Pacira BioSciences Announces FDA Acceptance of sNDA for EXPAREL Use in Pediatric Patients

August 4, 2020

sNDA submission based on positive Phase 3 data supporting expansion of the EXPAREL label to include use in children aged six and over

PARSIPPANY, N.J., Aug. 04, 2020 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX) today announced the U.S. Food and Drug Administration (FDA) has accepted the submission of its supplemental new drug application (sNDA) seeking expansion of the EXPAREL® (bupivacaine liposome injectable suspension) label to include single-dose infiltration to provide postsurgical analgesia in children aged six and over. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is March 22, 2021.

The sNDA is based on the positive data from the Phase 3 PLAY study of EXPAREL infiltration in pediatric patients undergoing spinal or cardiac surgeries. Overall findings were consistent with the pharmacokinetic and safety profiles for adult patients with no safety concerns identified at a dose of 4 mg/kg.

"The FDA acceptance of our sNDA submission confirms and reinforces our unwavering dedication to provide opioid alternatives to as many patients as possible," said Donald Manning, MD, PhD, chief medical officer at Pacira. "Currently, postsurgical moderate and severe pain in pediatric patients is principally managed with opioids, which we know come with unwanted and potentially life-threatening side effects. Expanding the EXPAREL label to the pediatric population will positively impact children, parents, clinicians, hospitals, and payers -- as there is a critical need for non-opioid options in this vulnerable population."

The PLAY study enrolled 98 patients to evaluate the pharmacokinetics and safety of EXPAREL for two patient groups: patients aged 12 to less than 17 years and patients aged 6 to less than 12 years. Per FDA guidance, the primary objectives of the PLAY study were to evaluate the pharmacokinetics and safety of EXPAREL. The full study results will be submitted for publication in the peer-reviewed medical literature later this year.

The company's pediatric program was designed in consultation with the FDA. EXPAREL is the only non-opioid, single-dose, long-acting local anesthetic that is FDA-approved for infiltration, field block and interscalene brachial plexus nerve block in patients 18 years of age and older. More than 7 million patients have received EXPAREL since its launch in 2012. If approved, EXPAREL will be the only long-acting local anesthetic approved for use in children.

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, Pacira 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 for Patients
EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies where EXPAREL was injected into the wound, the most common side effects were nausea, constipation, and vomiting. In studies where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. EXPAREL is not recommended to be used in patients younger than 18 years old or in pregnant women. Tell your healthcare provider if you have liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from your body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL: can affect your nervous system and your cardiovascular system; may cause an allergic reaction; may cause damage if injected into your joints.

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," "will," "would," "could," "can" 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; 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 ability to realize anticipated benefits and synergies from the acquisition of MyoScience; the ability to successfully integrate iovera° and any other future acquisitions into the company's existing business; the commercial success of iovera° 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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