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Phase IV Studies Published Supporting The Safety Of A Shortened Infusion Time Of Caldolor® (ibuprofen) Injection

- - Shortened infusion time offers convenient administration

NASHVILLE, Tenn., Feb. 2, 2015 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the publication of two Phase IV studies adding to the growing body of literature that support the tolerability and efficacy of a shortened infusion time of **Caldolor® (ibuprofen) Injection**. The studies included a total of 450 patients enrolled at over 30 leading U.S. medical centers. The new publications reporting on the study results are currently available as open access articles in the journal *Clinical Therapeutics*.



"These studies support the utility of intravenous ibuprofen in the management of various types of pain, both surgical and non-surgical and the shortened infusion time allows for more convenient administration," states Sergio Bergeese, MD, lead author and researcher from The Ohio State University Wexner Medical Center.

The first study entitled, "*The Shortened Infusion Time of Intravenous Ibuprofen Part 1: A Multicenter, Open-Label, Surveillance Trial to Evaluate Safety and Efficacy*," was conducted across 13 clinical centers in the United States and enrolled 150 hospitalized patients experiencing mild to severe pain or a fever of greater than 101.0°F.

The second study entitled, "*The Shortened Infusion Time of Intravenous Ibuprofen Part 2: A Multicenter, Open-Label, Surgical Surveillance Trial to Evaluate Safety and Efficacy*," was conducted across 21 clinical centers in the United States and enrolled 300 adults scheduled for elective surgical procedures.

Results from the 150 patient study continued to demonstrate the safety and efficacy of Caldolor, decreasing pain and temperature while supporting its use in hospitalized patients. Results from the study of 300 adults undergoing scheduled, elective surgical procedures affirmed the safety of a shortened infusion time in surgical patients. When started at induction of anesthesia, Caldolor provided pain reduction comparable to that observed in previous studies. Both studies allowed for administration of multiple doses of intravenous ibuprofen and demonstrated that the shortened infusion time of 5 to 10 minutes was well tolerated.

About Caldolor

Caldolor is indicated for the management of mild to moderate pain, management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever in adults. It was 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, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia and Omeclamox-Pak® for the treatment of *H. pylori* and duodenal ulcer disease.

Cumberland is dedicated to providing innovative products that improve quality of care for patients. For more information on Cumberland Pharmaceuticals Inc., please visit www.cumberlandpharma.com.

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