Pacira Announces Publication of Phase 3 Study of EXPAREL Infiltration in Pediatric Patients Undergoing Spinal or Cardiac Surgeries

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Study demonstrating safety and tolerability of EXPAREL published in Journal of Clinical Anesthesia

PARSIPPANY, N.J., Sept. 21, 2021 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX) today announced that full results of its Phase 3 PLAY study of EXPAREL® (bupivacaine liposome injectable suspension) administered via infiltration in pediatric patients undergoing spinal or cardiac surgeries have been published in *Journal of Clinical Anesthesia*. The study, which was designed to establish the safety and pharmacokinetics (PK) of EXPAREL in a pediatric population, found the PK profile was comparable across age groups and generally consistent with the profile in adult patients. No safety concerns were identified at a dose of 4 mg/kg.

Key findings include:

- The safety of EXPAREL was comparable to bupivacaine and consistent across treatment groups.
- There were no treatment-related cardiac or nervous system adverse events (AEs) in the EXPAREL arm.
- EXPAREL was well tolerated for all age groups, with no discontinuations due to AEs.

“Traditionally, clinicians seeking pain control in pediatric patients have been forced to choose between opioids or traditional local anesthetics that require the use of cumbersome catheters or pumps to provide the duration of pain control needed in historically painful surgical procedures,” said Christopher Tirotta, MD, Chief of Anesthesiology at Nicklaus Children's Hospital and lead author in the PLAY study. “The results from this study demonstrate the excellent safety profile of EXPAREL, which provides prolonged pain control and offers versatility of administration without many of the unwanted side effects that often come with opioids.”

The PLAY study was the basis of U.S. Food and Drug Administration (FDA) approval of the expansion of the EXPAREL label to include single-dose infiltration to produce postsurgical local analgesia in patients 6 years of age and older on March 22, 2021.

This study was a multicenter, open-label, randomized trial that enrolled 98 patients to two patient groups: patients aged 12 to less than 17 years and patients aged 6 to less than 12 years. Results demonstrated that plasma bupivacaine levels following local infiltration with EXPAREL remained below the toxic threshold in adults across age groups and procedures. Additionally, AEs were mild to moderate, supporting the safety of EXPAREL in pediatric patients undergoing spine or cardiac surgery.

Dosing for both age groups was weight-based, with dose selection aimed at use of the maximal dose of each drug that would be predictably safe. Across age groups and surgical procedures, surgeons administered EXPAREL or bupivacaine HCl via local infiltration prior to wound closure, with EXPAREL and bupivacaine HCl administered in small increments into the deep and superficial layers along the entire length of the incision site to ensure uniform drug distribution.

“Children who undergo surgery often experience moderate to severe pain following their procedure, and unmanaged postsurgical pain frequently leads to delayed healing, prolonged length of stay, and even the development of chronic postsurgical pain,” said Roy Winston, MD, Chief Medical Officer at Pacira. “We are grateful for the opportunity to provide EXPAREL, the first and only FDA approved long-acting local analgesic for the pediatric population as young as age six, as a safe and effective pain management option to pediatric patients and their families.”

Results of this study build upon a growing body of evidence supporting the use of EXPAREL in pediatric procedures. A recent retrospective cohort study found that, in patients ≤18 years of age undergoing spine deformity correction surgery, EXPAREL administration via wound infiltration was associated with lower pain scores, reduced opioid consumption, and a lower complication rate than standard pain management.[1]

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 www.pacira.com.

About EXPAREL®

EXPAREL (bupivacaine liposome injectable suspension) is indicated in patients 6 years of age and older for single-dose infiltration

to produce postsurgical local analgesia, and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. Since its launch, EXPAREL has been used in over nine million patients. 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 for Patients

EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies in adults where EXPAREL was injected into a wound, the most common side effects were nausea, constipation, and vomiting. In studies in adults where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. In the study where EXPAREL was given to children, the most common side effects were nausea, vomiting, constipation, low blood pressure, low number of red blood cells, muscle twitching, blurred vision, itching, and rapid heartbeat. EXPAREL can cause a temporary loss of feeling and/or loss of muscle movement. How much and how long the loss of feeling and/or muscle movement depends on where and how much of EXPAREL was injected and may last for up to 5 days. EXPAREL is not recommended to be used in patients younger than 6 years old for injection into the wound, for patients younger than 18 years old for injection near a nerve, and/or in pregnant women. Tell your health care provider if you or your child has liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from the body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL can affect the nervous system and the cardiovascular system; may cause an allergic reaction; may cause damage if injected into the joints; and can cause a rare blood disorder.

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

Media Contact:
Coyne Public Relations
Kristin Capone
(973) 588-2108
kcapone@coynepr.com

[1] Chughtai, M., Sultan, A. A., Hudson, B., Goodwin, R. C., Seif, J., Khlopas, A., ... & Ballock, R. T. (2020). Liposomal bupivacaine is both safe and effective in controlling postoperative pain after spinal surgery in children: A controlled cohort study. *Clinical spine surgery*, *33*(10), E533-E538.