Pacira Announces FDA Approval of Expanded EXPAREL Label to Include Two Additional Nerve Block Indications

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—EXPAREL is the only FDA-approved single-dose regional analgesic to safely demonstrate four days of superiority versus bupivacaine in two clinical studies —

— New indications for use as an adductor canal block and sciatic nerve block in the popliteal fossa will significantly extend reach within more than 3 million lower extremity procedures —

TAMPA, Fla., Nov. 10, 2023 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental new drug application (sNDA) to expand the EXPAREL® (bupivacaine liposome injectable suspension) label to include administration in adults as an adductor canal block and a sciatic nerve block in the popliteal fossa.

An adductor canal block is used for anesthesia and analgesia for surgery of the knee, medial lower leg, and ankle surgeries. A sciatic nerve block in the popliteal fossa is used for anesthesia and analgesia for foot, ankle, achilles tendon, and other lower leg surgeries.

“We are thrilled that today’s approval offers clinicians and patients another option for achieving long-lasting non-opioid pain control with EXPAREL and an increased ability to transition procedures to the ambulatory environment,” said Dave Stack, chief executive officer and chairman of Pacira BioSciences. “In line with our corporate mission to provide a non-opioid to as many patients as possible, this new indication provides additional flexibility in the use of EXPAREL as a regional analgesic for more than 3 million lower extremity procedures annually, further increasing the utility of EXPAREL for major orthopedic procedures.”

The approval is supported by two successful randomized, double-blind, active-controlled, multicenter Phase 3 studies designed to evaluate the efficacy, safety, and pharmacokinetics of EXPAREL versus bupivacaine HCl. One study evaluated EXPAREL as a single-dose adductor canal block and the second study evaluated EXPAREL as a single-dose sciatic nerve block in the popliteal fossa. Both studies met their primary endpoints by demonstrating a statistically significant reduction in cumulative pain scores from 0 to 96 hours compared with bupivacaine HCl (P<0.01).

Additionally, EXPAREL achieved statistical significance for the studies’ secondary endpoint of reduced postsurgical opioid consumption (P<0.01). EXPAREL as a sciatic nerve block in the popliteal fossa also achieved statistical significance for the percentage of opioid-free subjects (P<0.01). In both studies, EXPAREL maintained a safety profile consistent with bupivacaine HCl.

“The addition of these new blocks, coupled with the previously approved interscalene brachial plexus nerve block and the ability to utilize EXPAREL as a fascial plane block provides clinicians with a wide array of applications to treat postsurgical pain with long-lasting, non-opioid analgesia via a single dose administration,” said Jeffrey Gadsden, MD, Chief of Orthopaedic, Plastic, and Regional Anesthesiology and Professor of Anesthesiology at Duke University School of Medicine. “Enhanced recovery protocols built around EXPAREL regional and fascial plane blocks continue to play a critical—and expanding—role in achieving increased clinician and patient preference to avoid opioids and achieve same-day discharge when appropriate.”

About the Phase 3 Studies

EXPAREL as an adductor canal block

The Phase 3, randomized, double-blind, multicenter, active-controlled study was designed to evaluate the efficacy, safety, and pharmacokinetics of EXPAREL admixed with bupivacaine HCl versus bupivacaine HCl administered as an adductor canal block for postsurgical analgesia in subjects undergoing primary unilateral total knee arthroplasty. In total, 166 subjects were randomized 1:1 to receive either 10 mL (133 mg) of EXPAREL admixed with 10 mL 0.5% bupivacaine HCl or 10 mL 0.5% of bupivacaine HCl mixed with 10 mL normal saline. All subjects also received 15 mL of 0.25% bupivacaine HCl via an infiltration between the popliteal artery and capsule of the knee (iPACK) block. 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.

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. Pacira has submitted the full results from the Phase 3 studies for publication in a peer-reviewed journal.

About Pacira

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 analgesic currently approved for infiltration, fascial plane block, and as an interscalene brachial plexus nerve block, an adductor canal nerve block, and a sciatic nerve block in the popliteal fossa 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^{o}®, 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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