Pacira Pharmaceuticals Announces Favorable Resolution With U.S. Food and Drug Administration, Which Reaffirms the Broad Indication for EXPAREL®

December 15, 2015

-- Terms Include Labeling Changes to Reinforce that the Use of EXPAREL is not Limited to Pivotal Trial Surgical Models, and Formal FDA Rescission of 2014 Warning Letter –

-- Conference Call Today at 8:30 am EST –

PARSIPPANY, N.J., Dec. 15, 2015 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced that it has achieved an amicable resolution with the United States in its lawsuit filed on September 8, 2015, *Pacira Pharmaceuticals, Inc. et al v. United States Food & Drug Administration et al,* 15-cv-07055 (SDNY Sept. 8, 2015)(LAK). The resolution confirms that EXPAREL (bupivacaine liposome injectable suspension) is, and has been since 2011, broadly indicated for administration into the surgical site to provide postsurgical analgesia.

"We are pleased to announce a successful collaboration with the FDA to resolve this matter in an expeditious and meaningful way that allows us to get back to the important task at hand—reducing postsurgical opioid exposure by providing a non-opioid option like EXPAREL to as many patients as appropriate," stated Dave Stack, chief executive officer and chairman of Pacira. "This is especially important given the burgeoning U.S. opioid epidemic, underscored by the reality that one in 15 patients will go on to long-term use after receiving an opioid in the hospital setting."

The key features of the resolution are as follows:

- The U.S. Food and Drug Administration (FDA) confirms that **EXPAREL has, since its approval on October 28, 2011, been approved for "administration into the surgical site to produce postsurgical analgesia"** in a variety of surgeries not limited to those studied in its pivotal trials.

- **The FDA approved a labeling supplement which amends the EXPAREL Package Insert (PI) to clarify and reinforce that:**

    - The use, efficacy and safety of EXPAREL is not limited to any specific surgery type or site;
    - The proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, with the two surgical models utilized in the pivotal trials provided as examples for the purpose of providing general guidance;
    - There was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy study;
        - The description of that duration of effect now includes a graphical representation of the mean pain intensity scores over time for the EXPAREL and placebo groups for the full 72-hour efficacy period, as well as information about median time to first opioid use and percentage of opioid-free patients in each treatment group
    - EXPAREL may be admixed with bupivacaine—including co-administered in the same syringe—provided certain medication ratios are observed.

- **The September 2014 Warning Letter is formally withdrawn via a "Rescission Letter"** from Dr. Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research (CDER) to Dave Stack.

    - At the request of Pacira, the Rescission Letter includes FDA guidance related to two key procedures:
        - Infiltration into the transversus abdominis plane (TAP), which is a field block technique covered by the approved indication for EXPAREL
        - Infiltration to produce postsurgical analgesia at the site of oral surgery procedures including tooth extractions, which is also covered by the approved indication for EXPAREL

- **The United States acknowledges that the rescission of the Warning Letter and approval of the Labeling Supplement reflect the scope of the indication** in the NDA that FDA approved on October 28, 2011.

- **Pacira and FDA agree that, in future interactions, they will deal with each other in an open, forthright and fair manner**.

Background on the Legal Complaint and Resolution

In September 2014, the FDA Office of Prescription Drug Promotion (OPDP) issued Pacira a Warning Letter related to certain promotional materials.

Pacira took actions to address the immediate FDA concerns and minimize further disruption to its business, but ultimately sought a court order to defend against any retroactive attempt to limit the broad indication for EXPAREL and restrict communications supported by the approved label.

Pacira and the individual physician plaintiffs were represented in this lawsuit by Ropes & Gray LLP. Pacira is also represented by Latham & Watkins LLP and Lowenstein Sandler LLP.

Today's Conference Call and Webcast Information

Pacira will host a conference call today, December 15, 2015, at 8:30 a.m. ET to discuss the legal resolution reached with the FDA. The call can be accessed by dialing 1-877-845-0779 (domestic) or 1-720-545-0035 (international) ten minutes prior to the start of the call and providing the Conference ID 2303742. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and providing the Conference ID 2303742. The replay of the call will be available for two weeks from the date of the live call.

The live, listen-only webcast of the conference call can also be accessed on the "Investors & Media" section of the company's website at investor.pacira.com. A replay of the webcast will be archived on the Pacira website for two weeks following the call.

About EXPAREL®

EXPAREL (bupivacaine liposome injectable suspension) is currently 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. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing significant reductions in cumulative pain score with a 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://media.corporate ir.net/media_files/IROL/22/220759/The_New_Label_with_Approval_Cover_Letter.pdf

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 flagship product, EXPAREL® (bupivacaine liposome injectable suspension), indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia, was commercially launched in the United States in April 2012. EXPAREL and two other products have successfully utilized DepoFoam®, a unique and proprietary product delivery technology that encapsulates drugs without altering their molecular structure, and releases them over a desired period of time. Additional information about Pacira is available at www.pacira.com.

Forward Looking Statements

Any statements in this press release about our future expectations, plans, outlook and prospects, 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 use of EXPAREL to additional indications and opportunities, including nerve block, oral surgery and chronic pain, as well as pediatrics, and the timing and success of any related clinical trials; the related timing and success of a United States Food and Drug Administration supplemental New Drug Application; the outcome of the U.S. Department of Justice inquiry; 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, 2014 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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