Data Update Supports Infiltration with EXPAREL® into the Transversus Abdominis Plane for Postsurgical Pain Management

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PARSIPPANY, N.J.--(BUSINESS WIRE)--Jan. 29, 2014-- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced key findings supporting the use of EXPAREL® (bupivacaine liposome injectable suspension) infiltrated into the transversus abdominis plane (or *iTAP*) for postsurgical pain management.

A recent independent study led by Andras Sandor, M.D., FACS, FASMBS, chairman of the Department of Surgery and director of the Hallmark Health Center for Weight Management/Weight Loss Surgery in Medford, Mass., evaluated 90 patients receiving laparoscopic bariatric surgery (vertical sleeve gastrectomy [VSG] or Roux-en-Y gastric bypass [RYGB]). Half of the patients (n=45) were treated with multimodal therapy including an EXPAREL iTAP, while the control group received ketorolac as well as a mixture of lidocaine and bupivacaine/epinephrine for perioperative pain control, and hydromorphone pain-controlled analgesia (PCA) pumps for postsurgical pain management. Both arms were allowed oral opioids on the second day following surgery if flatus occurred. Patients who received EXPAREL experienced:

- **A 60.7 percent reduction in opioid consumption** at 48 hours ($P<0.001$)
- **Higher return of bowel function** within 48 hours ($P<0.001$)

After presenting these findings at the 2013 Annual Meeting of the American Society for Metabolic & Bariatric Surgery in Atlanta, Dr. Sandor said, “The risks of opioids are pronounced in the bariatric population; utilizing a non-opioid platform with EXPAREL iTAP at its foundation contributed to decreasing both the amount of opioids needed and their resultant opioid-related adverse effects.”

Additionally, a Phase 4 study (the “TRANSCEND” trial) was conducted by Pacira in patients undergoing gynecologic or colorectal surgery. Prior to surgery, patients received either EXPAREL or sham (normal saline) iTAP as part of a multimodal pain regimen. The study goal was to demonstrate the utility of EXPAREL by achieving either co-primary endpoint of Day 3 Overall Benefit of Analgesia Score (OBAS) or total opioid rescue. A pre-planned interim analysis was performed on the first 39 patients recruited, which revealed a signal in one of the co-primary endpoints (OBAS), but poor compliance with the algorithm for total opioid rescue in the protocol and no signal for that co-primary endpoint. As a result, the decision was made not to continue the trial, but rather to analyze all of the patients recruited up to that point (n=67). In this analysis, the total opioid rescue continued to show no signal (with only 35 percent of patients protocol compliant), while the OBAS demonstrated an advantage for EXPAREL ($P<0.05$) compared to the sham-treated group.

These data reinforce earlier findings from two studies, one of which was presented at the 2013 Annual Meeting of the International Anesthesia Research Society (IARS), which demonstrated that patients treated with EXPAREL via iTAP after open abdominal hernia repair experienced low pain scores and high patient satisfaction. The other study prospectively evaluated 24 patients who received EXPAREL via bilateral iTAP immediately following robotic laparoscopic prostatectomy. Both dose groups in this study experienced a high level of patient satisfaction while requiring almost no opioids (the mean total amount used was <1 tablet/day after discharge), and no treatment-related adverse events were seen.

“We believe that the growing body of clinical evidence continues to support EXPAREL as the foundation of a multimodal platform for long-acting postsurgical pain management; these studies show its benefit when administered via iTAP compared to traditional TAP procedures, while minimizing the use of opioid-based PCA devices for pain control that are associated with opioid-related adverse events,” said Dave Stack, president, chief executive officer and chairman of Pacira. “Used in either the peri- or postsurgical settings to produce postsurgical analgesia, EXPAREL use is growing across a broad spectrum of surgical procedures.”

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 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 http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf.

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: 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 to include nerve block, including the timing and success of an sNDA; 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 factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2012, 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. 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.

Source: Pacira Pharmaceuticals, Inc.

Company Contact:
Pacira Pharmaceuticals, Inc.
Jessica Cho, 973-254-3574
or
Media Contact:
Pure Communications, Inc.
Susan Heins, 864-286-9597