Caldolor® Clinical Study in Hospitalized Burn Patients Published in Journal of Burn Care & Research

- Study demonstrates Caldolor significantly reduces fever in patients with severe thermal burns
- Publication supports safety of Caldolor administration over five days

NASHVILLE, Tenn., May 16, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (NASDAQ: CPIX) today announced that results from a clinical study evaluating the safety and efficacy of **Caldolor® (*ibuprofen*) Injection** in treating fever and pain in hospitalized burn patients was published in Volume 32, Number 1 of the *Journal of Burn Care & Research*. The study demonstrated that Caldolor significantly reduces fever in these patients, including those with severe thermal burns. The newly published study also supports the safety of Caldolor as it involved the highest dose and duration of exposure to IV ibuprofen to date, demonstrating that the recommended maximum daily dose of 3200mg/day over five days of treatment was well tolerated.

"Immediate and sustained regulation of body temperature and reduction of fever following a burn injury is critical to patient recovery as well as comfort," said Dr. John T. Promes, principal investigator of the study, Director of Trauma Services and Associate Director for Surgical Education at Orlando Regional Medical Center, Assistant Professor of Surgery at the University of Central Florida College of Medicine, and Clinical Assistant Professor in the Department of Surgery at the Florida State University College of Medicine. "Because oral administration of antipyretics in hospitalized burn patients is often impossible due to sedation, intubation and a variety of factors, IV fever reduction with an agent such as Caldolor is not only convenient but often necessary. Further, as a non-steroidal anti-inflammatory drug (NSAID), Caldolor has the potential to arrest the cascade of inflammation caused by burn injury and thereby alleviate pain in addition to fever."

The prospective, multicenter, randomized, double-blind, placebo-controlled trial was conducted at five U.S. and international sites, including hospital burn units and burn centers. The study evaluated 61 adult burn patients with second or third degree burns covering more than 10 percent total body surface area with an anticipated hospital stay of more than 72 hours and fever evidenced by temperatures of 38.0 degrees C (100.4 degrees F) or greater. Patients were administered 800mg of Caldolor every six hours for five consecutive days. The primary efficacy endpoint of the study was to reduce fever as measured by area under the curve for temperature (AUC-T degrees) over the first 24 hours of treatment, compared with a target temperature of 37.0 degrees C (98.6 degrees F). Statistical significance was achieved for the primary endpoint of the study, as **there was a significant reduction in temperature (AUC-T degrees, 0-24 hours) in patients receiving Caldolor compared with those receiving placebo (*p*=0.008)**. Caldolor was well tolerated and there was no significant difference in adverse events between patients receiving placebo and those receiving Caldolor.

"The publication of this study supports hospital physicians' ability to rely on Caldolor to treat burn patients, who often suffer from both fever and pain," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "These study results supporting use of Caldolor to treat fever in this patient population offer strong evidence of both efficacy and safety, and the product stands to help thousands of patients suffering from severe burns."

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.(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.

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 marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information, visit the Company's website at www.cumberlandpharma.com.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that 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 operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include market conditions, competition from existing and new products, an inability or failure of manufacturers to produce the Company's products on a timely basis or to comply with stringent regulations applicable to drug manufacturers, maintaining and building an effective sales and marketing infrastructure, government regulation, the possibility that patent rights may provide limited protection from competition, and other factors including those 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 11, 2011. There can be no assurance that results anticipated by Cumberland will be realized or, if realized, 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. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof.

References

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

SOURCE Cumberland Pharmaceuticals Inc.