New Retrospective Analysis Shows EXPAREL Associated with Significantly Less Opioid Use Following Third Molar Extraction

June 26, 2019

Results presented at 97th general session and exhibition of the International Association for Dental Research

PARSIPPANY, N.J., June 26, 2019 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX) today announced results of a new analysis of patients undergoing elective third molar ("wisdom teeth") extraction with at least one bony mandibular (impacted) tooth. Patients who received EXPAREL® (bupivacaine liposome injectable suspension) were prescribed significantly fewer opioids, including refills, compared to those who did not receive the product. The research was presented at the 97th General Session and Exhibition of the International Association for Dental Research in Vancouver, Canada.

"The results of this analysis are encouraging because they suggest the addition of EXPAREL to multimodal pain management protocols provides an opportunity to significantly reduce opioid use for postsurgical pain control," said Stuart Lieblich, DMD, oral and maxillofacial surgeon at Avon Oral, Facial and Dental Implant Surgery, faculty member at the University of Connecticut School of Dental Medicine and an investigator and author on the research. "Because many younger adults are exposed to opioids for the first time following procedures like wisdom tooth extraction—a surgery performed 3.5 million times annually in the United States—alternatives like EXPAREL play a vital role in managing pain while reducing the need for opioids and their associated side effects and long-term risks including addiction and dependence."

In this retrospective analysis, researchers reviewed data from 600 patients who underwent third molar extractions between 2012 and 2018. Deidentified data from 300 patients who received EXPAREL were compared to data from 300 patients who did not receive an infiltration of EXPAREL. Data from two dental clinics, Avon Oral, Facial and Dental Implant Surgery in Avon, CT and Carolinas Center for Oral and Facial Surgery in Charlotte, NC, were pooled for this analysis.

Patients in the EXPAREL treatment group received:

- **Lower number of total opioid tablets prescribed**, including refills, compared to patients in the non-EXPAREL group (mean [SD] of 6.4 [3.3] tablets vs 15.5 [6.3] tablets, respectively; *P*<0.0001)
- **Fewer additional opioid prescriptions** compared to the non-EXPAREL group (3.3% of patients required a refill vs 7.7% of patients, respectively)

"We continue to see positive data supporting the fact that EXPAREL significantly decreases the need for opioids in third molar extraction patients," said Richard Scranton, MD, MPH, chief medical officer of Pacira. "This retrospective analysis shows the clinical value of EXPAREL in the oral surgery space, where we know many patients—and their parents—would prefer a non-opioid option to manage postsurgical pain."

About Pacira BioSciences
Pacira BioSciences, Inc. (NASDAQ: PCRX) is a leading provider of non-opioid pain management and regenerative health solutions dedicated to advancing and improving outcomes for health care practitioners and their patients. 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, the company 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 www.pacira.com.

About EXPAREL
EXPAREL (bupivacaine liposome injectable suspension) is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. The product combines bupivacaine with DepoFoam®, a proven product delivery technology that delivers medication over a desired time period. EXPAREL represents the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing significant reductions in cumulative pain scores with up to a 78 percent decrease in opioid consumption; the clinical benefit of the opioid reduction was not demonstrated. Additional information is available at www.EXPAREL.com.

Important Safety Information
EXPAREL is contraindicated in obstetrical paracervical block anesthesia. Adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation. If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine. EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Warnings and Precautions Specific to EXPAREL: Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL. EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks other than interscalene brachial plexus nerve block, or intravascular or intra-articular use. The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials. Warnings and Precautions for Bupivacaine-Containing Products: Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include

persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression. Cardiovascular System Reactions: Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias, sometimes leading to death. Allergic Reactions: Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients. Chondrolysis: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use. Methemoglobinemia: Cases of methemoglobinemia have been reported with local anesthetic use. Full Prescribing Information is available at www.EXPAREL.com.

Company Contact:
Pacira Pharmaceuticals, Inc.
Susan Mesco, (973) 451-4030
Susan.Mesco@pacira.com

Media Contact:
Coyne Public Relations
Alyssa Schneider, (973) 588-2270
aschneider@coynepr.com

Source: Pacira BioSciences