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## NEWLY PUBLISHED CLINICAL DATA SHOWS

## CALDOLOR® (IBUPROFEN) INJECTION REDUCES OPIOID USE WHILE IMPROVING PAIN RELIEF IN POST-OPERATIVE PATIENTS

- *Data demonstrates that IV ibuprofen is associated with significant reduction in morphine use in managing pain over immediate 24 hours following surgery*
- *Intravenous ibuprofen also significantly reduces post-operative pain compared to patients with open access to morphine*

**NASHVILLE, Tenn., Oct. 19, 2009 – Cumberland Pharmaceuticals Inc. (Nasdaq:CPIX)** announced today that its Phase III study on intravenous ibuprofen as a post-operative analgesic was published in Volume 31, Number 9 of the peer-reviewed journal *Clinical Therapeutics,* distributed in October. The study concludes that patients emerging from orthopedic and abdominal surgeries required less narcotic and experienced less pain with 800 mg of intravenous ibuprofen every six hours compared to morphine alone.

In the United States, approximately 80 percent of patients experience pain following surgery, with 86 percent of these patients reporting moderate to severe pain[1,2]. Both the World Health Organization and the American Society of Anesthesiologists Task Force recommend a multi-modal approach to pain management, with non-opioid analgesics such as ibuprofen recommended as first-line treatment[3,4].

"These clinical findings support the use of intravenous ibuprofen in achieving improved post-operative pain control," said Stephen Southworth, M.D., orthopaedic surgeon at the North Mississippi Sports Medicine & Orthopaedic Clinic, PLLC and lead author of the study. "IV ibuprofen is a valuable pain management option for physicians seeking a multi-modal approach to post-operative pain management for their orthopaedic and abdominal patients."

The goal of this study was to evaluate the safety and efficacy of two different doses of intravenous ibuprofen as an effective post-operative analgesic medication. It focused on the results of hospitalized patients undergoing orthopedic or abdominal surgery who were randomized to receive either a placebo or 400 or 800 mg of intravenous ibuprofen every six hours. All patients had access to morphine by patient controlled analgesia (PCA). The first dose of ibuprofen was administered intra-operatively at the initiation of surgical closure. The double-blind, placebo-controlled trial was conducted at 17 different sites in three countries on 406 patients who were scheduled to undergo elective, single-site orthopedic or abdominal surgery between February 2005 and September 2006.

Median morphine use and pain assessed at rest and with movement were significantly reduced during the first 24 hours after administration in patients who received the 800-mg dose of ibuprofen. Pain reduction with Caldolor was also significantly greater versus patients with open access to morphine.

According to the study, "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Intravenous Ibuprofen 400 and 800 mg Every 6 Hours in the Management of Postoperative Pain," intravenous ibuprofen is safe and well-tolerated when administered intra- and post-operatively. There was no significant difference between placebo and IV ibuprofen in the number of patients with renal function abnormalities, bleeding adverse events or in the incidence of blood transfusions. The publication can be found online at www.clinicaltherapeutics.com.

SOURCE: Cumberland Pharmaceuticals Inc.

**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® for the treatment of acetaminophen poisoning and Kristalose®, a prescription laxative. The Company also recently launched Caldolor®, 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 recently completed the initial public offering of its common stock.

For more information on Cumberland Pharmaceuticals, please visit www.cumberlandpharma.com.

**About Clinical Therapeutics Journal**

*Clinical Therapeutics*, published monthly, provides peer-reviewed, rapid publication of original reports of recent developments in drug therapy, as well as in-depth review articles on specific drug therapies or disease states. The journal serves an international audience of scientists and clinicians in a variety of research, academic, and clinical practice settings by quickly

disseminating research findings. In addition, the articles are indexed by all major biomedical abstracting databases.

Published articles range from studies exploring new drugs and new indications for existing drugs to large, multicenter Phase III and IV trials. In addition to publishing the results of a broad range of multispecialty clinical studies, the journal features two specialty sections, Pharmaceutical Economics & Health Policy, which addresses pharmacoeconomic, health outcomes, and contemporary issues related to drug therapy; and Pediatric Research which addresses matters regarding safe and effective drug therapy in infants, children, and adolescents. The journal also encourages submission of brief reports and commentaries on topics that are timely or provocative.

**References**

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