

# New Analysis Shows iovera<sup>°</sup> Plays a Critical Role in Achieving Significant Reductions in Opioid Use, Pain Scores, and Hospital Stay Following Total Knee Arthroplasty

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# Results demonstrate the addition of preoperative iovera° treatment to a multimodal pain management protocol leads to improved outcomes during 6-week recovery period

PARSIPPANY, N.J., July 29, 2021 (GLOBE NEWSWIRE) -- <u>Pacira BioSciences, Inc.</u> (Nasdaq: PCRX) today announced new data on the ability of the iovera<sup>®</sup>® system to reduce pain, opioid consumption, and length of stay (LOS) following total knee arthroplasty (TKA). The findings show that patients receiving preoperative iovera<sup>®</sup> as part of a multimodal pain management protocol reduced both opioid intake and in-hospital pain while optimizing outcomes during the 6-week recovery period after TKA. The results of the study, *A Multimodal Pain Management Protocol Including Preoperative Cryoneurolysis for Total Knee Arthroplasty to Reduce Pain, Opioid Consumption, and Length of Stay, were published in <u>Arthroplasty Today</u>.* 

This retrospective analysis utilized data from patients who underwent TKA by a single surgeon at one center. Patients who received iovera<sup>o</sup> before TKA were compared with a historical control group including patients who underwent TKA without iovera<sup>o</sup>. Both groups received a similar perioperative multimodal pain management protocol. The primary outcome was opioid intake at various time points from hospital stay to 6 weeks after discharge. Additional outcomes included pain, length of stay (LOS), and range of motion. The study population included a total of 267 patients, with 169 patients in the iovera<sup>o</sup> group and 98 patients in the control group.

Results showed that patients undergoing TKA who received iovera° compared to those who did not demonstrated a significant:

- Decrease in daily opioid consumption, as the iovera° group had 51% lower daily morphine milligram equivalents (MMEs) than the control group (47 vs 97 MMEs; ratio estimate, 0.49 [95% confidence interval (CI), 0.43-0.56]; *P*<.0001)
- Decrease in mean and maximum pain scores (*P*<.0001)
- Decrease in average hospital LOS (P<0.0001), with 17% of patients having an overall LOS of 2 or more days, compared with 99% of patients in the control group (P<.0001)
- Greater range of motion, as indicated by greater flexion degree at discharge (P<.0001)

"Our analysis underscores the benefits of optimizing pain control in the perioperative period with the addition of iovera° to a multimodal TKA pain protocol," said Dr. Joshua Urban, M.D., orthopedic surgeon at OrthoNebraska and lead author on the study publication. "This approach allows patients to take fewer opioids during hospitalization and the 6-week recovery period, reduce their hospital LOS, decrease readmission rate and face fewer postoperative complications."

Results of this study are consistent with findings from clinical trial and retrospective data that indicate a multimodal pain management protocol with preoperative iovera<sup>o</sup> treatment of the superficial genicular nerves reduced opioid consumption without increasing pain for up to 12 weeks after TKA compared with a standard multimodal pain management protocol.<sup>1,2</sup>

#### **About Pacira BioSciences**

Pacira BioSciences, Inc. (Nasdaq: PCRX) is the industry leader in its commitment to non-opioid pain management and regenerative health solutions to improve patients' journeys along the neural pain pathway. The company's long-acting local analgesic, EXPAREL® (bupivacaine liposome injectable suspension) was commercially launched in the United States in April 2012. EXPAREL utilizes DepoFoam®, a unique and proprietary product delivery technology that encapsulates drugs without altering their molecular structure, and releases them over a desired period of time. In April 2019, Pacira acquired the iovera° system, a handheld cryoanalgesia device used to deliver precise, controlled doses of cold temperature only to targeted nerves. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit <u>www.pacira.com.</u>

#### About iovera°®

The iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. In one study, the majority of the patients suffering from osteoarthritis of the knee experienced pain and system relief beyond 150 days.<sup>3</sup> The iovera° system's "1×90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. The iovera° system is not indicated for treatment of central nervous system tissue.

## Important Safety Information

The iovera° system is contraindicated for use in patients with the following: Cryoglobulinemia; Paroxysmal cold hemoglobinuria; cold urticaria; Raynaud's disease; open and/or infected wounds at or near the treatment line. Potential complications: As with any surgical treatment that uses needle-based therapy, there is potential for temporary site-specific reactions, including but not limited to: bruising (ecchymosis); swelling (edema); inflammation and/or redness (erythema); pain and/or tenderness; altered sensation (localized dysesthesia). Typically, these reactions resolve with no physician intervention. Patients may help the healing process by applying ice packs to the affected sites, and by taking over-the-counter analgesics.

## **Company Contact:**

Pacira BioSciences, Inc. Susan Mesco, (973) 451-4030 susan.mesco@pacira.com <sup>1</sup> V. Dasa, G. Lensing, M. Parsons, et al., Percutaneous freezing of sensory nerves prior to total knee arthroplasty Knee, 23 (2016), p. 523

<sup>2</sup> W.M. Mihalko, A. Kerkhof, J.L. Guyton, et al., *Cryoneurolysis prior to total knee arthroplasty reduces postoperative pain and opioid use*, Orthop Proc, 101-B (2019), p. 69

<sup>3</sup> Radnovich, R. et al. "Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial." Osteoarthritis and Cartilage (2017) p1-10.