Pacira Pharmaceuticals, Inc. Announces Positive Interim Analysis of EXPAREL in Femoral Nerve Block for Total Knee Arthroplasty

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Completed Dose Ranging Portion of Pivotal Nerve Block Trial; Phase 3 Initiating; sNDA on Track for Early 2014

PARSIPPANY, N.J.--(BUSINESS WIRE)--May. 29, 2013-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced findings from the completed first part of its Phase 2/3 clinical trial assessing the use and administration of EXPAREL® (bupivacaine liposome injectable suspension) as a single-dose injection femoral nerve block for total knee arthroplasty surgery (TKA). Results show safety and efficacy of EXPAREL in femoral nerve block to support initiation of the Phase 3 portion of the pivotal trial.

"We are pleased with the interim analysis of the safety and efficacy of EXPAREL in this important orthopedic indication," said Dave Stack, president and chief executive officer of Pacira. "Based on the independent Data Safety Monitoring Board analysis, we believe that a single-dose injection of EXPAREL as a femoral nerve block can provide several days of analgesia without significant motor blockade. We look forward to initiating the Phase 3 portion of this trial and ultimately to providing orthopedic patients with a new option that could significantly contribute to the management of their postsurgical pain by replacing a perineural catheter, drug reservoir and pump with a single-dose injection of EXPAREL."

Designed as a two-part study, the first part of this double-blind, placebo-controlled trial evaluated the safety and efficacy of three doses of EXPAREL in 100 total patients to identify a single therapeutic dose for further investigation. A total of 100 patients received a femoral nerve block prior to TKA of 67 mg, 133 mg or 266 mg of EXPAREL or placebo (25 patients per group). Based on the evaluation of both safety and efficacy after 72 hours of follow-up, a single dose level was to be selected for assessment in the second part of the study. Following the review of the data, the committee responsible for assessing the safety and efficacy profile determined that EXPAREL should be dosed at 266 mg in the Phase 3 portion of the study, which will be initiated shortly. The committee also confirmed that if results from the Phase 2 portion of the trial are replicated in Phase 3, the target enrollment of 180 patients should be adequate to demonstrate the safety and efficacy of the indication.

In the Phase 3 portion of the study, those 180 patients will receive either 266 mg of EXPAREL or placebo as a femoral nerve block (90 randomized to each arm). In addition to pharmacokinetic and safety data, multiple efficacy endpoints will be measured.

In addition, Pacira also reported today that patient enrollment was completed in a second Phase 3 nerve block clinical trial. This double-blind, placebo-controlled intercostal nerve block study enrolled 180 patients (90 patients on each arm) who were undergoing thoracotomy. The Company expects that results from this additional Phase 3 study will contribute to a planned U.S. Food and Drug Administration supplemental New Drug Application (sNDA) submission anticipated for early 2014.

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 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.

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 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 to include nerve block; 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, 2012, 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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