



## **Pacira Pharmaceuticals, Inc. Announces Phase 3 EXPAREL™ Data Presentation at the American Society of Colon and Rectal Surgeons 2011 Annual Meeting**

May 16, 2011

### **Data Demonstrate the Utility of EXPAREL in Reducing Pain and Opioid Use for 72 Hours Following Hemorrhoidectomy Surgery**

PARSIPPANY, N.J., May 16, 2011 /PRNewswire via COMTEX/ --

Pacira Pharmaceuticals, Inc., (Nasdaq: PCRX), an emerging specialty pharmaceutical company, today announced that positive results from its Phase 3 study evaluating EXPAREL™ in patients following hemorrhoidectomy will be presented at the 2011 American Society of Colon and Rectal Surgeons (ASCRS) Annual Scientific Meeting in Vancouver, British Columbia. Results from this multicenter, randomized, double-blind, parallel-group, placebo-controlled study demonstrated that patients experienced less pain and a reduction in opioid use for 72 hours following a single injection of EXPAREL at the end of the surgical procedure. This is the first time this study data has been presented at a major North American medical meeting.

The poster presentation, titled "Extended-Release Multivesicular Liposome Bupivacaine (EXPAREL™) Is Superior to Placebo for Post-Hemorrhoidectomy Pain Reduction," will be presented by Dr. Stephen R. Gorfine, clinical professor of surgery in the Division of Colorectal Surgery at The Mount Sinai Medical Center, on Tuesday, May 17, 2011 at 11:30 a.m. EDT.

"These Phase 3 data demonstrate that the median time to first opioid rescue for patients treated with EXPAREL following hemorrhoidectomy was significantly longer than those treated with placebo," said David Stack, president and CEO of Pacira Pharmaceuticals. "Patients in this study underwent excisional hemorrhoidectomy using the Milligan-Morgan technique, a painful soft tissue surgery. We believe that these data coupled with our positive Phase 3 data from our bunionectomy trial will help support the potential utility of EXPAREL in a clinical setting and build important mindshare among key opinion leaders. This is the first time that these Phase 3 data are being presented at a North American medical meeting and we believe this is another important milestone as we execute on our clinical and pre-commercial strategies."

Key findings from this study include:

- The study met its primary endpoint with a statistically significant reduction in cumulative pain score in patients receiving EXPAREL compared to placebo ( $p < 0.0001$ ).
- A total of 189 patients were treated at 12 clinical sites in Europe.
- The percentage of patients who were entirely opioid free was higher ( $p < 0.0008$ ) with EXPAREL than with placebo.
- The median time to first opioid rescue was 14 hours and 20 minutes in the EXPAREL group, more than 10 times longer than the placebo group (1 hour and 10 minutes) ( $p < 0.0001$ ).
- EXPAREL patients consumed statistically significantly less opioid rescue medication through 72 hours compared to the placebo group ( $p = 0.0006$ ).

In addition, the study showed that EXPAREL was well tolerated, with the incidence of adverse events (AEs) similar to placebo. GI side effects, commonly associated with opioid use, were reduced in the EXPAREL group compared to placebo, and there were no serious adverse events (SAEs) reported in patients receiving EXPAREL. Overall, 94.7% of patients treated with EXPAREL were "satisfied" or "extremely satisfied" with their postsurgical analgesia at 72 hours compared with 73.9% in the placebo group ( $p < 0.0007$ ).

There were no deaths or withdrawals due to an AE in the study. There was one SAE (mild thrombophlebitis), which occurred in a patient who had received placebo, and was resolved the next day after treatment. The most common AEs experienced were gastrointestinal in nature, occurring in 8.4% of EXPAREL patients and 13.8% of placebo patients.

For more information or to view the full poster, please visit the scientific presentations page located in the investors and media section on the Pacira website at <http://www.pacira.com/>.

#### **About Pacira**

Pacira Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company focused on the development, manufacture and commercialization of novel pharmaceutical products, based on its proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. In December 2010, Pacira announced that its New Drug Application (NDA) for EXPAREL, the company's most advanced investigational product candidate, had been accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of July 28, 2011 for the review of the EXPAREL NDA. EXPAREL is a bupivacaine-based product and has completed extensive Phase 3 clinical development for postoperative analgesia by infiltration. EXPAREL consists of bupivacaine encapsulated in DepoFoam, which is designed to address the limitations of widely used medications by enhancing their dosing and/or administration profile. Additional information about Pacira is available at <http://www.pacira.com/>.

#### **About EXPAREL™**

EXPAREL is Pacira's proprietary drug candidate consisting of bupivacaine encapsulated in DepoFoam®, both of which are currently used separately in FDA-approved products. Bupivacaine is a well-characterized anesthetic/analgesic that has an established safety profile with more than 20 years of use in the United States. Market data indicate that there is an unmet medical need for a longer-acting anesthetic/analgesic for postsurgical pain management. Several Phase 2 and Phase 3 clinical trials have been completed for EXPAREL and suggest statistically significant reduction of pain in

soft tissue and orthopedic surgery in different surgical models. Clinical data from Phase 3 trial 316 suggests that EXPAREL provides analgesia for up to 72 hours post-surgery, the primary endpoint for the trial. The safety of EXPAREL was evaluated in 10 randomized, double-blind, local administration into the surgical wound clinical studies involving 823 patients; the most common adverse events following EXPAREL administration were nausea, constipation, and vomiting.

#### **Forward Looking Statements**

*Any statements in this press release about our future expectations, plans and prospects, including statements about EXPAREL's potential, 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 timing of, and our ability to obtain regulatory approval of EXPAREL; the timing of our anticipated commercial launch 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 commercialization and marketing capabilities; and other factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2010, 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.*

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