



FDA Posts Briefing Documents for Advisory Meeting Reviewing sNDA for EXPAREL® as a Nerve Block for Regional Analgesia

February 12, 2018

-- Anesthetic and Analgesic Drug Products Advisory Committee Meeting February 14-15 --

PARSIPPANY, N.J., Feb. 12, 2018 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced that the U.S. Food and Drug Administration (FDA) has posted briefing materials for the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) meeting that will review the company's supplemental New Drug Application seeking expansion of the current EXPAREL® (bupivacaine liposome injectable suspension) label for infiltration to include use as a nerve block for regional analgesia.

The Advisory Committee meeting is scheduled for February 14-15, 2018. The briefing materials can be found on the FDA website at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm591101.htm>. The FDA's docket for public comment for this meeting can be found at https://www.regulations.gov/document?D=FDA_FRDOC_0001-8060. All comments received on or before January 31, 2018 were provided to AADPAC; comments received after that date through February 13, 2018 will be taken into consideration by FDA.

"We are confident in our robust data package and believe our filing contains all of the information FDA indicated would be required for expansion of the label to include nerve block following our end of review meeting in 2015," said Dave Stack chairman and chief executive officer at Pacira. "We look forward to discussing this information with the Anesthetic and Analgesic Drug Products Advisory Committee this week."

The sNDA filing is based on positive data from a Phase 3 study of EXPAREL in femoral nerve block for total knee arthroplasty (lower extremity) and a Phase 3 study of EXPAREL in brachial plexus block for shoulder surgeries (upper extremity). It includes data from eight company-sponsored studies with safety and pharmacokinetic data through 120 hours. In addition, the sNDA includes data from two investigator-initiated studies that provide additional experience in smaller, peripheral nerve block settings.

The Prescription Drug User Fee Act (PDUFA) date for completion of the FDA's review of the company's sNDA for EXPAREL is April 6, 2018.

The AADPAC reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery and makes appropriate recommendations to the Commissioner of Food and Drugs.

EXPAREL is currently indicated for infiltration into the surgical site to produce postsurgical analgesia and has been used in over 3.5 million patients across the United States.

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 currently indicated for single-dose infiltration into the surgical site to produce postsurgical 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 score with up to a 45 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, 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, 2016 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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