



## Caldolor(R) (ibuprofen) Injection Gaining Approval on Formulary at U.S. Medical Centers

### Product being used in various patient populations to treat pain and fever

NASHVILLE, Tenn., Sept 23, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced that Caldolor(R) (*ibuprofen*) Injection is gaining momentum and being approved for use in a growing number of medical facilities across the country. Several key U.S. hospitals, including **Orlando Regional Medical Center**, **St. Elizabeth Healthcare** in the Greater Cincinnati region and the **Joseph M. Still Burn Centers**, have added the product to their formularies for patient use. Designed primarily for use in the hospital setting, Caldolor is the first injectable product approved for use in the United States for the treatment of pain and fever.

**Orlando Regional Medical Center** (ORMC) is one of more than 230 institutions that have granted formulary approval since the drug's September 2009 launch. The 808-bed hospital serves as Central Florida's only Level One Trauma Center.

"Since the introduction of Caldolor at ORMC I have had the opportunity to use the product in a variety of patients, but most notably in my trauma patients," said Dr. John T. Promes, Director of Trauma Services and Associate Director for Surgical Education at Orlando Regional Medical Center. "Severe pain is difficult to treat, especially in patients with complex issues such as numerous fractures, impaired breathing from a collapsed lung and any number of other issues. Adding Caldolor to my practice has enabled me to decrease reliance on opioids and make patients more comfortable more quickly than with opioids alone. Getting patients moving around sooner can lead to faster recovery and decreased potential need for transfer to the intensive care unit. While opioids alone generally mask pain, adding Caldolor represents a new and multi-faceted approach to pain management, allowing me to treat pain at the source."

In clinical trials, using Caldolor as adjunct therapy has demonstrated pain relief above and beyond that which was provided by narcotics alone, while also reducing narcotic use. A recently published clinical trial shows that dosing Caldolor at induction of analgesia and post-operatively is effective in treating pain and reducing morphine use in adult patients. The newly 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 concludes that IV ibuprofen significantly decreased pain with movement by 26% ( $p < 0.001$ ) and decreased morphine use by 31% ( $p < 0.001$ ) when compared with placebo. There was no significant difference between placebo and IV ibuprofen in the number of patients with bleeding adverse events, the incidence of blood transfusions or other serious adverse events. More patients receiving IV ibuprofen experienced vomiting and more patients receiving placebo experienced dyspepsia.

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.<sup>(1)</sup> Caldolor offers IV delivery of ibuprofen to control pain while allowing physicians to limit opioid use. Reduction in opioid use could potentially reduce opioid-related side effects such as sedation, nausea, vomiting, cognitive impairment and respiratory depression.

Dr. Dean Adams, colon and rectal surgeon at **St. Elizabeth Healthcare** in Greater Cincinnati and owner of Colorectal Care of Northern Kentucky, has also seen a substantial improvement in patients recovering from colorectal surgeries when treated with Caldolor. Rated by HealthGrades as a Distinguished Hospital for Clinical Excellence, St. Elizabeth ranks in the top 5 percent in the nation for quality of care and is one of the oldest, largest and most respected medical providers in the Greater Cincinnati region.

"Using Caldolor to manage post-operative pain is providing a real benefit for my patients as they are reporting substantially lower levels of pain following surgery," said Dr. Adams. "Caldolor definitely reduces their narcotic consumption. This can speed recovery of gut function after bowel surgery, and a number of my patients have used little or even no narcotic after a colon resection. Caldolor has made a real improvement in post-operative pain control in my practice."

The **Joseph M. Still Burn Center** (JMS) in Augusta, Georgia, has found similar results in using Caldolor to treat fever and pain in burn patients. An independent burn facility with 59 beds, including 25 critical care beds, JMS is the largest burn center in the country and the third largest in the world.

"My experience with Caldolor in reducing fever in patients with severe burns has been excellent," said Dr. Richard J. Cartie, who practices critical care medicine at JMS. "These patients often suffer from intensely high fever, and burns are obviously also associated with severe pain. Caldolor is an ideal treatment option because it is an anti-inflammatory agent that quickly and effectively reduces fever while also controlling pain."

According to the American Burn Association, 1.1 million burn injuries require medical attention each year in the United States. Of these, approximately 50,000 burn injuries require hospitalization, 20,000 are major burn injuries affecting 25 percent of total body surface area and 4,500 people die. In addition, up to 10,000 people in the United States die every year from burn-related infections.(2)

"We believe that the clinical data supporting the safety and efficacy of Caldolor is being validated by the experiences of these and other premier institutions," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "The types and numbers of patients that stand to benefit from treatment with this product are just beginning to be discovered. We are thrilled to be on the forefront of what we believe is a breakthrough in the very broad spectrum of treatment for pain and fever."

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](http://www.caldolor.com).

#### 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](http://www.searo.who.int/linkfiles/publications_ch11.pdf). Updated April 26, 2006. Accessed July 15, 2009.

(2) American Burn Association (2002). Burn Incidence Fact Sheet.

#### 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](http://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's product portfolio includes Acetadote(R) (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning and Kristalose(R) (*lactulose*) for Oral Solution, a prescription laxative. The Company also recently launched Caldolor(R) (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit [www.cumberlandpharma.com](http://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 including language such as "decrease reliance", "more comfortable", "faster recovery", "moving sooner", "decreased need to transfer", "dramatic improvement" and "speeding recovery". Such 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. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof.

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