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Caldolor® Demonstrates Significant Post Surgical Pain Reduction and Decrease in Opioid Use

New study data supports the use of Caldolor® in controlling pain and reducing opioid use in surgical patients

NASHVILLE, Tenn., March 27, 2017 /PRNewswire/ -- Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX)** today announced the publication of a trial providing evidence that using Caldolor in multimodal pain control strategies improves postoperative pain control and reduces opioid use in patients undergoing transsphenoidal surgery. The trial was conducted at the Department of Neurosurgery, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center in Phoenix, Arizona, and was published in the *Journal of Neurosurgery*, March 2017.

"The United States is in the midst of an epidemic of excessive opioid use, misuse, and abuse to control chronic pain," said AJ Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "The more we can prevent postsurgical pain from transitioning into chronic pain, the more likely we are to decrease reliance on opioids and improve the quality of life for patients long-term. We are thrilled to add this study to the growing body of literature supporting the safety and use of Caldolor in hospitalized patients."

The trial compared outcomes in two groups of patients treated with multimodal pain management protocols following transsphenoidal surgery for pituitary lesions: Group 1 patients treated intraoperatively with IV Ibuprofen (Caldolor 800 mg q 8 hr), scheduled oral acetaminophen and rescue opioids, versus Group 2 patients treated with IV saline placebo q 8 hr, scheduled oral acetaminophen, and rescue opioids. The Caldolor Group 1 patients demonstrated a significant reduction of 43% mean VAS scores compared with Placebo Group 2 patients. Opioid use was also significantly different with a 58% reduction in the Caldolor Group 1 patients compared to Placebo Group 2 patients.

The study had two aims. The primary endpoint was patient pain scores measured on a 0-10 Visual Analog Scale (VAS), and the secondary endpoint was the estimated oral morphine equivalent (OME) used for breakthrough pain in the first 48 hours after surgery. The study was terminated early because the planned interim analysis demonstrated that the primary and secondary endpoints had been reached.

About Caldolor®
Caldolor is indicated in adults and pediatric patients six months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. 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 a history of asthma or other 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 specialty pharmaceutical company focused on acquisition, development, and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland's six marketed products include Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, for the treatment of pain and fever, Kristalose® (*lactulose*) for Oral Solution, a prescription laxative, Vaprisol® (*conivaptan*) Injection, for the treatment of hyponatremia, Omeclamox-Pak® for the treatment of H. pylori infection and duodenal ulcer disease, and Ethyol ® (*amifostine*) for Injection, for the

treatment of oncology patients. Cumberland is developing Hepatoren® (*ifetroban*) Injection for the treatment of Hepatorenal Syndrome, Boxaban® (*ifetroban*) Oral Capsule for the treatment of Aspirin-Exacerbated Respiratory Disease, Vasculan™ (*ifetroban*) Oral Capsule for the treatment of Systemic Sclerosis, and Portaban™, for the treatment of Portal Hypertension.

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