



Pacira Pharmaceuticals, Inc. Announces Results from EXPAREL™ Pivotal Trial Published in *Diseases of the Colon & Rectum*

December 19, 2011

Data Demonstrate Significant Reduction in Cumulative Pain Scores and Opioid Use with EXPAREL in Soft Tissue Surgical Model

PARSIPPANY, N.J., Dec. 19, 2011 /PRNewswire/ -- [Pacira Pharmaceuticals, Inc.](#) (Nasdaq: PCRX) today announced the publication of data from a placebo-controlled, pivotal Phase 3 trial of EXPAREL™ (bupivacaine liposome injectable suspension), a non-opioid local analgesic that was recently approved by the U.S. Food and Drug Administration (FDA) for administration into the surgical site to produce postsurgical analgesia. The results, which demonstrate statistically significantly lower pain scores and decreased opioid requirements for up to 72 hours with EXPAREL, were published in the December print edition of the peer-reviewed journal *Diseases of the Colon & Rectum*.

The multicenter, randomized, double-blind, placebo-controlled study compared the magnitude and duration of postsurgical analgesia from a single dose of EXPAREL with that of placebo administered intraoperatively via deep tissue infiltration in patients undergoing a two- or three-column excisional hemorrhoidectomy under general anesthesia using the Milligan-Morgan technique. Patients in both populations who experienced inadequate pain control were eligible to receive opioids for rescue pain relief.

The primary efficacy endpoint was postsurgical pain control, measured by assessing patients' cumulative pain score, a measure of pain intensity over time, through 72 hours. Opioid use and patient satisfaction were also investigated.

Key findings included:

- Administration of EXPAREL resulted in a statistically significant reduction in pain compared to placebo at all time points, including a 30 percent reduction in the cumulative pain score at 72 hours ($P<0.0001$).
- The median time to first opioid use was more than 12 times longer in the EXPAREL group compared to the placebo group (14.3 hours vs 1.2 hours, respectively; $P<0.0001$).
- Patients administered EXPAREL consumed 45 percent fewer opioids than patients administered placebo ($P=0.0006$), and approximately three times as many EXPAREL patients avoided opioid use entirely compared to placebo patients (28 percent vs 10 percent, respectively; $P<0.0008$).
- Ninety-five percent of patients in the EXPAREL group were "satisfied" or "extremely satisfied" with their postsurgical analgesia at 72 hours compared to 73 percent of patients in the placebo group ($P=0.0007$).

The overall incidence of treatment-emergent adverse events in this study was similar between the EXPAREL and placebo groups, with the majority of adverse events being mild in severity. The most frequently reported treatment-emergent adverse events were anal hemorrhage and painful defecation.

"The results of this trial demonstrate that EXPAREL provides significant postsurgical pain control with a decreased reliance on opioids and improved patient satisfaction compared to placebo in a soft tissue surgical model," said Stephen R. Gorfine, M.D., lead author of the manuscript and clinical professor of surgery at Mount Sinai Medical Center, New York, NY. "Our study showed that EXPAREL is a useful therapeutic option for postsurgical pain management that may reduce the use of opioids, which are associated with a range of unwanted and potentially severe side effects."

"We are pleased to have the efficacy and safety data from this pivotal study of EXPAREL published and available in the public domain," said Dave Stack, president and chief executive officer of Pacira Pharmaceuticals, Inc. "With our recent FDA approval, this manuscript provides further support for the important role EXPAREL can play in optimizing postsurgical pain management."

The paper, titled "Bupivacaine Extended-Release Liposome Injection for Prolonged Postsurgical Analgesia in Patients Undergoing Hemorrhoidectomy: A Multicenter, Randomized, Double-blind, Placebo-controlled Trial" is available in both the print and [online](#) versions of *Diseases of the Colon and Rectum*. The publication is the official journal of the American Society of Colon and Rectal Surgeons.

About EXPAREL™

EXPAREL is an innovative product that combines bupivacaine with DepoFoam®, a proven product delivery technology that delivers medication over a desired time period. It 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 for an extended period of 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; 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 $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting.

Please see the full Prescribing Information for more details available at www.EXPAREL.com

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 approved for administration into the surgical site to produce postsurgical analgesia by the U.S. Food and Drug Administration in October 2011. EXPAREL and two other commercially available products utilize 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.

Forward Looking Statements

This press release contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934 (collectively, forward-looking statements), about our business, including statements related to the future development of product candidates and the timing thereof, the timing and results of our clinical trials, potential indications for our product candidates, the timing and likelihood of the commercialization of additional products and future financial results. Biopharmaceutical development inherently involves significant risks and uncertainties, the risks outlined under "Risk Factors" and elsewhere in the final prospectus related to our public offering filed with the Securities and Exchange Commission on November 16, 2011, and in other filings that we periodically make with the SEC. Our actual results may differ materially from our expectations due to these risks and uncertainties, including risks related to, sales of EXPAREL, manufacturing of our products, competition, market acceptance of our products, results of our clinical trials, intellectual property matters, ongoing regulatory oversight, reimbursement, our ability to raise sufficient capital and other matters. These forward-looking statements are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Pacira Pharmaceuticals, Inc. undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in Pacira Pharmaceuticals' expectations.

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