative pain in older patients," said Dr. Tong Joo Gan, MD, MBA, Division Head of Anesthesiology, Critical Care and Pain Medicine at MD Anderson Cancer Center. "The significant reduction in opioid consumption is particularly important for this vulnerable population, who face heightened risks from opioid-related adverse events including falls, respiratory depression and cognitive impairment."

"We've long recognized the need for effective non-opioid analgesic options for older surgical patients," noted Dr. Stephen Southworth, MD, four-time board-certified orthopaedic surgeon at Orthopaedic Institute of North Mississippi. "This analysis demonstrates that Caldolor not only reduces pain intensity but also decreases the need for opioid medication, potentially improving overall recovery outcomes in this growing demographic. The majority of pain from injury and surgery is inflammatory in nature and is unaddressed by opioids which is why Caldolor has become a cornerstone of our multi-modal pain regimen."

Key findings include:

- Caldolor treatment resulted in a 24% reduction in pain at rest ( $p=0.008$ ) and a 20% reduction in pain with movement ( $p=0.001$ ) between 6 and 24 hours post-surgery compared with placebo.
- Caldolor treatment led to a 23.2% reduction in total post-operative morphine requirement ( $p=0.031$ ) compared with placebo.
- The incidence of adverse events was lower in Caldolor-treated patients compared to placebo (55% vs 90% in older patients).
- No notable increases in gastrointestinal, renal, cardiovascular or bleeding adverse events were observed with Caldolor treatment.
- There were no significant differences in the efficacy and safety profiles of Caldolor in older patients compared with those in younger patients, despite the higher cumulative doses of the product administered to older patients.

“These impressive results validate our commitment to providing safe and effective pain management options across diverse patient populations,” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “As the global aging population continues to grow, there is an increasing need for evidence-based treatment approaches specifically evaluated in older individuals. This analysis demonstrates that Caldolor can be an important component of multimodal analgesia regimens for older patients, supporting our mission to improve patient care through innovative therapies.”

Today’s announcement builds on Cumberland’s ongoing commitment to expanding the clinical applications of Caldolor. In June 2023, the company announced the publication of positive results from a clinical study investigating the safety and pharmacokinetics of Caldolor in newborn infants, which supported the FDA approval of Caldolor for use in infants 3 to 6 months of age. With these latest findings in older patients, Cumberland continues to demonstrate Caldolor’s safety and efficacy across the full age spectrum, from infants to older adults.

Caldolor is FDA-approved for the management of mild to moderate pain, management of moderate to severe pain as an adjunct to opioid analgesics, and reduction of fever in adults and pediatric patients three months and older. This new data supports its use specifically in the older patient population. Next steps include further outreach to health care providers treating older patients to share these important findings.

More information regarding Cumberland’s approved products can be found at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

#### **References:**

Gan TJ, et al. The Safety and Efficacy of Intravenous Ibuprofen in Older Patients: A Retrospective Subgroup Analysis. *Clinical Therapeutics* 2025.

#### **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**<sup>®</sup> (*acetylcysteine*) injection, for the treatment of acetaminophen poisoning;
- **Caldolor**<sup>®</sup> (*ibuprofen*) injection, for the treatment of pain and fever;
- **Kristalose**<sup>®</sup> (*lactulose*) oral, a prescription laxative, for the treatment of constipation;
- **Sancuso**<sup>®</sup> (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol**<sup>®</sup> (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **Vibativ**<sup>®</sup> (*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 Phase 2 clinical studies evaluating its ifetroban product candidate in patients with Duchenne muscular dystrophy, systemic sclerosis and idiopathic pulmonary fibrosis.

For more information on Cumberland’s approved products, including full prescribing information, please visit the individual product websites, which can be found on the company’s website: [www.cumberlandpharma.com](http://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. Forward-looking statements include, among other things, statements regarding the company's intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate," "look forward" and other comparable terms or the negative thereof. 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 operation results. These factors include macroeconomic conditions, including rising interest rates and inflation, competition, an inability of manufacturers to produce Cumberland's products on a timely basis, failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, natural disasters, public health epidemics, maintaining an effective sales and marketing infrastructure, and other events beyond the company's control as more fully discussed in its most recent annual report on Form 10-K as filed with the U.S. Securities and Exchange Commission ("SEC"), as well as the company's other filings with the SEC from time to time. 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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