Pacira BioSciences Completes Enrollment in Multicenter Registration Study of EXPAREL® in Pediatric Patients

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Top-line data expected in fourth quarter of 2019

PARSIPPANY, N.J., Sept. 17, 2019 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), a leading provider of innovative non-opioid pain management options, today announced that it has reached full enrollment of its Phase 3 study of EXPAREL® (bupivacaine liposome injectable suspension) administered as a single-dose infiltration in pediatric patients aged six to less than 17 years undergoing spinal or cardiac surgeries. The company intends that these study results will provide the foundation for a supplemental New Drug Application submission to the U.S. Food and Drug Administration (FDA) seeking expansion of the EXPAREL label to include children aged six and over.

“Pediatric patients—arguably our most vulnerable surgical population—urgently need opioid-free options to manage postsurgical pain. This is particularly true for children six to 12 years of age who do not have any FDA-approved local anesthetic options today,” said Dave Stack, chairman and chief executive officer of Pacira. “Currently, the standard way to manage moderate to severe pain in these patients is through the use of opioids, which we know are fraught with unwanted and potentially life-threatening side effects.”

The study, which is known as PLAY, 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. The study includes bupivacaine HCl as an active comparator arm for the older patient population.

In addition to the PLAY study, the company’s pediatric program includes collaboration with FDA to define a Phase 3 registration study of EXPAREL as a nerve block in the pediatric setting. The company’s label expansion strategy also includes launching a Phase 3 registration study evaluating EXPAREL versus bupivacaine HCl as a lower extremity nerve block in adult patients undergoing foot and ankle surgeries.

“Looking ahead, we believe EXPAREL is well-positioned for long-term market leadership with a broad label that will include pediatrics and flexible regional approaches that utilize ultrasound-guided field and nerve blocks. In addition, we have a growing partnership network of EXPAREL-based enhanced recovery after surgery collaboratives and a highly successful partnership with Johnson & Johnson that we expect will continue to be a key growth driver in the years ahead. This collaboration will be particularly beneficial in the pediatric setting, where we expect to benefit from their professional education resources and sports medicine and spine sales verticals,” continued Mr. Stack.

EXPAREL is the only non-opioid, single-dose, long-acting local analgesic that is FDA-approved for infiltration, field block and brachial plexus nerve block. The EXPAREL formulation allows for expansion with saline for larger procedures, as well as admixture with bupivacaine so that pain management can be tailored to the patient’s needs across a broad range of small and large procedures. More than 5.5 million patients have received EXPAREL since its launch in 2012.

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," "could" 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 failure to realize anticipated benefits and synergies from the acquisition; the ability to successfully integrate iovera° and MyoScience into the company's existing business; the commercial success of iovera°, 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; 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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