



Pacira Pharmaceuticals, Inc. Launches EXPAREL® Pivotal Nerve Block Trial

September 25, 2012

First patient enrolled in two-part study to assess the safety and efficacy of EXPAREL in femoral nerve block

PARSIPPANY, N.J.--(BUSINESS WIRE)--Sep. 25, 2012-- [Pacira Pharmaceuticals, Inc.](http://www.pacira.com) (NASDAQ: PCRX) today announced initiation of its Phase 2/3 pivotal trial of [EXPAREL®](http://www.pacira.com) (bupivacaine liposome injectable suspension) administered as a single-dose injection femoral nerve block for total knee arthroplasty surgery. Results from this study and a forthcoming second trial focused on intercostal nerve block for thoracotomy will contribute to a planned U.S. Food and Drug Administration supplemental New Drug Application (sNDA) filing in late 2013 or early 2014.

The first of approximately 280 patients undergoing total knee arthroplasty (TKA) has been enrolled in the study. Designed as a two-part study, the first part will evaluate the safety and efficacy of three doses of EXPAREL to identify a single therapeutic dose for further investigation. In the second part of the study, patients will receive either the selected dose of EXPAREL or placebo as a femoral nerve block.

In addition to pharmacokinetic and safety data, multiple efficacy endpoints will be measured, including:

- **Primary endpoint:** Cumulative pain scores (pain intensity over time) through 72 hours
- **Other endpoints:**
 - Total postsurgical opioid consumption through 72 hours
 - Time to first opioid rescue
 - Patient satisfaction with postsurgical analgesia at 72 hours and 30 days
 - Proportion of patients who are pain free

The term *nerve block* pertains to the placement of a local anesthetic in close proximity to a nerve in order to create local analgesia. Bupivacaine, whose analgesic effect typically lasts for up to eight hours, is the current standard of care in many nerve block procedures.

"Patients undergoing orthopedic procedures, such as a total knee arthroplasty, traditionally experience several days of postsurgical pain. Currently, to obtain analgesia that spans multiple days, anesthesiologists can implement a continuous nerve block by inserting a catheter into the body that is hooked to an external drug reservoir and pump in order to bathe the nerve in local anesthetic," said Gary Patou, MD, chief medical officer at Pacira. "Just as we have seen with elastomeric pumps addressing postsurgical pain through local infiltration, these devices can be prone to migration, infection and leakage, all of which can significantly impact postsurgical analgesia and patient recovery. A femoral nerve block that can potentially provide several days of analgesia with a single-dose injection of EXPAREL could eliminate the need for external catheters and devices and significantly contribute to the management of postsurgical pain."

EXPAREL is currently indicated for single-dose administration, or infiltration, into the surgical site to produce postsurgical analgesia. In a pivotal, placebo-controlled soft tissue trial (excisional hemorrhoidectomy), the product demonstrated postsurgical pain control with reduced opioid requirements for up to 72 hours.

"With its current indication for single-dose infiltration, EXPAREL provides clinicians with a solid non-opioid foundation for a multimodal approach to postsurgical pain management that aims to mitigate the use of opioids, which are often associated with unwanted, costly and potentially severe adverse events," said Dave Stack, president and CEO of Pacira. "The potential to extend that non-opioid foundation beyond wound infiltration and into nerve block is something we are very excited about offering to our customers in the anesthesiology community."

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 administration 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.

Pacira Pharmaceuticals, Inc.
James S. Scibetta, 973-254-3570
or
Media Contact:
Pure Communications, Inc.
Susan Heins, 864-286-9597