



Pacira Pharmaceuticals, Inc. Announces Resolution of Warning Letter with FDA's Office of Prescription Drug Promotion

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PARSIPPANY, N.J.--(BUSINESS WIRE)--Feb. 11, 2015-- [Pacira Pharmaceuticals, Inc.](#) (NASDAQ: PCRX) today announced resolution of matters pertaining to certain promotional aspects of EXPAREL detailed in a recent Warning Letter from the U.S. Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP). Pacira announced receipt of the Warning Letter on September 25, 2014 and has since been in constructive discussions with OPDP.

The resolution between Pacira and OPDP is summarized below. Pacira is actively working to ensure that its sales force and other promotional channels communicate these points to customers thoroughly and accurately:

- EXPAREL is broadly indicated for administration into the surgical site to produce postsurgical analgesia. Approval was based on pivotal trials conducted in excisional hemorrhoidectomy and bunionectomy surgical models, and thus, the basis for assessment of safety and efficacy was limited to those two procedures.
- Regarding duration of efficacy, in both pivotal trials, EXPAREL demonstrated a significant reduction in pain intensity scores compared to placebo for up to 24 hours. In the hemorrhoidectomy trial, which had a primary endpoint of cumulative pain scores over the first 72 hours, there was minimal to no difference in pain intensity scores between EXPAREL and placebo from 24 to 72 hours; however, there was a cumulative decrease in opioid consumption through 72 hours. The clinical benefit of that reduction was not demonstrated.

As per the FDA approval documents, in both clinical trials, the mean pain intensity score for the placebo patients decreased to levels similar to the EXPAREL patients. All patients had access to rescue opioid medication to control pain as needed after surgery; in the hemorrhoidectomy trial, 88 percent of patients in the placebo group had rescued with opioids by 24 hours.

"We are pleased to have reached a mutually acceptable resolution with the OPDP regarding the matters raised in the warning letter," said Dave Stack, president, chief executive officer and chairman of Pacira. "In the face of our nation's burgeoning opioid abuse epidemic, we continue to believe that EXPAREL plays a critical role in reducing our reliance on and overuse of opioids in the acute care setting by providing a viable non-opioid alternative."

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.

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 significant reductions in cumulative pain scores with a 45% 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.

Forward Looking Statements

Any statements in this press release about our future expectations, plans 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 indications of EXPAREL, including nerve block, oral surgery, chronic pain or repeat administration, pediatrics and the related timing and success of a United States Food and Drug Administration supplemental New Drug Application; 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, 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. 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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