Pacira Announces FDA Approval of Enhanced EXPAREL Manufacturing Process

August 2, 2021

-- New 200-liter suite doubles capacity to meet growing EXPAREL demand --

-- Patent covering enhanced manufacturing process extends proprietary position to January 2041 --

PARSIPPANY, N.J., Aug. 02, 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 company's enhanced manufacturing process for EXPAREL ® (bupivacaine liposome injectable suspension) which is housed at a custom facility in Swindon, England under a partnership with Thermo Fisher Scientific Pharma Services. The company expects to start selling commercial product manufactured in this 200-liter suite later this year.

"This FDA approval underscores the quality assurance of our enhanced manufacturing process, which is essential as we scale the production of EXPAREL," said Dave Stack, chairman and chief executive officer of Pacira BioSciences. "Launching this new manufacturing site marks an important milestone for Pacira that will allow us to double our capacity to meet the growing demand for EXPAREL, while simultaneously improving our gross margins and extending our market exclusivity into 2041."

In June 2021, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,033,495 related to EXPAREL. The patent, "Manufacturing of Bupivacaine Multivesicular Liposomes," claims composition of EXPAREL prepared by the improved manufacturing process and has an expiration date of January 22, 2041. Pacira submitted this patent for listing in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) in July 2021.

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.

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 success of the company's sales and manufacturing efforts in support of the commercialization of EXPAREL and iovera°; the rate and degree of market acceptance of EXPAREL and iovera°; the size and growth of the potential markets for EXPAREL and iovera° and the company's ability to serve those markets; the company's plans to expand the use of EXPAREL and iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL and iovera°; the ability to successfully integrate any future acquisitions into the company's existing business and 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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