



## **Pacira Pharmaceuticals, Inc. Announces EXPAREL Phase 3 Clinical Trial in Femoral Nerve Block Meets Primary Efficacy Endpoint**

February 27, 2014

*sNDA Submission Expected in Second Quarter of 2014 with a 10-month PDUFA Timeline*

PARSIPPANY, N.J.--(BUSINESS WIRE)--Feb. 27, 2014-- [Pacira Pharmaceuticals, Inc.](http://www.pacira.com) (NASDAQ:PCRX) today announced that the Phase 3 clinical trial assessing the safety and efficacy of [EXPAREL®](http://www.exparel.com) (bupivacaine liposome injectable suspension) in femoral nerve block for total knee arthroplasty met its primary efficacy endpoint.

This pivotal Phase 3 trial evaluated 183 patients who were randomized to receive either 266 mg of EXPAREL or placebo, with all patients offered rescue narcotics as needed. Results demonstrated statistical significance in favor of EXPAREL for cumulative pain scores over 72 hours as measured by the area under the curve (AUC) ( $P < 0.0001$ ). The preliminary safety analysis was comparable between the two groups.

"We are pleased to report the positive results of the femoral nerve block trial and look forward to filing for a nerve block indication," said Dave Stack, president, chief executive officer and chairman of Pacira. "We believe that the expansion of the EXPAREL label to include nerve block will further enhance its clinical utility and broaden its access among anesthesiologists and surgeons."

### **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 current emphasis is the development of non-opioid products for postsurgical pain control, and its lead product, EXPAREL® (bupivacaine liposome injectable suspension), was commercially launched in the United States in April 2012. EXPAREL and two other products have utilized the Pacira proprietary product delivery technology DepoFoam®, a unique platform that encapsulates drugs without altering their molecular structure and then releases them over a desired period of time. Additional information about Pacira is available at [www.pacira.com](http://www.pacira.com).

### **About EXPAREL®**

EXPAREL (bupivacaine liposome injectable suspension) is 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 in the same fashion as current local anesthetics. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing analgesia with reduced opioid requirements for up to 72 hours. Pivotal studies have demonstrated the safety and efficacy of EXPAREL in patients undergoing bunionectomy or hemorrhoidectomy procedures and additional studies are underway to further demonstrate the safety and efficacy in other procedures. Additional information is available at [www.exparel.com](http://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](http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf).

### **Forward Looking Statements**

*Any statements in this press release about our future expectations, plans and prospects, including statements about our plans and expectations regarding EXPAREL, and other statements containing the words "believes," "anticipates," "plans," "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 indications of EXPAREL, including for nerve block and the related timing and success of an sNDA; 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; 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, 2013, 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. 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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