



Pacira Pharmaceuticals, Inc. Announces Additional Data Supporting Safety of EXPAREL® in Peripheral Nerve Block

October 13, 2014

-- Analysis Presented at the 2014 Annual Meeting of the American Society of Anesthesiologists Finds the Safety of EXPAREL Similar to Placebo and Bupivacaine HCl --

PARSIPPANY, N.J.--(BUSINESS WIRE)--Oct. 13, 2014-- [Pacira Pharmaceuticals, Inc.](#) (NASDAQ: PCRX) today announced data demonstrating that EXPAREL® (bupivacaine liposome injectable suspension) used in peripheral nerve blocks has comparable safety to placebo and bupivacaine HCl. The analysis, based on a review of six Phase 1-3 clinical trials, will be presented during a podium session at the annual meeting of the American Society of Anesthesiologists in New Orleans this week.

"Our review of this peripheral nerve block clinical program found that EXPAREL administered at doses up to 266 mg as a femoral, intercostal or ankle block exhibited a similar safety profile to both placebo and bupivacaine HCl," said Brian Ilfeld, M.D., the study's lead investigator and chair for clinical research for the Division of Regional Anesthesia at the University of California San Diego. "This safety profile involving peripheral nerve blocks is similar to that found with wound infiltration and suggests that EXPAREL will have the same safety success with peripheral nerve blocks as it has exhibited for wound infiltration and hundreds-of-thousands of applications."

The comparative analysis found that all groups experienced a similar rate of adverse events (AEs) — 76% for EXPAREL vs 76% for placebo vs 61% for bupivacaine HCl — and that these appeared to be related to the procedure or opioid rescue rather than the study medication itself. The most common events were in the gastrointestinal disorders class, followed by general disorders/administration site conditions and nervous system disorders.

Additionally, the EXPAREL and placebo groups experienced a similar incidence of:

- Serious AEs (8% for EXPAREL vs 10% for placebo); none of these were assessed as being related to the study drug
- Nervous system AEs (21% in both groups)
- Cardiac AEs (9% vs 12%, respectively)

Older patients and patients with more co-morbidities were more prone to experience adverse events, as expected, and this trend was true across all groups.

"Building on the solid foundation of EXPAREL data that formed the basis of our sNDA for an expanded nerve block indication, we are pleased to announce that the first comprehensive review of our peripheral nerve block program reinforces the safety profile of the product," added Dave Stack, president, chief executive officer and chairman of Pacira. "If approved for a nerve block indication, we believe that EXPAREL could not only improve patient quality of life by providing multiple days of postsurgical analgesia while eliminating pumps and catheters, but also conserve hospital and provider resources associated with the placement and management of continuous nerve blocks."

EXPAREL is indicated for single-dose administration into the surgical site to produce postsurgical analgesia. Pacira has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for a nerve block indication for EXPAREL, with a target Prescription Drug User Fee Act (PDUFA) date of March 5, 2015.

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 analgesia with reduced opioid requirements for up to 72 hours. 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.

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: our ability to adequately resolve the issues raised in the FDA’s warning letter; our and Patheon’s ability to successfully and timely construct dedicated EXPAREL manufacturing suites; 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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