



Pacira Announces FDA Acceptance of sNDA for Exparel Nerve Blocks to Produce Regional Analgesia in Lower Extremity Procedures

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TAMPA, Fla., March 29, 2023 (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 accepted the submission of its supplemental new drug application (sNDA) seeking expansion of the EXPAREL label to include both single-dose sciatic nerve block in the popliteal fossa as well as femoral nerve block in the adductor canal. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is November 13, 2023.

The sNDA is supported by two successful Phase 3 studies in which EXPAREL achieved statistically significant and clinically meaningful reductions in postsurgical pain and opioid consumption through 96 hours compared with bupivacaine HCl following lower extremity surgical procedures including bunionectomy and total knee arthroplasty. In both studies EXPAREL was well tolerated with a safety profile consistent with bupivacaine HCl.

"We believe these positive datasets provide the basis for broadening the EXPAREL label to include both sciatic and femoral nerve blocks, which represents the opportunity to manage pain with a single 10 mL dose of EXPAREL for more than 3 million lower extremity procedures annually," said Dave Stack, chief executive officer and chairman of Pacira BioSciences. "Importantly, this potential approval would give clinicians a safe and effective tool to provide four days of postsurgical pain control, reduce opioid requirements, and continue to migrate relevant orthopedic procedures to the outpatient setting."

EXPAREL is currently indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Since initial approval in 2011, more than 12 million U.S. patients have been treated with EXPAREL.

About Pacira

Pacira BioSciences, Inc. (Nasdaq: PCRX) is committed to providing a non-opioid option to as many patients as possible to redefine the role of opioids as rescue therapy only. The company is also developing innovative interventions to address debilitating conditions involving the sympathetic nervous system, such as cardiac electrical storm, chronic pain, and spasticity. Pacira has three commercial-stage non-opioid treatments: EXPAREL[®] (bupivacaine liposome injectable suspension), a long-acting local analgesic currently approved for infiltration, fascial plane block, and as an interscalene brachial plexus nerve block for postsurgical pain management; ZILRETTA[®] (triamcinolone acetone extended-release injectable suspension), an extended-release, intra-articular injection indicated for the management of osteoarthritis knee pain; and Iovera[®], a novel, handheld device for delivering immediate, long-acting, drug-free pain control using precise, controlled doses of cold temperature to a targeted nerve. 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 multivesicular liposomes, 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 multivesicular liposome 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 about EXPAREL for Patients

EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies in adults where EXPAREL was injected into a wound, the most common side effects were nausea, constipation, and vomiting. In studies in adults where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. In the study where EXPAREL was given to children, the most common side effects were nausea, vomiting, constipation, low blood pressure, low number of red blood cells, muscle twitching, blurred vision, itching, and rapid heartbeat. EXPAREL can cause a temporary loss of feeling and/or loss of muscle movement. How much and how long the loss of feeling and/or muscle movement depends on where and how much of EXPAREL was injected and may last for up to 5 days. EXPAREL is not recommended to be used in patients younger than 6 years old for injection into the wound, for patients younger than 18 years old for injection near a nerve, and/or in pregnant women. Tell your health care provider if you or your child has liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from the body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL can affect the nervous system and the cardiovascular system; may cause an allergic reaction; may cause damage if injected into the joints; and can cause a rare blood disorder.

Forward-Looking Statements

Any statements in this press release about Pacira's future expectations, plans, trends, 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 Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to our growth and future operating results and trends, our strategy, plans, objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, including our plans with respect to the repayment of our indebtedness, anticipated product portfolio, development programs, patent terms, development of products,

strategic alliances and intellectual property and other statements that are not historical facts. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to, among others: risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur; risks related to future opportunities and plans for Flexion and its products, including uncertainty of the expected financial performance of Flexion and its products; the possibility that if we do not achieve the perceived benefits of the Flexion acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of our common stock could decline; the impact of the COVID-19 pandemic on elective surgeries, our manufacturing and supply chain, global and U.S. economic conditions (including inflation and rising interest rates), and our business, including our revenues, financial condition, cash flow and results of operations; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL, ZILRETTA and iovera[®]; the rate and degree of market acceptance of EXPAREL, ZILRETTA and iovera[®]; the size and growth of the potential markets for EXPAREL, ZILRETTA and iovera[®] and our ability to serve those markets; our plans to expand the use of EXPAREL, ZILRETTA and iovera[®] to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL, ZILRETTA and iovera[®]; the commercial success of EXPAREL, ZILRETTA and iovera[®]; the related timing and success of U.S. Food and Drug Administration supplemental New Drug Applications and premarket notification 510(k)s; the related timing and success of European Medicines Agency Marketing Authorization Applications; our plans to evaluate, develop and pursue additional product candidates utilizing our proprietary multivesicular liposome (“pMVL”) drug delivery technology; the approval of the commercialization of our products in other jurisdictions; clinical trials in support of an existing or potential pMVL-based product; our commercialization and marketing capabilities; our ability to successfully complete an EXPAREL capacity expansion project in San Diego, California; our ability to successfully complete a ZILRETTA capital project in Swindon, England; the outcome of any litigation; the ability to successfully integrate Flexion or any future acquisitions into our existing business; the recoverability of our deferred tax assets; assumptions associated with contingent consideration payments; and factors discussed in the “Risk Factors” of our most recent Annual Report on Form 10-K and in other filings that we periodically make with the Securities and Exchange Commission (the “SEC”). In addition, the forward-looking statements included in this press release represent our 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 we anticipate that subsequent events and developments will cause our views to change. Except as required by applicable law, we undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, and readers should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in the “Risk Factors” of our most recent Annual Report on Form 10-K and in other filings that we periodically make with the SEC.

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