Pacira Pharmaceuticals Announces Completion of End-of-Review Process with FDA Regarding EXPAREL sNDA for Nerve Block

May 28, 2015

PARSIPPANY, N.J.--(BUSINESS WIRE)--May 28, 2015-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced that it completed an End-of-Review process with the U.S. Food and Drug Administration (FDA) regarding its supplemental New Drug Application (sNDA) for the use of EXPAREL® (bupivacaine liposome injectable suspension) for administration as a nerve block to provide postsurgical analgesia.

Pacira requested an End-of-Review meeting in March 2015 following its receipt of a complete response letter (CRL). In April 2015, members of the executive team and regulatory advisors for Pacira participated in the End-of-Review meeting with the U.S. Food and Drug Administration (FDA) Division of Anesthesia, Analgesia and Addiction Products (DAAAP) of the Center for Drug Evaluation and Research.

Based upon the FDA guidance that the expected use of EXPAREL will be for a broad spectrum of nerve blocks and not limited to the narrow indication of a single nerve block, Pacira plans to conduct additional Phase 3 studies for upper extremity and lower extremity nerve blocks that together would cover the majority of nerve blocks performed today in the U.S.

Pacira anticipates working with the FDA to finalize the design of the Phase 3 trials and expects to initiate the studies by the end of 2015.

“We are appreciative that the DAAAP staff and leadership engaged the Pacira team in constructive dialogue regarding the development of EXPAREL use in nerve block,” said Dave Stack, president, chief executive officer and chairman of Pacira. “We believe our plan to generate additional data provides a path forward for the nerve block indication for EXPAREL, consistent with the Pacira commitment to provide non-opioid alternatives for postsurgical pain in the acute care environment, where opioid use begins for so many Americans.”

DepoFoam® Spray Manufacturing Process Update

Pacira requested a Type C meeting in March 2015 to discuss the DepoFoam spray manufacturing process for EXPAREL. Pacira recently received feedback from the FDA DAAAP that the proposed approach to demonstrate comparability and to provide adequate data in support of the spray process appears acceptable.

Based on this feedback, Pacira intends to pursue the manufacturing of DepoFoam-based products using the spray process.

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, including statements about expected non-GAAP operating expenses, 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, 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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