Pacira BioSciences Announces Positive Results from Phase 3 PLAY Study of EXPAREL® in Pediatric Patients

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-- New data expected to support expansion of EXPAREL label to include children aged six and over --

PARSIPPANY, N.J., Dec. 17, 2019 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), a leading provider of innovative non-opioid pain management options, today announced positive results from its Phase 3 PLAY study of EXPAREL® (bupivacaine liposome injectable suspension) administered as a single-dose 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.

These results will provide the foundation for the company's supplemental New Drug Application submission in the first half of 2020 to the U.S. Food and Drug Administration (FDA) seeking expansion of the EXPAREL label to include children aged six and over. The Company's pediatric program has been designed in consultation with FDA with a second Phase 3 registration study of EXPAREL administered as a nerve block in the pediatric setting expected to initiate in 2020.

"Pediatrics will be a very important addition to the EXPAREL label as there is an urgent need for non-opioid options for managing moderate to severe postsurgical pain in this vulnerable population," said Dave Stack, chairman and chief executive officer of Pacira BioSciences. "The current standard of care for managing moderate to severe pain in children is opioids, which are associated with serious and potentially life-threatening side effects. If approved, EXPAREL will be the only local anesthetic approved for use in children and thus we believe will be an imperative formulary listing."

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.

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 6 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.

About iovera°

The iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. In one study, the majority of the patients suffering from osteoarthritis of the knee experienced pain and system relief beyond 150 days.[1] The iovera° system's "1×90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. The iovera° system is not indicated for treatment of central nervous system tissue.

[1]Radnovich, R. et al. “Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial.” Osteoarthritis and Cartilage (2017) p1-10.

Important Safety Information

The iovera° system is contraindicated for use in patients with the following: Cryoglobulinemia; Paroxysmal cold hemoglobinuria; cold urticaria; Raynaud’s disease; open and/or infected wounds at or near the treatment line. Potential complications: As with any surgical treatment that uses needle-based therapy, there is potential for temporary site-specific reactions, including but not limited to: bruising (ecchymosis); swelling (edema); inflammation and/or redness (erythema); pain and/or tenderness; altered sensation (localized dysesthesia). Typically, these reactions resolve with no physician intervention. Patients may help the healing process by applying ice packs to the affected sites, and by taking over-the counter analgesics.

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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