Pacira BioSciences Announces Notice of Allowance of New Patent for EXPAREL

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Composition claims for EXPAREL 200-liter process extend patent protection into 2041

PARSIPPANY, N.J., May 18, 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 that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application Serial Number 17/156,400 related to EXPAREL® (bupivacaine liposome injectable suspension). The allowed application, “Manufacturing of Bupivacaine Multivesicular Liposomes” claims composition of EXPAREL prepared by the company’s 200-liter commercial-scale manufacturing process. A Notice of Allowance is issued after the USPTO determines that the prosecution on the merits of a patent has been completed. The USPTO then grants the patent upon payment of the patent issuance fee. The new patent will have an expiration date of January 22, 2041.

“This new patent marks the first deliverable from our comprehensive patent strategy and adds yet another layer of market exclusivity that extends our proprietary position for EXPAREL into the 2040s,” said Dave Stack, chairman and chief executive officer of Pacira BioSciences. “The comprehensive nature of the allowed claims underscores the deep multivesicular liposome manufacturing expertise that Pacira has accumulated over more than 25 years. Over the last six years, we have invested more than $100 million to create, design and commercialize a more efficient method for making EXPAREL, exceeding the U.S. Food and Drug Administration’s (FDA) rigorous standards for safety and bioequivalence. Our innovative manufacturing processes for EXPAREL are a core competency that we are committed to safeguarding globally.”

“Our growing intellectual property portfolio provides significant barriers of entry, protects us from would be competitors, and gives us confidence in long-term market leadership for EXPAREL as the only non-opioid, single-dose, long-acting local analgesic that is FDA-approved for infiltration, field block and brachial plexus nerve block,” continued Mr. Stack.

Pacira intends to submit the patent for listing in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) after securing FDA approval of its 200-liter manufacturing process. The FDA is currently reviewing the company’s supplemental New Drug Application (sNDA) for this manufacturing process, which offers enhanced efficiencies. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of August 6, 2021 for the sNDA.

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 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.

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, 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 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 on our business and results of operations; the cost and timing of an early termination payment to DePuy Synthes Sales, Inc.; 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 for EXPAREL; 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°; the rate and degree of market acceptance of iovera°; the size and growth of the potential markets for iovera° and our ability to serve those markets; our plans to expand the use of iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for iovera°; the recoverability of our deferred tax assets 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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