Pacira Pharmaceuticals Announces FDA Acceptance of sNDA for EXPAREL as a Nerve Block to Produce Regional Analgesia

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PARSIPPANY, N.J., Oct. 18, 2017 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced the U.S. Food and Drug Administration (FDA) has accepted the resubmission of its supplemental new drug application (sNDA) seeking expansion of the EXPAREL® (bupivacaine liposome injectable suspension) label to include administration via nerve block for prolonged regional analgesia. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is April 6, 2018.

The sNDA is based on the positive data from a Phase 3 study of EXPAREL in femoral nerve block for TKA (lower extremity) and a Phase 3 study of EXPAREL in brachial plexus block for shoulder surgeries (upper extremity). It also includes safety and pharmacokinetic data through 120 hours.

"We believe our filing contains all of the necessary information to satisfy the FDA requirements, namely another clinical trial that establishes the efficacy of EXPAREL in a clinical setting beyond femoral nerve block, as well as a robust safety database that includes pharmacokinetic profiles through the median time to maximum concentration of EXPAREL," said Dave Stack, chairman and chief executive officer at Pacira. "We look forward to working with the FDA to offer clinicians an additional option to provide postsurgical patients with long-lasting non-opioid pain control, in order to both reduce opioid requirements and support the increasing clinical goal of transitioning inpatient procedures to an outpatient setting."

Eight Pacira-sponsored studies support this expanded indication. In total, 570 subjects received a dose of EXPAREL ranging from 2 mg to 310 mg. In addition, the sNDA includes data from two investigator-initiated studies that provide additional experience in smaller, peripheral nerve block settings.

About Pacira
Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) is a specialty pharmaceutical company focused on the clinical and commercial development of new products that meet the needs of acute care practitioners and their patients. The company's flagship product, EXPAREL® (bupivacaine liposome injectable suspension), indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia, was commercially launched in the United States in April 2012. EXPAREL and two other products have successfully utilized 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. Additional information about Pacira is available at 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 period of time. 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. EXPAREL has not been studied for use in patients younger than 18 years of age. 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. Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL. Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. 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. In clinical trials, the most common adverse reactions (incidence greater-than or equal to 10%) following EXPAREL administration were nausea, constipation, and vomiting.

Forward Looking Statements
Any statements in this press release about our 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 our sales and manufacturing efforts in support of the commercialization of EXPAREL; the rate and degree of market acceptance of EXPAREL and our other products; the size and growth of the potential markets for EXPAREL and our ability to serve those markets; our 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; our plans to evaluate, develop and pursue additional DepoFoam-based product candidates; clinical trials in support of an existing or potential DepoFoam-based product; our commercialization and marketing capabilities; our and Patheon UK Limited's ability to successfully and timely construct dedicated EXPAREL manufacturing suites; and other factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this press release represent our views as of the date of this press release. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, and as such we anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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