

# Pacira Pharmaceuticals, Inc. Announces Submission of Prior Approval Supplement for Additional EXPAREL® Manufacturing Suite

December 5, 2013

## Anticipated PDUFA Date in Early April 2014

PARSIPPANY, N.J.--(BUSINESS WIRE)--Dec. 5, 2013-- <u>Pacira Pharmaceuticals. Inc.</u> (NASDAQ:PCRX) today announced that it has submitted a Prior Approval Supplement (PAS) with the U.S. Food and Drug Administration (FDA) for an additional bulk manufacturing suite for <u>EXPAREL®</u> (bupivacaine liposome injectable suspension). Under the reauthorization of the Prescription Drug User Fee Act (PDUFA), the FDA established a 4-month PDUFA goal for approval of a manufacturing PAS. Should the FDA accept the PAS for review, a PDUFA date in early April 2014 is anticipated.

EXPAREL is manufactured at the Pacira FDA-approved Science Center Campus facility located in San Diego.

### About Pacira

Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) is an emerging 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 <a href="https://www.pacira.com">www.pacira.com</a>.

### 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.

#### **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 at http://www.exparel.com/pdf/EXPAREL Prescribing Information.pdf.

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