



**CUMBERLAND PHARMACEUTICALS ANNOUNCES**

**FDA APPROVAL OF CALDOLOR™**

*New drug is first injectable product approved for sale in the United States  
for treatment of pain and fever*

**NASHVILLE, Tenn. (June 11, 2009)** – Cumberland Pharmaceuticals ([www.cumberlandpharma.com](http://www.cumberlandpharma.com)) today announced the U.S. Food and Drug Administration (FDA) has approved **Caldolor™**, an intravenous formulation of ibuprofen, through a priority review. Caldolor is the first and only injectable product approved for sale in the United States for the treatment of both pain and fever.

Caldolor will be used primarily in hospitalized patients who are unable to receive oral therapies for pain relief and fever reduction. The only injectable drugs currently available to reduce pain are opioids, such as morphine and meperidine, and ketorolac, a non-steroidal anti-inflammatory drug. Opioids can cause sedation, nausea, vomiting, cognitive impairment, and respiratory depression. Ketorolac is associated with an increased risk of bleeding as well as gastrointestinal and renal complications. Despite these side effects, the U.S. market for injectable pain relievers was approximately 679 million units in 2008. Currently, there is no FDA approved intravenous therapy for reduction of fever other than Caldolor.

“The approval of Caldolor gives physicians, long comfortable with the use of oral ibuprofen formulations, an alternative therapy for pain and fever in the hospital setting where an injectable medicine is often needed,” said Ken Holroyd, Assistant Vice Chancellor for Research and Associate Professor of Anesthesiology & Medicine at Vanderbilt University. “An FDA approved injectable fever therapy, and an alternative to injectable narcotic pain therapy, is welcomed.”

Clinical trials have shown Caldolor to be safe and effective in reducing both pain and fever in 1,400 hospitalized patients. In Phase III studies, patients who were given Caldolor reported a significant reduction in post-surgical pain intensity within the first 24 hours while also significantly reducing their morphine use. Clinical trials including critically ill and non-critically ill patients with fever showed a significant reduction in temperature as compared with those who received a placebo. No serious adverse events were directly attributed to Caldolor in any of these clinical studies.

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“We are delighted to obtain FDA approval for the first and only intravenous treatment for pain and fever in the U.S. market,” said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. “Cumberland is dedicated to providing innovative products that improve quality of care for patients and address unmet medical needs. We believe Caldolor represents a significant addition to our product portfolio and a substantial market opportunity.”

Caldolor is the third drug in Cumberland's portfolio and the second for which Cumberland has completed development and secured FDA approval. The company will promote Caldolor in the United States through its expanded hospital sales force and will use alliances with marketing partners for sales outside of the United States. Caldolor is expected to be available in the U.S. later this year.

### **About Caldolor**

Caldolor is indicated 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 in adults. It is the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or 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.

### **About Cumberland Pharmaceuticals**

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company that develops and markets branded, prescription products for targeted physician segments, including hospital acute care and gastroenterology. Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information, please visit the Cumberland Pharmaceuticals web site at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

### **Forward-Looking Statements**

This release contains forward-looking statements which reflect management's current views of future events and operations. Forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from these statements. Cumberland does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

Caldolor™ is a trademark of Cumberland Pharmaceuticals Inc.