



Anesthesiologists Use Caldolor® To Provide Preemptive Pain Control for Surgical Patients at U.S. Medical Centers

- Dosed at induction of analgesia, Caldolor preemptively addresses surgical pain and inflammation**
- IV ibuprofen offers improved pain control vs. opioids alone while reducing opioid consumption**

NASHVILLE, Tenn., March 2, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced that Caldolor® (*ibuprofen*) Injection is being used by anesthesiologists in a growing number of hospitals and surgery centers to provide preemptive analgesia for surgical patients. In 2009, Caldolor became the first injectable product approved by the FDA with a dual indication for treatment of pain and fever in adults. Designed primarily for use in the hospital setting, Caldolor is on formulary at a growing number of U.S. medical centers.

Due to its broad indication, Caldolor is being used by physicians in a wide variety of settings to treat pain and fever in hospitalized patients. This includes an increasing number of anesthesiologists who are using Caldolor at induction of analgesia to preemptively address pain and inflammation associated with surgical procedures.

"Caldolor provides an important mechanism to control onset of pain for surgical patients, which is translating to notable improvements in patient recovery following surgery," said Michael H. Rock, M.D., who specializes in pain medicine and anesthesiology at Our Lady of the Resurrection Medical Center and RHC Ambulatory Services in Chicago. "The ability to safely administer IV ibuprofen prior to the surgical incision represents an important new development in my practice. Caldolor is the only parenteral, non-opioid analgesic that I trust to be used in the full perioperative period, as it has been shown in clinical trials to be safe for pre- and post-operative dosing."

The World Health Organization has recommended a multi-modal approach to pain management, with non-opioid analgesics such as ibuprofen recommended as first-line treatment.(1) Caldolor offers IV delivery of ibuprofen to control pain and has significantly reduced opioid consumption by up to 31% immediately following surgery. Reduction in opioid use could reduce opioid-related side effects such as sedation, nausea, vomiting, cognitive impairment and respiratory depression.

William Weisberg, D.O., anesthesiologist and medical director at the Surgery Center at Coral Springs in Coral Springs, Florida, has also seen improved post-surgical outcomes by administering Caldolor to patients at induction of anesthesia. "Initiating Caldolor's analgesic and anti-inflammatory properties prior to surgery minimizes the cascade of pain and inflammation, which is resulting in improved pain relief in the 24 hour period following surgery," said Dr. Weisberg. "This method of addressing pain before it occurs coupled with Caldolor's ability to achieve better pain control than opioids alone translates to less patient pain and a lower requirement for opioids. Our use of opioid rescue in the PACU (post-anesthesia care unit) has decreased, and incorporation of Caldolor into our multi-modal pain management model has led to increased patient satisfaction."

In clinical trials, Caldolor has demonstrated pain relief above and beyond that which was provided by opioids alone, while also reducing opioid use. A published study, entitled "A Multicenter, Randomized, Double-Blind Placebo-Controlled Trial of Intravenous-Ibuprofen (IV-Ibuprofen) for Treatment of Pain in Post-Operative Orthopedic Adult Patients," appeared in the August 2010 edition of the peer-reviewed journal *Pain Medicine*, and concluded that dosing Caldolor at induction of analgesia as well as post-operatively is effective in treating pain and reducing morphine use in adult patients. This study provides safety and efficacy data supporting use of Caldolor in surgical patients not only during recovery, but also when administered prior to surgery.

"In the practice of acute pain medicine, reducing reliance on opioids is a strategic imperative," said Jonathan S. Jahr, M.D., Co-Editor of [The Essence of Analgesia and Analgesics](#), published in 2011. "There is no question that multimodal approaches to treating pain are becoming the new standard. Using IV ibuprofen, which has been safely administered prior to surgery and in the immediate 24-hours following surgery, as baseline treatment with opioids offers a new level of pain care that is progressive."

"Our data supporting safe use of Caldolor prior to surgery, coupled with its capacity to reduce narcotic use while improving pain control in the immediate 24-hour period after surgery, makes it an important treatment option for addressing pain in surgical patients," said A.J. Kazimi, Chief Executive Officer at Cumberland Pharmaceuticals. "Garnering support from anesthesiologists is very rewarding, as we believe they are critical to helping us bring this important new medication to the many patients who can experience improved post-operative recovery because of it."

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 for the reduction of fever in adults. For full prescribing information, including boxed warning,

visit www.caldolor.com.

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

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland markets Acetadote® for the treatment of acetaminophen poisoning, Caldolor®, the first injectable ibuprofen treatment for pain and fever approved in the United States, and Kristalose®, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information, please visit www.cumberlandpharma.com.

Important Note Regarding Forward-Looking and External Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to 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 operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include, among others, those factors discussed in Cumberland's Annual Report on Form 10-K as filed with the SEC on March 19, 2010. There can be no assurance that results or developments anticipated by Cumberland will be realized or, even if realized, that they will have the expected effects. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

This press release also contains external statements from healthcare professionals. These statements are the expressed opinions of the quoted medical professionals based upon their individual experiences. Cumberland cannot independently verify these statements and readers are cautioned not to place undue reliance on them. The healthcare professionals who provided these statements have presented information on Caldolor at medical meetings.

References

(1) World Health Organization. Pain relief and palliative care. In: *Clinical Management of HIV and AIDS at District Level*. New Delhi, India: WHO Regional Office for South-East Asia Web site. http://www.searo.who.int/linkfiles/publications_ch11.pdf. Updated April 26, 2006. Accessed July 15, 2009.

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