EXPAREL Phase 3 Clinical Trial in Intercostal Nerve Block Does Not Meet Primary Endpoint

August 1, 2013

Based upon Ongoing Femoral Nerve Block Trial, sNDA Submission Still Planned for Early 2014

PARSIPPANY, N.J.--(BUSINESS WIRE)--Aug. 1, 2013-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced results from its second pivotal, Phase 3 clinical trial assessing the safety and efficacy of EXPAREL® (bupivacaine liposome injectable suspension) in intercostal nerve block for posterolateral thoracotomy. The study did not achieve its primary endpoint of a reduction of cumulative pain scores over 72 hours.

The 180 patients in this randomized, double-blind study across the U.S., Bulgaria, Georgia, Poland and the Czech Republic received either 266 mg of EXPAREL or placebo. Patients recruited in Bulgaria and Georgia demonstrated a response favoring EXPAREL over placebo, but this response was less pronounced in patients in Poland and missing in patients recruited in the Czech Republic (there were too few U.S. patients in the study to be meaningful). The complete data set from the trial will be available in the next few weeks, and further analyses are currently underway to better understand why patients in some countries had positive results while others had a very high placebo response.

In May 2013, Pacira reported positive findings from the Phase 2 portion of its other pivotal nerve block trial, a femoral nerve block study for total knee arthroplasty; the Phase 3 portion of this study is ongoing. The U.S. Food and Drug Administration (FDA) indicated to the company at its End-of-Phase 2 Meeting that a single pivotal trial meeting its primary endpoint would be sufficient to gain approval for the nerve block indication, assuming demonstration of adequate safety. Pacira plans to submit data from the ongoing femoral nerve block study to demonstrate efficacy and safety, as well as safety data from the intercostal nerve block study, for a supplemental New Drug Application (sNDA) anticipated in early 2014.

"While we will further examine the efficacy results for this trial, we are pleased with the initial assessment of safety in this model," said Dave Stack, president, chief executive officer and chairman of Pacira. "Given the FDA's position that a single positive pivotal trial would be sufficient for the approval of a nerve block indication and knowing that pain trials frequently fail to meet their primary endpoint, we had already planned two Phase 3 clinical trials as a risk mitigation strategy. We believe that with the positive interim results from the femoral nerve block study and the preliminary safety data from the intercostal block trial, we remain on track for submitting an sNDA next year."

EXPAREL is currently indicated for single-dose administration into the surgical site to produce postsurgical analgesia. EXPAREL has broad applications across a wide range of surgical specialties from general, colorectal, and orthopedic surgery to bariatric and plastic surgery procedures.

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, including the timing and success of an sNDA; 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.

Source: Pacira Pharmaceuticals, Inc.

Pacira Pharmaceuticals, Inc.
Jessica Cho, 973-254-3574
Jessica.Cho@pacira.com
or
Pure Communications, Inc.
Susan Heins, 864-286-9597
sjheins@purecommunicationsinc.com