Pacira Announces Publication of Pivotal Study of EXPAREL as a Sciatic Nerve Block in the Popliteal Fossa for Patients After Bunionectomy

February 15, 2024

– Findings demonstrate significant reduction in pain and opioid consumption through 96 hours versus active comparator –

– Significantly greater proportion of opioid-free patients receiving EXPAREL –

TAMPA, Fla., Feb. 15, 2024 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc., (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced the publication of its pivotal Phase 3 study supporting the efficacy and safety of EXPAREL® (bupivacaine liposome injectable suspension) as a single-dose sciatic nerve block in the popliteal fossa in patients undergoing bunionectomy. The results demonstrate that EXPAREL significantly improved pain control and reduced opioid consumption through 96 hours versus bupivacaine HCl. The data, which provided the basis for FDA approval for this indication was published in the *Journal of Clinical Anesthesia*.

“This data provides unequivocal evidence of the safety and efficacy of EXPAREL as the first and only single-dose product to safely provide four days of superior non-opioid pain control compared to bupivacaine HCl,” said Frank D. Lee, Chief Executive Officer of Pacira BioSciences. “Importantly, the use of EXPAREL as a sciatic nerve block in the popliteal fossa affords clinicians additional flexibility in their opioid-sparing pain management approaches for foot and ankle procedures, which continue to migrate to the outpatient environment where success is predicated on the ability to provide appropriate pain control without the need for a significant opioid burden.”

Key findings for EXPAREL 133 mg versus bupivacaine HCl 50 mg administered as a single-dose sciatic nerve block in the popliteal fossa for patients undergoing bunionectomy demonstrated statistically significant and superior pain control over bupivacaine for 4 days post-surgery:

- **There was a 44% difference in pain scores** through 96 hours—the study’s primary endpoint—as measured by the area under the curve, or AUC, of the Numerical Rating Scale pain intensity scores from 0 to 96 hours post-surgery; *P*<0.00001
- **Patients receiving EXPAREL consumed 61% fewer opioids** through 96 hours—the study’s secondary endpoint—LSM total opioid consumption; *P*<0.00001
- Almost **one quarter** of patients in the EXPAREL group needed no rescue opioids through 96 hours compared to the bupivacaine group (24.4% vs 6% of patients, respectively)
    - Additionally, patients in the EXPAREL 133 mg arm had approximately five-fold higher odds of being opioid-free compared with the bupivacaine HCl 50 mg arm; *P*=0.0003

The safety profiles of EXPAREL 133 mg and bupivacaine HCl 50 mg were similar, with a similar proportion of adverse events (AEs) and serious adverse events (SAEs), and all AEs were mild to moderate in severity.

“The role of EXPAREL as a sciatic nerve block in the popliteal fossa, particularly for pain control following foot and ankle procedures, is pivotal as clinical goals toward outpatient migration continue to grow,” said Gary Schwartz, MD, FASA, Vice Chair of Pain and Anesthesiology at Maimonides Medical Center and lead author on the publication. “The ability to deliver four days of pain control and reduce reliance on opioids with a single-administration—eliminating the burden of cumbersome catheters and pumps—provides not only a valuable addition to the pain management armamentarium, but also an opportunity to improve patient satisfaction and outcomes for same-day surgical procedures.”

About the Phase 3 Study of EXPAREL as a Sciatic Nerve Block in the Popliteal Fossa
The Phase 3, randomized, double-blind, active-controlled, multicenter study was designed to evaluate the efficacy, safety, and pharmacokinetics of EXPAREL versus bupivacaine HCl administered as a sciatic nerve block in the popliteal fossa. The study was conducted in two parts, with Part A completed and analyzed before enrollment in Part B was initiated.

In total, the study randomized 185 subjects. In Part A, 66 subjects undergoing bunionectomy were randomized 1:1:1 to receive a sciatic nerve block in the popliteal fossa with a single dose of EXPAREL 266 mg, EXPAREL 133 mg or 20 mL 0.25% bupivacaine HCl. In part B, an additional 119 subjects undergoing bunionectomy were randomized 1:1 to receive a sciatic nerve block in the popliteal fossa with a single dose of EXPAREL 133 mg or 20 mL 0.25% bupivacaine HCl. All subjects in Part A and Part B received a Mayo field block with 20 mL 0.5% bupivacaine HCl after study drug administration in the operating room immediately prior to surgical incision. The study’s primary endpoint was the area under the curve, or AUC, of the Numerical Rating Scale pain intensity scores from 0 to 96 hours post-surgery comparing EXPAREL to bupivacaine HCl. Secondary endpoints included total postsurgical opioid consumption from 0 to 96 hours comparing EXPAREL to bupivacaine HCl and percent opioid free from 0-96 hours.

About Pacira BioSciences
Pacira BioSciences, Inc. (Nasdaq: PCRX) is committed to providing a non-opioid option to as many patients as possible to redefine the role of opioids as rescue therapy only. The company is also developing innovative interventions to address debilitating conditions involving the sympathetic nervous system, such as cardiac electrical storm, chronic pain, and spasticity. Pacira has three commercial-stage non-opioid treatments: EXPAREL® (bupivacaine liposome injectable suspension), a long-acting, local analgesia currently approved for postsurgical pain management; ZILRETTA® (triamcinolone acetonide extended-release injectable suspension), an extended-release, intra-articular, injection indicated for the management of osteoarthritis knee pain; and iovera$^{\circ}$®, a novel, handheld device for delivering immediate, long-acting, drug-free pain control using precise, controlled doses of cold temperature to a targeted nerve. 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 to produce postsurgical local analgesia via infiltration in patients aged 6 years and older, and postsurgical regional analgesia via an interscalene brachial plexus block in adults, a sciatic nerve block in the popliteal fossa in adults, and an adductor canal block in adults. The safety and effectiveness of EXPAREL have not been established to produce postsurgical regional analgesia via other nerve blocks besides an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, or an adductor canal block. The product combines bupivacaine with multivesicular liposomes, 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 multivesicular liposome 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 about EXPAREL 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.

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