



Pacira Announces FDA Approval of Supplemental New Drug Application for EXPAREL® as a Nerve Block to Produce Regional Analgesia

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EXPAREL is now an opioid-free option for use as an interscalene brachial plexus block for upper extremity surgeries

Conference call on Monday, April 9, 2018 at 8:30 a.m. EST

PARSIPPANY, N.J., April 06, 2018 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental new drug application (sNDA) to broaden the use of EXPAREL® (bupivacaine liposome injectable suspension) to include administration via interscalene brachial plexus block to produce postsurgical regional analgesia. With this approval, EXPAREL is the first long-acting, single-dose nerve block available for patients undergoing upper extremity surgeries, such as total shoulder arthroplasty or rotator cuff repair.

"Brachial plexus blocks are emerging as a mainstay of postsurgical pain control for upper extremity procedures, and are well positioned to comprise more than 60 percent of all regional nerve block procedures within the next two years," said Dave Stack, chairman and chief executive officer at Pacira Pharmaceuticals. "In line with our corporate mission, we are very gratified to offer clinicians and patients another option for achieving long-lasting non-opioid pain control with EXPAREL, and to provide an increased ability to transition procedures commonly thought of as inpatient to the ambulatory setting."

Since its initial approval in 2011 for single-dose infiltration into the surgical site, more than 3.75 million patients have been treated with EXPAREL in the post-marketing setting. The expansion of the EXPAREL label to now also include interscalene brachial plexus nerve block allows clinicians to potentially eliminate the need for cumbersome catheters and pumps traditionally used to extend the duration of regional analgesia.

"There is a critical need in the postsurgical setting for non-opioid options that turn off pain at the surgical site and reduce the need for opioids," said Jeffrey Gadsden, MD, Chief of Orthopaedics, Plastics, and Regional Anesthesiology and Associate Professor of Anesthesiology at Duke University School of Medicine. "The ability to provide effective regional analgesia with a single dose of EXPAREL is a tremendous victory for patients and advances the imperative need for low- or no-opioid pain management strategies."

The sNDA approval was based on positive data from a Phase 3 study of EXPAREL in brachial plexus block for shoulder surgeries, in which EXPAREL demonstrated statistical significance for the primary endpoint of cumulative pain scores over 48 hours as measured by the area under the curve ($P < 0.0001$). EXPAREL also achieved statistical significance versus placebo for the study's key secondary endpoints as follows: total postsurgical opioid consumption through 48 hours ($P < 0.0001$); opioid-free subjects through 48 hours ($P < 0.01$); and time to first opioid rescue through 48 hours ($P < 0.0001$).

The safety profile for EXPAREL in the interscalene brachial plexus nerve block study was consistent with the previously reported safety profile of EXPAREL in wound infiltration, and also with the profile of bupivacaine when used as a brachial plexus nerve block.

The study randomized 156 patients across 17 sites in a 1:1 ratio to receive a single dose of either EXPAREL 133 mg in 10 mL expanded in volume with 10 mL of normal saline for a total volume of 20 mL or placebo 20 mL. EXPAREL was administered as a single-dose brachial plexus block under ultrasound guidance at least one hour prior to surgery. All patients were eligible to receive postsurgical rescue opioids upon request for pain control.

Conference Call and Webcast

The Pacira management team will host a conference call to discuss the contents of this press release, on Monday, April 9, 2018, at 8:30 a.m. ET. The call can be accessed by dialing 1-877-845-0779 (domestic) or 1-720-545-0035 (international) ten minutes prior to the start of the call and providing the Conference ID 7299666.

A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and providing the Conference ID 7299666. The replay of the call will be available for two weeks from the date of the live call.

The live, listen-only webcast of the conference call can also be accessed by visiting the "Investors & Media" section of the company's website at investor.pacira.com. A replay of the webcast will be archived on the Pacira website for two weeks following the call.

About Pacira

Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) is a specialty pharmaceutical company dedicated to advancing and improving postsurgical outcomes for acute care practitioners and their patients. The company's flagship product, 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. 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. 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. In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting. 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. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations. EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks other than interscalene brachial plexus block, or intravascular or intra-articular use. Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL. Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesias. 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.

Forward Looking Statements

Any statements in this press release about the company's future expectations, plans, outlook and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may" 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 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 and the company's other products; 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; the related timing and success of United States Food and Drug Administration supplemental New Drug Applications; the outcome of the U.S. Department of Justice inquiry; the company's plans to evaluate, develop and pursue additional DepoFoam-based product candidates; clinical trials in support of an existing or potential DepoFoam-based product; the company's commercialization and marketing capabilities; the company's and Patheon UK Limited's ability to successfully and timely construct dedicated EXPAREL manufacturing suites; and other factors discussed in the "Risk Factors" of the company's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2017 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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