EXPAREL Achieves Primary and Key Secondary Endpoints in Phase 4 CHOICE Study in Cesarean Section Patients

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EXPAREL TAP block superior to morphine spinal–based standard of care

PARSIPPANY, N.J., Jan. 07, 2020 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX) today announced that its Phase 4 study of EXPAREL® (bupivacaine liposome injectable suspension) in patients undergoing Cesarean section (C-section) achieved its primary endpoint with a statistically significant reduction in total postsurgical opioid consumption while maintaining pain scores through 72 hours ($P \leq 0.001$). EXPAREL demonstrated statistical significance for the key secondary endpoint of a reduction in the incidence and severity of itching for 72 hours after surgery ($P \leq 0.05$). Full study results will be submitted for publication in the peer-reviewed medical literature later this year.

The Phase 4, multicenter, randomized, active-controlled study across 18 clinical sites in the United States, enrolled 169 patients undergoing elective C-section. Patients were randomized (1:1:1) to receive either 150 mcg morphine spinal anesthesia plus standard of care postoperative pain regimen, 50 mcg morphine spinal anesthesia plus EXPAREL transversus abdominis plane (TAP) field block or opioid-free spinal anesthesia plus EXPAREL TAP block. Patients in the EXPAREL arms received a protocol-defined postoperative pain management regimen comprised of ketorolac, acetaminophen and ibuprofen. All patients could receive opioid rescue pain medicine upon request for breakthrough pain.

“Providing safe and effective non-opioid postsurgical pain management is a critical element to helping new mothers recover and care for themselves and their newborn following C-section surgery,” said Dave Stack, chairman and chief executive officer of Pacira BioSciences. “We believe the results of our CHOICE study will support the transformation of the standard of pain management for C-section patients to EXPAREL TAP block, given its demonstrated ability to reduce opioid requirements and the associated adverse events like pruritus.”

The company’s previous Phase 4 clinical study of EXPAREL in the C-section setting is awaiting publication in a peer-reviewed medical journal. That study demonstrated the superiority of an EXPAREL TAP block to a bupivacaine TAP block in patients undergoing C-section, achieving a 52% reduction in opioid use for EXPAREL-treated patients while also reducing pain scores through 72 hours post-surgery. Importantly, the study demonstrated a statistically significant higher percentage of opioid-spared patients in the EXPAREL group, with EXPAREL treated patients taking no more than one opioid tablet and experiencing no opioid-related side effects through 72 hours.

Mr. Stack continued: “Opioid addiction in women is growing at an alarming rate and studies have shown women are 40% more likely than men to become newly persistent users of opioids following surgery. This, coupled with the need to provide new mothers with effective pain control without the unwanted and potentially debilitating side effects of opioids, makes EXPAREL well-positioned to play an important role in reducing opioid use in C-section patients and, consequently, in contributing to our five-year growth trajectory.”

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.

Forward-Looking Statements

Any statements in this press release about the company's future expectations, plans, outlook, projections and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may," "could" 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 failure to realize anticipated benefits and synergies from the acquisition; the ability to successfully integrate iovera° and MyoScience into the company's existing business; the commercial success of iovera°, 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; 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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