Pacira BioSciences Announces Top-line Results from Phase 3 STRIDE Study Evaluating EXPAREL as a Lower Extremity Nerve Block

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-- Study did not demonstrate statistical significance for primary endpoint of pain reduction from 0 to 96 hours for EXPAREL versus bupivacaine HCl --

-- EXPAREL achieves highly statistically significant reductions in pain and total opioid consumption from 24 to 96 hours versus bupivacaine HCl (p<0.01) --

-- EXPAREL also hits statistical significance for area under the curve cumulative pain scores from 12 to 96 hours versus bupivacaine HCl (p<0.02) --

PARSIPPANY, N.J., May 26, 2021 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced topline results from its Phase 3, randomized, double-blinded, active-controlled, multicenter STRIDE study. EXPAREL administered as combined sciatic (in popliteal fossa) and saphenous (in adductor canal) nerve blocks did not demonstrate statistical significance for the study's primary endpoint of reduction in cumulative pain scores from 0 to 96 hours as measured by the area under the curve versus bupivacaine HCl. EXPAREL did achieve statistical significance versus bupivacaine HCl for secondary endpoints of reducing cumulative pain scores from 24 to 96 hours post-surgery ($p<0.001$) and total opioid consumption from 24 to 96 hours post-surgery ($p<0.01$). EXPAREL also achieved statistical significance versus bupivacaine HCl for area under the curve cumulative pain scores from 12 to 96 hours ($p<0.02$). The EXPAREL group achieved and maintained mild pain at 36 hours (Least Square Mean NRS 3.0) while bupivacaine HCl was in the moderate range (Least Square Mean NRS 4.7).

There were no clinically relevant safety issues observed in STRIDE, specifically no reports of falls and no serious adverse events observed in the study.

Next Steps

- STRIDE offers important insights into the critical position of EXPAREL as the cornerstone of multimodal protocols to achieve both early onset and prolonged pain management goals.
- The company will complete a full analysis of the STRIDE study and plans to discuss these highly informative data and next steps with the U.S. Food and Drug Administration (FDA).
- Pacira plans to submit the full results from the Phase 3 STRIDE study for presentation at future scientific conferences and for publication in a peer-reviewed journal.

"In the absence of preoperative multimodal therapy, the study demonstrated the advantages of EXPAREL versus bupivacaine from 24 hours and beyond. The findings from this study are valuable and demonstrate the ability of an EXPAREL long-acting lower extremity nerve block to provide significant pain relief that extends to 96 hours. These data also add to the significant body of evidence supporting the excellent safety profile of EXPAREL," said Dave Stack, chairman and chief executive officer of Pacira BioSciences. "The market is in need of additional approaches to safe and effective opioid-sparing pain management as the surgical suite remains a key gateway to opioid misuse and abuse. We look forward to discussing these important findings with FDA and defining the next steps for broadening the EXPAREL label to include lower extremity nerve blocks."

About STRIDE

This Phase 3, multicenter, randomized, double-blind, active controlled, 3-arm study evaluated 120 subjects undergoing lower extremity surgeries after receiving ultrasound-guided combined sciatic (in popliteal fossa) and saphenous (in adductor canal) nerve blocks. Subjects were randomized (1:1:1) to one of the following three treatments arms administered in an equally divided dose to the two nerves:

- **EXPAREL:** Subjects received 20 mL (266 mg) EXPAREL mixed with 20 mL saline
- **EXPAREL + bupivacaine HCl:** Subjects received 20 mL (266 mg) EXPAREL admixed with 20 mL (50 mg) 0.25% bupivacaine HCl
- **Bupivacaine HCl:** Subjects received 40 mL (100 mg) 0.25% bupivacaine HCl

The study's primary endpoint was the area under the curve (AUC) of the NRS pain intensity scores from 0 to 96 hours post-surgery comparing EXPAREL to 0.25% bupivacaine HCl. Secondary endpoints included total postsurgical opioid consumption from 0 to 96 hours comparing EXPAREL to bupivacaine HCl and the AUC of the NRS pain intensity scores from 24 to 96 hours post-surgery comparing EXPAREL to bupivacaine HCl.

Prior to each procedure, patients in this study received mild sedation with 1 to 2 mg of midazolam intravenously (IV) before the block was administered. For all arms, the total volume (40 mL) was split such that 20 mL was administered as the sciatic nerve block and 20 mL was administered as the saphenous nerve block. Following the procedure, medications including acetaminophen or nonsteroidal anti-inflammatory drugs were used for the initial treatment of postsurgical pain. Rescue opioid medication was available upon request.

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. 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.

Forward-Looking Statements

Any statements in this press release about the company's future expectations, plans, trends, outlook, projections and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may," "will," "would," "could," "can" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: the impact of the worldwide COVID-19 (Coronavirus) pandemic and related global economic conditions on our business and results of operations; the cost and timing of an early termination payment to DePuy Synthes Sales, Inc.; the success of the company's sales and manufacturing efforts in support of the commercialization of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and the company's ability to serve those markets; the company's plans to expand the use of EXPAREL to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL; the ability to realize anticipated benefits and synergies from the acquisition of MyoScience; the ability to successfully integrate iovera° and any other future acquisitions into the company's existing business; the commercial success of iovera°; the rate and degree of market acceptance of iovera°; the size and growth of the potential markets for iovera° and our ability to serve those markets; our plans to expand the use of iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for iovera°; the recoverability of our deferred tax assets and other factors discussed in the "Risk Factors" of the company's most recent Annual Report on Form 10-K and in other filings that the company periodically makes with the SEC. In addition, the forward-looking statements included in this press release represent the company's views as of the date of this press release. Important factors could cause actual results to differ materially from those indicated or implied by forward-looking statements, and as such the company anticipates that subsequent events and developments will cause its views to change. However, while the company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date of this press release.

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