Caldolor® Rapid Infusion Shown to be Safe and Well Tolerated in Newly Published Clinical Study

- Peak plasma concentration achieved in 6.5 minutes with rapid IV infusion
- Maximum plasma concentration with Caldolor approximately twice that of oral ibuprofen

NASHVILLE, Tenn., Feb. 15, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the publication of data from a clinical trial evaluating the pharmacokinetics, safety and tolerability of a rapid infusion of Caldolor® (*ibuprofen*) Injection compared to oral ibuprofen. The study, which was published in the January issue of *American Journal of Health-System Pharmacy*, demonstrated that the maximum plasma concentration (*C*max) of IV ibuprofen when administered over five to seven minutes was approximately twice that of oral ibuprofen. In addition, the time to the maximum plasma concentration (*t*max) of IV ibuprofen was 6.5 minutes compared with 1.5 hours for oral ibuprofen. The study results indicated that the rapid infusion of IV ibuprofen was both safe and well tolerated.

Caldolor, which was approved by the U.S. Food and Drug Administration in 2009, is the only U.S. approved injectable ibuprofen product and is indicated for the treatment of pain and fever in adults. In previous clinical trials Caldolor has been shown to significantly improve pain control while also reducing opioid requirements in the post-operative setting, as well as to significantly reduce fever in hospitalized patients. These previously published studies found the product to be safe and effective in treating pain and fever when administered over 30 to 60 minutes. The newly published data demonstrates the product's ability to be infused over a shorter period of time.

"Shorter infusion time of injectable analgesics and antipyretics could hasten onset of action," said Leo Pavliv, Cumberland's Senior Vice President of Operations and lead author of the study. "Speeding delivery of IV ibuprofen prior to and following a surgical procedure provides more convenient dosing to accomplish preemptive analgesia and post-operative, opioid-sparing pain control as well as anti-inflammatory effects — all of which help treat pain at its source."

In the United States, approximately 80% of patients experience pain following surgery, with 86% 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).

Oral analgesics and antipyretics have a relatively slow clinical effect due to the time required for absorption. Inadequate pain and fever management can lead to more serious problems in the hospital setting. Patients with acute pain that is inadequately managed not only experience high levels of discomfort, but also may suffer consequences such as delayed ambulation and potential for progression from acute to chronic pain, both of which can increase costs.

"Caldolor's ability to effectively treat pain and fever has been previously documented, and this new data provides physicians increased flexibility in treating hospitalized patients with a need for timely relief," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "These study results reinforce our belief that Caldolor is a safe treatment option and will be key in helping us communicate the value of the product to the medical community."

The newly published study, entitled "Pharmacokinetics, Safety, and Tolerability of a Rapid Infusion of IV Ibuprofen in Healthy Adults," appears in Volume 68 of *American Journal of Health-System Pharmacy*, and is available at http://www.ajhp.org/cgi/content/abstract/68/1/47.

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, Caldolor®, the first injectable ibuprofen treatment for pain and fever approved in the United States, and Kristalose®, a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, visit the Company website at www.cumberlandpharma.com.

About American Journal of Health-System Pharmacy

The *American Journal of Health-System Pharmacy* is the official publication of the American Society of Health-System Pharmacists. It publishes peer reviewed scientific papers on contemporary drug therapy and pharmacy practice innovations in hospitals and health systems. With a circulation of nearly 40,000, AJHP is the most widely recognized and respected clinical pharmacy journal in the world.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to 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, among others, those factors discussed in Cumberland's Annual Report filed on Form 10-K as filed with the SEC on March 19, 2010. There can be no assurance that results or developments anticipated by Cumberland will be realized or, even if realized, that they will have the expected effects. Readers are cautioned not to place undue reliance on these 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 or to reflect the occurrence of unanticipated events.

References

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