# Pacira Pharmaceuticals Seeks Court Injunction to Defend its Rights to Share Information about EXPAREL® Consistent with its FDA-Approved Indication

September 8, 2015

*Complaint Challenges FDA's Unlawful Efforts to Retroactively Restrict the Promotion of EXPAREL Despite Its Broad Indication*

PARSIPPANY, N.J.--(BUSINESS WIRE)--Sep. 8, 2015-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today filed a lawsuit against the U.S. Food and Drug Administration (FDA) seeking to exercise its lawful rights to communicate truthful and non-misleading information about its flagship product, EXPAREL® (bupivacaine liposome injectable suspension). EXPAREL was approved in 2011 for administration into the surgical site to produce postsurgical analgesia.

The complaint outlines the Company's belief that the FDA has violated the Administrative Procedure Act (APA), Fifth Amendment, and its own guidance materials and precedent by threatening enforcement action for promoting EXPAREL consistent with its approved indication. Additionally, the lawsuit alleges that the FDA violated the First Amendment rights of Pacira and the co-plaintiffs by restricting the exchange of truthful and non-misleading speech. The complaint, which was filed in the United States District Court for the Southern District of New York, can be accessed here: http://phx.corporate-ir.net/phoenix.zhtml?c=220759&p=irol-lawsuit.

Dave Stack, president, chief executive officer, and chairman of Pacira, remarked, "EXPAREL is an effective alternative to opioid-based postsurgical pain management, which is critically important to patient care as our nation battles an opioid addiction epidemic. In filing this lawsuit, we aim to restore our lawful right to communicate truthful and non-misleading information about EXPAREL consistent with the broad indication, for administration into the surgical site for postsurgical analgesia, granted by the FDA in 2011. It is unfortunate that the Agency's unwillingness to respond to repeated requests for discussion around these issues have left us with no choice but to take legal action."

**Background on the Complaint**

In September 2014, the FDA issued Pacira a Warning Letter related to certain promotional materials. At FDA's insistence, Pacira took certain actions to address the immediate FDA concerns and minimize further disruption to its business, but at the same time presented the Agency with evidence in defense of its marketing practices and requested multiple follow-up discussions.

Over the last year, Pacira repeatedly sought a dialogue with the FDA to address points of misunderstanding and disagreement, and repeatedly was denied. Six weeks ago, while continuing to deny the Company's requests for a meeting, and declining to offer further insight into its interpretation of the EXPAREL label, the Agency issued a close-out letter, indicating that it regarded the matter of the Warning Letter to be closed.

Pacira brings three counts in its complaint:

1. The unilateral attempt by the FDA to narrow the approved broad indication for EXPAREL without observing the procedure required by law for modifying a drug's label violates The Administrative Procedure Act (APA).

2. The FDA regulations as applied to Pacira are vague, deprive the company of fair notice of what is prohibited, and operate as a retroactive, ex post facto penalty, all in violation of the Due Process Clause of the Fifth Amendment.

3. FDA's actions attempting to forbid Pacira from sharing truthful and non-misleading information regarding both the efficacy and the administration of EXPAREL violate the Company's First Amendment right to engage in truthful and non-misleading speech.

Pacira seeks declaratory relief as well as a preliminary and/or permanent injunction preventing the FDA and other defendants from taking any action to violate the Company's aforementioned rights. The Company's motion for an injunction, which will be filed subsequent to the complaint, will be supported by several key declarants, including Larry Goldkind, MD, a former Deputy Director of the Division of Anti-inflammatory, Analgesic and Ophthalmic Drug Products in the FDA's Center for Drug Evaluation and Research (CDER), and Dr. Lee-Jen Wei, Professor of Biostatistics at the Harvard T.H. Chan School of Public Health.

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

**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.

**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 up to a 45 percent 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, 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 adverse effects and impacts of FDA warning letters; 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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