

Pacira Pharmaceuticals, Inc. Announces Receipt of FDA Warning Letter

September 25, 2014

PARSIPPANY, N.J.--(BUSINESS WIRE)--Sep. 25, 2014-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced the receipt of a Warning Letter (attached for reference) from the U.S. Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) referencing certain promotional materials on EXPAREL[®] (bupivacaine liposome injectable suspension).

"We take regulatory compliance very seriously and believe that our current labeling supports the claims being challenged by the FDA," said Dave Stack, president, chief executive officer and chairman of Pacira. "We plan to explain our position to the FDA and will provide an update upon resolution of these issues."

EXPAREL is indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia in adult patients 18 years of age or older.

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.

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; 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 filings that we periodically make with the SEC. In addition, the forward-looking statements included in 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.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20140925005209/en/

Source: Pacira Pharmaceuticals, Inc.

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