



## Cumberland Pharmaceuticals Partners in Canada With Alveda Pharmaceuticals to Commercialize Caldolor(R)

### Expands international presence for Caldolor(R) (ibuprofen) Injection

NASHVILLE, Tenn., April 28, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced it has entered into an exclusive agreement with Alveda Pharmaceuticals Inc. (Alveda Pharma), a Toronto-based specialty pharmaceutical company, for the commercialization of Caldolor(R) (*ibuprofen*) Injection in Canada. Designed to treat pain and fever in the hospital setting, Caldolor was approved by the U.S. Food and Drug Administration (FDA) and launched by Cumberland in the United States in 2009.

The agreement is Cumberland's third for the international commercialization of Caldolor. In 2009, the company partnered with Phebra Pty Ltd. for the commercialization of Caldolor in Australia and New Zealand, and DB Pharm Korea Co. Ltd. for South Korea. Cumberland manages the commercialization of Caldolor in the United States.

"We are pleased to add Alveda Pharma to our growing network of international partners," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Alveda Pharma's emphasis on filling unmet and under-met medical needs along with their strong experience in marketing hospital injectables makes them an ideal partner for Cumberland. We look forward to working together to expand access to this important drug."

According to the terms of the agreement, Alveda Pharma will seek Canadian regulatory approval for Caldolor and, upon approval, handle ongoing regulatory requirements as well as product marketing, distribution and sales throughout Canada. Cumberland will maintain responsibility for product formulation, development and manufacturing. In exchange for the license to the product, Cumberland will receive royalties on future sales of Caldolor in addition to upfront and milestone payments as well as a transfer price.

Caldolor is used primarily in hospitalized patients who are unable to receive oral therapies for pain relief and fever reduction. If approved for marketing in Canada, it would be the first and only injectable ibuprofen product available in the country for treatment of pain and fever, featuring analgesic, antipyretic and anti-inflammatory properties.

"There is a significant and growing body of research that supports the safety and efficacy of Caldolor for the treatment of pain and fever in adults," said Albert Beraldo, President of Alveda Pharma. "Due to Caldolor's attributes and strong performance in clinical trials, we are excited to share this innovative product with physicians and patients and to continue building a strong hospital presence throughout Canada."

A recent meta-analysis published in the March 2010 edition of the peer-reviewed journal *The Annals of Pharmacotherapy* showed that ibuprofen demonstrated superior efficacy compared to acetaminophen for the treatment of pain and fever in the majority of evaluated studies, and found no significant safety differences between the drugs.

The data supports findings from several previously published studies on the effectiveness of Caldolor for the treatment of pain and fever. A study published in Volume 31, Number 9 of the peer-reviewed journal *Clinical Therapeutics*, entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Intravenous Ibuprofen for the Management of Postoperative Pain in Adults," concluded that postoperative patients receiving Caldolor required less narcotic and experienced less pain compared to patients receiving morphine alone. 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)

### 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 available 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).

## **About Alveda Pharmaceuticals**

Alveda Pharmaceuticals is a Canadian company specializing in the marketing and distribution of quality pharmaceuticals and medical devices that address the unmet and under-met medical needs of the Canadian healthcare system. By working in conjunction with healthcare providers, wholesalers, and distributors across the country, Alveda Pharma ensures patients receive the best available products while improving medication safety. For more information, please visit [www.alvedapharma.com](http://www.alvedapharma.com).

## **Important Note Regarding Forward-Looking 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, however, 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 market conditions, intense competition from existing and new products, an inability of manufacturers to produce Caldolor on a timely basis or a failure of manufacturers to comply with stringent regulations applicable to pharmaceutical drug manufacturers, maintaining an effective sales and marketing infrastructure, government regulation, the possibility that marketing exclusivity and patent rights may provide only limited protection from competition, and other factors set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in Cumberland's Form 10-K filed with the SEC on March 19, 2010. There can be no assurance that the results or developments anticipated by Cumberland will be realized or, even if substantially 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 forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

## **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.

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