EXPAREL® as the Foundation of a Multimodal Regimen Achieves Statistical Significance in All Primary Endpoints, Including a 60 Percent Reduction in Length of Hospital Stay

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IMPROVE trial compares the cost of care between a standard opioid-based regimen and an EXPAREL-based multimodal regimen for postsurgical pain management

PARSIPPANY, N.J.--(BUSINESS WIRE)--Oct. 8, 2012-- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced topline results from the first completed IMPROVE study in its prospective Phase 4 clinical program. The study was designed to compare the difference in three primary endpoints —cost, opioid consumption and hospital length of stay (LOS)—between one group of patients receiving a standard opioid-based postsurgical pain management regimen and a second group of patients receiving EXPAREL® (bupivacaine liposome injectable suspension) as the foundation of an opioid-sparing multimodal regimen.

The EXPAREL-based multimodal regimen achieved a statistically significant reduction in each primary endpoint, including a 60 percent reduction in LOS in patients undergoing open colectomy, a surgical procedure to remove all or part of the colon through an incision in the abdominal wall. EXPAREL is a non-opioid local analgesic indicated for administration into the surgical site to produce postsurgical analgesia. The overall safety profile for EXPAREL was consistent with previous experiences in the Phase 3 program.

“Results of this study, coupled with the results of our pivotal soft tissue trial, where EXPAREL demonstrated a 30 percent reduction in pain and a 45 percent reduction in opioid use through 72 hours following excisional hemorrhoidectomy, help to quantify the impact a non-opioid foundation such as EXPAREL can have on our postsurgical patients,” said Dave Stack, president and CEO of Pacira. “We look forward to seeing the data from the remainder of the IMPROVE study sites and sharing these results in the public domain.”

Southern Regional Medical Center is the first site to complete a prospective, open-label IMPROVE study. These studies will be carried out in up to five institutions across the United States. Colorectal surgeon Stephen M. Cohen, MD, FACS, FASCRS at Southern Regional Medical Center was the primary investigator of this study and performed all surgeries included in the study population. Eighteen patients were enrolled in the opioid-based group; 21 patients were enrolled in the EXPAREL-based multimodal regimen group.

“I have now used EXPAREL in more than 75 open bowel resection cases and my patients have reported excellent pain control in both the recovery room and in the postsurgical period lasting up to three days,” said Dr. Cohen. “Because it’s administered as an infiltration directly into the surgical site, EXPAREL gives surgeons the ability to treat the pain directly at the source. I believe the use of EXPAREL as the foundation of multimodal therapy represents a significant advancement in postsurgical pain management.”

Full data from this center are being submitted for publication.

About IMPROVE

The IMPROVE studies are prospective, open-label, sequential studies designed to compare the differences in the incidence of opioid-related adverse events and cost of care between two treatment groups undergoing open colectomy, laparoscopic colectomy, or ileostomy reversal surgical procedures. The first patient group receives a standard opioid-based pain management regimen that includes intravenous (IV) morphine or hydromorphone delivered via patient-controlled analgesia device (PCA) and access to opioid-based rescue medication. The second group receives an opioid-sparing multimodal regimen centered around an intraoperative infiltration of 266 mg EXPAREL (one 1.3%, 20-mL vial) into the surgical site at the close of surgery. In the postsurgical setting, patients receive IV or oral acetaminophen and ibuprofen. Patients in both groups are offered rescue analgesia with IV opioid and/or oral opioid + acetaminophen medications.

About Pacira

Pacira Pharmaceuticals, Inc. (Nasdaq: PCRX) is an emerging 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 http://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.

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 www.EXPAREL.com.

Source: Pacira Pharmaceuticals, Inc.

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