



Caldolor(R) (Ibuprofen) Injection Shown to Significantly Reduce Fever in Malaria Patients in Newly Published Clinical Trial

--Caldolor associated with significant fever reduction within the first 24 hours --Study is the first to document a decisive effect of an IV NSAID on malarial fever

NASHVILLE, Tenn., July 12, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced that data supporting the efficacy of Caldolor in treating fever associated with falciparum malaria was published in the July edition of the peer-reviewed *American Journal of Tropical Medicine and Hygiene*. The study, which is the first to document an antipyretic effect of an injectable non-steroidal anti-inflammatory drug (NSAID) on fever caused by malaria, demonstrated that patients who received intravenous ibuprofen experienced a greater reduction in their temperatures than those who received placebo.

According to the Centers for Disease Control, there are 300 to 500 million cases of malaria each year worldwide and more than 1 million people die from it. Fever is one of the most common symptoms of the disease and many patients with severe malaria may deteriorate when their fever rises. Falciparum malaria is the most serious type of malaria and can be fatal within a few hours of the first symptoms. Currently, few options exist to treat fever in hospitalized patients who are unable to swallow or retain oral antipyretic therapy.

"Controlling fever and its associated symptoms is extremely critical in patients suffering from falciparum malaria," said Dr. David A. Warrell, Emeritus Professor of Tropical Medicine in the Nuffield Department of Clinical Medicine at the University of Oxford in the U.K., and lead author on the study. "Injectable ibuprofen provided rapid and well tolerated relief of fever for these patients and represents an especially important antipyretic treatment alternative for patients who are unable to take oral medicines."

The newly published data support findings from other previously published studies on the effectiveness of Caldolor(R) (*ibuprofen*) Injection for the treatment of both fever and pain. Designed for use in the hospital setting, Caldolor was approved by the U.S. Food and Drug Administration and launched by Cumberland in the United States in 2009. Caldolor is the first and only U.S.-approved injectable fever treatment and has been shown to significantly reduce pain and morphine use in the treatment of pain in adults.

"These findings validate our belief that Caldolor is a safe and effective way to reduce fever in patients suffering from a range of illnesses," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We believe the data supporting the efficacy of IV ibuprofen to reduce fever in critically ill malaria or sepsis patients offer strong support for its use in treating fever from a variety of sources, especially in patients who cannot tolerate oral medications."

A previous study, entitled "The Effects of Ibuprofen on the Physiology and Survival of Patients with Sepsis," was published in Volume 336, Number 13 of *The New England Journal of Medicine*. The results from that trial demonstrated that injectable ibuprofen reduced fever, pulse rate, and lactic acidosis in patients with sepsis, and was not associated with significant nephrotoxicity, gastrointestinal bleeding, transfusion requirements or other serious adverse events.

The newly published, double-blind, placebo-controlled malaria trial evaluated 60 hospitalized adults with acute uncomplicated falciparum malaria who were treated with artemisinin combination therapy. Thirty patients received 400 mg of intravenous ibuprofen and 30 received placebo every six hours for 72 hours. Patients who received IV ibuprofen experienced a greater reduction in fever than those who received placebo during the first 24 hours ($p=0.002$), and on through 72 hours ($p=0.0176$), following initial administration of study drug. The times for the mean temperature to fall below 37.0 degrees C were three hours for IV ibuprofen and 20 hours for placebo. Patients who received IV ibuprofen experienced a delay in parasite clearance, but this did not appear to be clinically important. Adverse events, none considered severe, occurred equally in both the ibuprofen and placebo groups. The study, entitled "Intravenous Ibuprofen (IV ibuprofen) Controls Fever Effectively in Adults with Acute Uncomplicated *Plasmodium falciparum* Malaria but Prolongs Parasitemia," can be found online at www.ajtmh.org.

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(R) for the treatment of acetaminophen poisoning and Kristalose(R), a prescription laxative. The Company also recently launched Caldolor(R), 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.

About the American Journal of Tropical Medicine and Hygiene

The American Journal of Tropical Medicine and Hygiene is the official scientific journal of the American Society of Tropical Medicine and Hygiene (ASTMH). The Society is a nonprofit, professional organization whose mission is to promote world health by the prevention and control of tropical disease through research and education.

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. As with any business, all phases of Cumberland's operations are subject to factors outside its control, and any one or combination of these factors could materially affect Cumberland's results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or a failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure 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 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.

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