Newly Published Data Demonstrates Caldolor® Significantly Reduces Pain and Morphine Use in Post-Operative Patients

- Significant reduction in morphine consumption seen within 24 hours following surgery
- Caldolor significantly reduces pain at rest and with movement and is well tolerated

NASHVILLE, Tenn., Jan. 27, 2011 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the publication of data affirming the safety and efficacy of Caldolor® (*ibuprofen*) Injection in treating post-operative pain in hospitalized patients. A Phase III study published in the peer-reviewed journal *Pain Practice* concluded that IV ibuprofen significantly reduced both morphine use and self-reported pain intensity in patients recovering from abdominal hysterectomy compared to morphine alone. Designed primarily for use in the hospital setting, Caldolor is the only FDA approved injectable ibuprofen product for treatment of both pain and fever.

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).

"This study offers further evidence that a multi-modal analgesic regimen comprised of Caldolor in addition to opioid treatment is effective in managing acute post-operative pain," said Peter B. Kroll, M.D., Director of Comprehensive Pain Specialists in Hendersonville, Tenn., and lead author of the study. "In addition to reducing opioid use and pain intensity, IV ibuprofen blocks inflammation. Opioids alone do not address the inflammatory cascade that occurs during surgery, and uncontrolled inflammation may lead to inadequate pain control and pain progression. Managing inflammatory response may reduce the need for opioids, improve recovery and speed time to ambulation."

The multicenter, randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of IV ibuprofen as a post-operative analgesic. A total of 319 patients were randomized to receive 800 mg of IV ibuprofen or placebo every six hours after undergoing total abdominal hysterectomy surgery. All participants had open access to morphine.

The study met its primary endpoint of reducing morphine consumption within the first 24 hours following surgery. The median morphine requirement was significantly reduced by 19% in patients who received IV ibuprofen compared with those who received morphine alone.

The study also met its secondary endpoints of significantly reducing pain intensity at rest and with movement as measured on the visual analog scale (VAS) in patients receiving IV ibuprofen compared to placebo. Time to ambulation was also significantly faster in patients receiving IV ibuprofen. Similar treatment emergent adverse events occurred across both study groups and there was no difference in the overall incidence of these events. There was no difference between the two groups with respect to blood pressure, bleeding, or bruising, which are sometimes associated with use of oral ibuprofen.

"This study asserts not only that Caldolor provides a valuable morphine-sparing effect, but that it also provides better pain relief than morphine alone," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "Publication of this relevant information provides us with an important new tool in a growing body of literature to help communicate the safety, efficacy and overall value of Caldolor to the medical community."

This new data affirms previous findings published in *Clinical Therapeutics* in October 2009. That study concluded that patients who underwent orthopedic and abdominal surgeries required less narcotic and experienced less pain with 800 mg of IV Ibuprofen every six hours compared to morphine alone.

The newly published study, entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Intravenous Ibuprofen (IV-Ibuprofen) in the Management of Postoperative Pain Following Abdominal Hysterectomy," appears in Volume 11 of *Pain Practice*, and is available at http://onlinelibrary.wiley.com/doi/10.1111/j.1533-2500.2010.00402.x/abstract.

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 Pain Practice

Pain Practice, the official journal of the World Institute of Pain, publishes international multidisciplinary articles on pain and analgesia that provide its readership with up-to-date research, evaluation methods, and techniques for pain management. Special sections including the Consultant's Corner, Images in Pain Practice, Case Studies from Mayo Clinic, Tutorials, and the Evidence-Based Medicine combine to give pain researchers, pain clinicians and pain fellows in training a systematic approach to continuing education in pain medicine.

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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