



Pacira Receives Complete Response Letter from FDA for sNDA Seeking Approval of EXPAREL® Use in Nerve Block to Provide Postsurgical Analgesia

March 2, 2015

PARSIPPANY, N.J.--(BUSINESS WIRE)--Mar. 2, 2015-- [Pacira Pharmaceuticals, Inc.](http://www.pacira.com) (NASDAQ: PCRX) today announced the receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) following a review of its supplemental New Drug Application (sNDA) for the use of EXPAREL® (bupivacaine liposome injectable suspension) in nerve block to provide postsurgical analgesia. Pacira will immediately schedule an End-of-Review meeting with the Division of Anesthesia, Analgesia and Addiction Products of the Center for Drug Evaluation and Research to discuss the contents of the CRL.

"We are reviewing the contents of the CRL and will work actively with the FDA to bring this important new indication to our core and growing business in infiltration," said Dave Stack, president, chief executive officer and chairman of Pacira. "Prescribed opioids in the acute care, postsurgical setting lead to chronic use and abuse in approximately one out of every 15 surgery patients in the United States; we remain committed to providing patients with long-acting, non-opioid analgesic options, like EXPAREL, to treat their pain while minimizing the risk of opioid-related adverse events. We look forward to finding solutions to address this public healthcare problem together with the FDA."

EXPAREL is currently indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. 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 a 45 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

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. EXPAREL has not been studied for use in patients younger than 18 years of age. Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL. Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations. In clinical trials, the most common adverse reactions (incidence greater-than or equal to 10%) following EXPAREL administration were nausea, constipation, and vomiting.

Please see the full Prescribing Information for more details available at http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf.

About Pacira

Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) is a specialty pharmaceutical company focused on the clinical and commercial development of new products that meet the needs of acute care practitioners and their patients. The company's flagship product, EXPAREL® (bupivacaine liposome injectable suspension), a non-opioid local analgesic for postsurgical pain control, was commercially launched in the United States in April 2012. EXPAREL and two other products have successfully utilized 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. Additional information about Pacira is available at www.pacira.com.

Forward Looking Statements

Any statements in this press release about our future expectations, plans, outlook and prospects, including statements about our expected revenues, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," 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 our 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 our ability to serve those markets; our plans to expand the use of EXPAREL to additional indications, including nerve block, oral surgery and chronic pain, as well as pediatrics; the related timing and success of a United States Food and Drug Administration supplemental New Drug Application; our receipt of FDA approval of our nerve block indication; the adverse effects and impacts of FDA warning letters; our plans to evaluate, develop and pursue additional DepoFoam-based product candidates; clinical studies in support of an existing or potential DepoFoam-based product; our plans to continue to manufacture and provide support services for our commercial partners who have licensed DepoCyt(e); our commercialization and marketing capabilities; our and Patheon UK Limited's ability to successfully and timely construct dedicated EXPAREL manufacturing suites; and other factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and in other filings that we periodically make with 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 our 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. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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