Pacira Announces FDA Approval of Supplemental New Drug Application for EXPAREL® (bupivacaine liposome injectable suspension) in Pediatric Patients

March 22, 2021

-- EXPAREL is the first and only FDA-approved long-acting local analgesic for children aged six and over –
-- Conference call tomorrow at 8:30 a.m. ET --

PARSIPPANY, N.J., March 22, 2021 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced the U.S. Food and Drug Administration (FDA) has approved the submission of its supplemental new drug application (sNDA) seeking expansion of the EXPAREL label to include use in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia. With this approval, EXPAREL is the first and only FDA approved long-acting local analgesic for the pediatric population as young as age six.

“The current standard of care for managing moderate-to-severe pain in children is opioids, which often come with unwanted severe and possibly life-threatening side effects in this vulnerable patient population,” said Dave Stack, Chairman and Chief Executive Officer at Pacira. “In line with our corporate mission to provide an opioid alternative to as many patients as possible, we are grateful for the opportunity to give clinicians and patients a new, safe and effective option for achieving long-lasting non-opioid pain control in children without the need for an indwelling catheter and pump.”

Since initial approval in 2011, more than 8 million patients have been treated with EXPAREL. With approximately one million pediatric procedures per year where opioids, catheters and pain pumps are the mainstay of postsurgical pain control, there is an urgent unmet need for opioid alternatives.

“There has been a significant gap in our pain control armamentarium as it relates to the ability to safely and effectively provide long-lasting non-opioid pain control for the pediatric surgical population,” said Christopher Tirotta, MD, Chief of Anesthesiology at Nicklaus Children's Hospital and an investigator in the pivotal PLAY study. “Traditional local anesthetics have not provided a duration of pain control that matches the time course of the most significant postsurgical pain, which has necessitated the reliance on opioids in an attempt to manage pain. With the addition of EXPAREL as an FDA-approved non-opioid option to provide prolonged pain control we are better equipped to treat our pediatric patients while reducing opioid exposure, and ultimately improving outcomes.”

The sNDA was 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 PLAY study enrolled 98 patients to evaluate safety and the pharmacokinetics 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.

“Moderate-to-severe postsurgical pain is experienced by 40% of hospitalized children, and every scoliosis patient I treat surgically. Over and under treated pain in pediatric patients is a significant cause of morbidity after surgery,” said Peter Newton, MD, Chief of the Division of Orthopedics & Scoliosis at Rady Children's Hospital-San Diego and Clinical Professor at UC San Diego School of Medicine. “Opioids are responsible for 50% of postsurgical respiratory failure events in children, and often cause unpleasant side effects delaying a patient’s recovery after surgery. This FDA approval is a remarkable victory for pediatric patients and their families and paves the way for opioid-minimizing pain management protocols in children undergoing surgery.”

Tomorrow’s Conference Call and Webcast Reminder
The Pacira management team will host a conference call to discuss the contents of this press release tomorrow, Tuesday, March 23rd, at 8:30 a.m. ET. To participate in the conference call, dial 1-877-845-0779 and provide the passcode 1185087. International callers may dial 1-720-545-0035 and use the same passcode. In addition, a live audio of the conference call will be available as a webcast. Interested parties can access the event through the “Events” page on the Pacira website at investor.pacira.com.

For those unable to participate in the live call, a replay will be available at 1-855-859-2056 (domestic) or 1-404-537-3406 (international) using the passcode 1185087. The replay of the call will be available for one week from the date of the live call. The webcast will be available on the Pacira website for approximately two weeks following the call.

About Pacira BioSciences
Pacira BioSciences, Inc. (Nasdaq: PCRX) is the industry leader in its commitment to non-opioid pain management and regenerative health solutions to improve patients’ journeys along the neural pain pathway. 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 in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia, and in adults 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 is not recommended to be used in patients younger than 6 years old for single-dose infiltration, or in patients younger than 18 years old as an interscalene brachial plexus nerve block, or in pregnant women. 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. 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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