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IV Ibuprofen Lessens Morphine Use Drug Discovery & Development - September 08, 2010

Cumberland Pharmaceuticals Inc. announced the publication of new data supporting the safety and efficacy of Caldolor (ibuprofen) Injection in pre- and post-operative orthopedic surgery patients. The study, which was published in the August edition of the peer-reviewed journal *Pain Medicine*, concludes that IV ibuprofen significantly decreased pain and morphine use when compared with placebo.

In the United States, more than 60% of patients with moderate or severe pain following surgery receive morphine. Both the World Health Organization and the American Society of Anesthesiologists Task Force recommend a multi-modal approach to pain management, with nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen as baseline therapy, which can minimize the risk of opioid-related side effects including sedation, nausea, vomiting, cognitive impairment and respiratory depression.

"These findings are significant in that they not only confirm that Caldolor is effective in reducing both post-operative pain and morphine use, but also demonstrate that it can be safely administered prior to the induction of anesthesia," said Neil Singla, M.D., Chief Executive Officer of Lotus Clinical Research, Inc. and principal investigator of the study. "This gives physicians additional options for controlling the onset of post-operative pain, which can help improve patient comfort and thereby facilitate recovery."

This multi-center, randomized, double-blind placebo-controlled trial evaluated 185 adult patients undergoing orthopedic surgery at eight hospitals. Patients were randomized to receive either 800 mg IV ibuprofen or placebo every six hours, and pain was measured through patient self-assessment using a visual analog scale (VAS) and a verbal response scale (VRS) in the immediate post-operative period through hour 28 of the study. All patients had access to intravenous morphine. The study met its primary endpoint as patients who received IV ibuprofen reported a 26% reduction in pain with movement ($p<0.001$). The study also met its secondary endpoints as pain assessed during rest was reduced by 32% in patients receiving IV ibuprofen ($p<0.001$), and these patients used nearly 31% less morphine than those who received placebo ($p<0.001$). There was no significant difference between placebo and IV ibuprofen in the number of patients with bleeding adverse events, the incidence of blood transfusions or other serious adverse events. More patients receiving IV ibuprofen experienced vomiting and more patients receiving placebo experienced dyspepsia.

The study demonstrated that both pre-operative and post-operative administration of Caldolor diminished post-surgical pain. In previous clinical studies of IV ibuprofen, the initial dose was administered intra-operatively. However, patients in this study received the first dose of study drug at the induction of anesthesia through a peripheral or central venous catheter. Pain assessments were performed at regular intervals following surgery, with the average first assessment occurring 2.8 hours post-operatively. The difference in pain scores between patients receiving Caldolor plus morphine compared to morphine alone was significant at this first measurement and remained significant at every point of measurement throughout the study period.

"This clinical study is so important because it provides strong safety and efficacy data supporting use of Caldolor in surgical patients not only during recovery, but also when administered prior to surgery," said A.J. Kazimi, Chief Executive Officer at Cumberland Pharmaceuticals. "Caldolor is the only IV-NSAID available in the United States that does not carry a contraindication for pre-operative use, and we believe this data will provide physicians with a new level of comfort in using IV ibuprofen to more effectively manage post-operative pain for their patients."

The new data supports a previous randomized, placebo controlled trial in surgical patients, which demonstrated that 800 mg of IV ibuprofen dosed every six hours produced a significant reduction in pain and morphine use in surgical patients. The study, entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Intravenous Ibuprofen 400 and 800 mg Every 6 Hours in the Management of Post-operative Pain," was published in Volume 31, Number 9 of the peer-reviewed journal *Clinical Therapeutics* in October 2009.

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Introduced in 2009, Caldolor is the first new injectable product available in the United States in 20 years for IV pain treatment, and provides safe and effective relief from both pain and fever.

Date: September 8, 2010
Source: [Cumberland Pharmaceuticals Inc.](#)

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