



**NEW REPORT SUPPORTS USE OF CALDOLOR® AS  
A STANDARD OF CARE ACROSS PATIENT POPULATIONS**

*Growing data shows intravenous ibuprofen is safe and effective  
for the treatment of pain and fever in adults, children and infants*

**NASHVILLE, Tenn. (April 2, 2024) – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX)**, a specialty pharmaceutical company, today announced the release of a [Special Report](#) evaluating the growing amount of current data supporting the use of its Caldolor® product (intravenous ibuprofen, or IVIB) as a standard of care for the treatment of pain and fever in adults, children and infants.

The report, published in *Anesthesiology News*, *General Surgery News* and *Pharmacy Practice News*, highlights the need for the prudent and careful management of pain, particularly as the prescription of opioids for pain treatment has become commonplace, often leading to dependence and misuse.

“My hope is that this Special Report will emphasize the use of Caldolor as a foundation for multimodal pain management, while also helping to address the opioid epidemic,” said Michael W. Lew, M.D., Clinical Professor and Past Chair for the Department of Anesthesiology and Perioperative Medicine at the City of Hope Cancer Center.

As part of a comprehensive safety and efficacy developmental plan, IVIB was studied in various treatment areas, including surgical pain, fever and nonsurgical acute pain. The results, which are highlighted in the report, show it’s a safe and effective treatment for pain and fever in adults, children and infants as young as 3 months of age.

Takeaways from the report note that:

- IVIB results in significant reduction in temperature compared with placebo (in adults) and with acetaminophen (in pediatric patients).
- Administration of the product prior to surgery leads to patients waking up in significantly less postsurgical pain, while also lessening or even eliminating the need for opioids.
- IVIB use in the hospital ED for acute pain can minimize opioid requirements, while achieving pain control.
- IVIB is the only non-opioid injectable analgesic approved for use in children as young as 3 months of age.
- IVIB should be considered a foundation for any multimodal pain regimen.

“Pain management has become one of the most common health care problems,” said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. “As this new report states, comprehensive multimodal pain regimens have become key in preventing pain and optimizing pain control, while minimizing the need for opioids. A non-steroidal anti-inflammatory drug, or NSAID, such as Caldolor has become a cornerstone for many treatment paradigms, and we are continually encouraged by the growing database from our studies of the product in patients of all ages.”

To learn more about the clinical results demonstrated with IVIB and read the full report at <https://www.pharmacypracticenews.com/Monographs-and-Whitepapers/Article/02-24/Intravenous-Ibuprofen-for-the-Treatment-of-Pain-and-Fever-An-Update/72896>.

For full prescribing and safety information, visit [www.caldolor.com](http://www.caldolor.com).

## **About Caldolor®**

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and the 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 as well as 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](http://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;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) oral, 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;
- **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. Investigational new study applications have been cleared by the FDA enabling Cumberland to launch clinical studies in each of these areas.

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 at [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.

SOURCE: Cumberland Pharmaceuticals Inc.

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