

CALDOLOR® DEMONSTRATES SIGNIFICANT REDUCTION

OF OPIOID USE IN ORTHOPEDIC TRAUMA PATIENTS

New study shows use of Caldolor[®] prolongs time to first narcotic administration

NASHVILLE, Tenn. (Monday, July 20, 2020) – Cumberland Pharmaceuticals Inc. (**NASDAQ: CPIX**), a specialty pharmaceutical company, today announced the results of a Level 1 Trauma Center study recently published in the Journal of Orthopedic Trauma. Results demonstrate Caldolor[®] (*ibuprofen*) Injection significantly reduces the quantity of opioids required to manage pain after a traumatic injury with fracture. In addition, the time to first narcotic medication was longer in the Caldolor group than with hospital standard of care. Further, pain was managed better in the Caldolor[®] group compared to standard of care narcotics¹.

This single-center, randomized, double-blind, placebo-controlled study was led by Drs. Russell Weisz, MD and Alexander Fokin at Delray Beach Medical Center in Delray Beach, Florida. The aim of the research was to evaluate the efficacy of Caldolor[®] administration in the management of acute pain in orthopedic trauma patients and to minimize opioid use. A total of 99 orthopedic trauma patients with fractures of the ribs, face, extremities, and/or pelvis were randomized to receive either 800 mg IV ibuprofen or placebo administered every 6 hours for a total of 8 doses within 48 hours of admission. Both cohorts were given access to the hospital's standard of care medications. Results demonstrated Caldolor[®] (IV Ibuprofen) statistically significantly reduced opioid consumption compared with placebo plus standard of care medications during the initial 48-hour period. The pain intensity level was also statistically less at 8 hours, and the time to first narcotic medication was significantly longer in the Caldolor[®] group.

"With at least 75% of patients coming to emergency departments with a chief complaint related to pain, prudent and careful management of pain is of utmost importance," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals Inc. "Pain management has become one of the most common healthcare problems, with annual direct and indirect costs exceeding that of heart disease and cancer.² Physicians are often the first people to prescribe an opioid to a patient experiencing severe pain due to trauma. Cumberland is excited to offer these physicians an alternative to opioids, such as Caldolor, available in a ready-to-use bag that requires no dilution."

References:

- 1. Weisz RD, Fokin AA, Lerner V et al. Intravenous Ibuprofen Reduces Opioid Consumption During the Initial 48 Hours After Injury in Orthopedic Trauma Patients. *Journal of Ortho Trauma*. 2020;34(7): 341 347
- 2. Gaskin DJ, Richard P. Relieving Pain in America: Relieving Pain in America: A Bluprint for Transforming Prevention, Care, Education, and Research. National Academies Press (U.S.) 2011. ISBN-13: 978-309-21484-1