

Caldolor Administered Prior To Surgery Provides More Effective Pain Control And Less Opioid Use Compared To Ketorolac

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New study data supports the use of Caldolor® in reducing pain and reliance on opioids compared to ketorolac.

NASHVILLE, Tenn. (October 22, 2018) – Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX)** today announced the publication of a study in patients undergoing arthroscopic knee surgery that reveals more effective pain control and opioid-sparing activity with Caldolor when compared to ketorolac. The clinical trial was published in print and online in the *Journal Frontiers in Surgery*, October 3, 2018

This single center, two-armed, randomized, double-blind study was led by Sergio D. Bergese, M.D., at The Ohio State Wexner Medical Center. It assessed the efficacy of Caldolor (ibuprofen) Injection compared to ketorolac for the treatment of postoperative pain in patients undergoing arthroscopic knee surgery. Out of the fifty-one participants completing the study, twenty subjects were in the ibuprofen group and thirty-one subjects in the ketorolac group. Pain at rest and during movement was assessed by asking the patients to rate their pain level by using a visual analog scale (VAS). Data was collected every 30 minutes in post anesthesia care unit (PACU) until discharge and at 24 hours after surgery. The median VAS pain scores during movement at PACU arrival was significantly less for the Caldolor group compared to the ketorolac group (p = 0.0064). The median VAS pain scores during movement at PACU arrival was significantly less for the Caldolor group compared to the ketorolac group (p = 0.0018). The study investigators also noted that VAS pain scores during movement taken at subsequent 30-minute intervals in the Caldolor group were less than half that of those reported in the ketorolac group for up to 90 minutes after arriving. Additionally, up until the time of PACU discharge, the amounts of opioid consumption in the Caldolor group was significantly lower than in the ketorolac group (P < 0.001).

"Prudent and careful management of pain is among the most important responsibilities of every healthcare provider," says Cumberland CEO, A.J. Kazimi. "These study results can help guide clinicians to use IV non-opioid alternatives to reduce, or avoid opioids, which is in the patient's best interest – mitigating the risks when opioids are prescribed."

Acute postoperative pain following knee arthroscopies remains a major problem resulting in multiple undesirable outcomes if inadequately controlled. More than 80% of patients undergoing a surgical procedure experience postoperative pain, with 86% of those reporting pain as moderate to severe. The results of this study demonstrated that the use of IV ibuprofen, compared to IV ketorolac, significantly lowered postoperative pain scores and opioid consumption in patients undergoing arthroscopic knee surgeries.