Caldolor(R) (Ibuprofen) Injection Demonstrates Significant Fever Reduction in Hospitalized Burn Patients

- New data supports safety of Caldolor over 5 days of treatment

NASHVILLE, Tenn., Nov 23, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- *Cumberland Pharmaceuticals Inc.* (Nasdaq: CPIX)todayannounced positive new top-line results from a study evaluating the safety and efficacy of Caldolor (*ibuprofen*) Injection in treating fever in hospitalized burn patients.

Statistical significance was achieved for the primary endpoint of reducing fever in burn patients over the first 24 hours of treatment. The study evaluated 61 adult burn patients with second or third degree burns covering more than 10 percent total body surface area. Other participant criteria included an anticipated hospital stay of more than 72 hours and 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 study raised no safety concerns and the medication was well tolerated. There was no difference in adverse effects between patients who received a placebo and those receiving Caldolor.

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)

"Hospitalized burn patients often suffer from both fever and pain and our review of this data, along with results from our previous clinical work, supports our belief that Caldolor can be extremely helpful in treating these patients," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Further, we are thrilled to reaffirm that Caldolor can be administered to hospitalized patients for five consecutive days with no safety issues."

The multicenter, randomized, double-blind, placebo-controlled trial was conducted at five U.S. and international clinical sites, including hospital burn units and burn centers. As with previous clinical trials, Cumberland Pharmaceuticals plans to submit the results of this study for publication as well as for medical meeting presentation.

SOURCE: Cumberland Pharmaceuticals Inc.

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. The Company completed the initial public offering of its common stock in August 2009. For more information on Cumberland Pharmaceuticals, please visit www.cumberlandpharma.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.

References

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

SOURCE Cumberland Pharmaceuticals Inc.

http://www.cumberlandpharma.com