Pacira Receives Positive CHMP Opinion for EXPAREL® (bupivacaine liposome injectable suspension) for the Treatment of Postsurgical Pain

September 18, 2020

-- CHMP opinion supported by four pivotal studies showing EXPAREL reduced pain scores and opioid use following surgery --

-- European Commission decision on the Marketing Authorization Application (MAA) expected in November 2020 --

PARSIPPANY, N.J., Sept. 18, 2020 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), a leading provider of innovative non-opioid pain management options, today announced the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for EXPAREL for postsurgical analgesia.

"This positive CHMP opinion brings Pacira one step closer to realizing our vision of establishing Pacira as the global leader in innovative non-opioid pain management," said Dave Stack, Chief Executive Officer and Chairman of Pacira BioSciences. "We are particularly pleased with the CHMP's broad recommendation for EXPAREL across a variety of surgical settings and administration techniques. We look forward to the EMA's final decision and the opportunity to bring a safe and effective opioid alternative to surgical patients across Europe."

The CHMP is a scientific committee of the EMA that reviews medical product applications on their scientific and clinical merit. The CHMP recommended granting EXPAREL marketing authorization with the following indication: EXPAREL is indicated as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults. EXPAREL should be administered in a setting where trained personnel and appropriate equipment are available. The European Commission will review the CHMP opinion and is expected to adopt a final decision in November 2020. The decision will be applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein.

The CHMP positive opinion was based on the results of four pivotal Phase 3 studies that demonstrated improvements in pain reduction and opioid use. These studies include:

- **Lower Extremity Nerve Block Study:** This study assessed the safety and efficacy of EXPAREL as a femoral nerve block in patients undergoing total knee arthroplasty. Results demonstrated that EXPAREL resulted in a significant reduction in cumulative pain scores over 72 hours compared to placebo. A higher percentage of patients who received EXPAREL were pain-free, consumed fewer opioids and reported higher satisfaction with their pain control.
- **Upper Extremity Nerve Block Study:** This study assessed the safety and efficacy of EXPAREL as an interscalene brachial plexus nerve block in patients undergoing total shoulder arthroplasty or rotator cuff repair. Results demonstrated that EXPAREL significantly improved pain control and reduced opioid consumption through 48 hours compared with placebo and a standardized pain management protocol alone.
- **Hard Tissue Infiltration Study:** This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing bunionectomy. Results demonstrated that EXPAREL significantly reduced pain and opioid consumption compared with placebo over the first 24 hours following surgery than patients administered placebo.
- **Soft Tissue Infiltration Study:** This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing hemorrhoidectomy. Results demonstrated that EXPAREL significantly reduced pain compared to placebo at all time points, including a 30 percent reduction in the cumulative pain scores at 72 hours. Patients who received EXPAREL consumed significantly fewer opioids than patients administered placebo.

EXPAREL is indicated in the United States for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Since its launch, EXPAREL has been used in over seven million patients.

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 impact of the worldwide COVID-19 (Coronavirus) pandemic and related global economic conditions; 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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