Pacira Announces FDA Advisory Committee Meeting to Review sNDA for EXPAREL® as a Nerve Block for Regional Analgesia

November 14, 2017

PARSIPPANY, N.J., Nov. 14, 2017 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced that the U.S. Food and Drug Administration (FDA) has notified the company that its supplemental New Drug Application (sNDA) for EXPAREL® (bupivacaine liposome injectable suspension) as a nerve block for regional analgesia will be discussed at a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). The meeting is tentatively scheduled for February 14-15, 2018. A definitive date for the advisory committee meeting is expected to be published by FDA in the Federal Register at least 15 days prior to such meeting. The Prescription Drug User Fee Act (PDUFA) goal date for completion of review by FDA of April 6, 2018 remains unchanged.

"We believe our robust dataset supports the expansion of the EXPAREL label to include nerve block and we look forward to a productive discussion with the advisory committee," said Dave Stack, chairman and chief executive officer of Pacira. "We remain steadfast in our commitment to continuing to work closely with the FDA toward our common goal of ensuring patients have access to safe and effective non-opioid treatments for postsurgical pain."

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 EXAREL 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 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.

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.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. In clinical trials, the most common adverse reactions (incidence ≥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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