Pacira Pharmaceuticals, Inc. Announces sNDA Submission for EXPAREL Nerve Block Indication

May 7, 2014

Expected PDUFA Date of March 5, 2015

PARSIPPANY, N.J.--(BUSINESS WIRE)--May 7, 2014-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for a nerve block indication for EXPAREL® (bupivacaine liposome injectable suspension). The sNDA is based on positive data from a Phase 3 study assessing the safety and efficacy of EXPAREL in femoral nerve block for total knee arthroplasty, and will also include additional safety data from a Phase 3 study of EXPAREL used to perform an intercostal nerve block for thoracotomy.

The timeline for review of the sNDA, under the Prescription Drug User Fee Act (PDUFA), is 10 months. If the FDA accepts the sNDA filing, a PDUFA target date of March 5, 2015 is expected.

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. 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.

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