Pacira Pharmaceuticals Announces Official Launch of EXPAREL to the Oral Surgeon Community to Treat Pain Following Oral and Maxillofacial Procedures

September 21, 2016

New research presented at AAOMS 2016 shows EXPAREL is safe and effective for pain relief following removal of wisdom teeth

PARSIPPANY, N.J., Sept. 21, 2016 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) today announced new data regarding the benefit of EXPAREL® (bupivacaine liposome injectable suspension) for patients undergoing third molar (wisdom teeth) extraction, marking the official launch of the product to the oral surgeon community. EXPAREL is a local analgesic that provides prolonged non-opioid postsurgical pain control.

As the nation battles the opioid addiction crisis, there is a particular opportunity to offer opioid alternatives to treat postsurgical pain in oral surgery patients. A recent study published in the *Journal of the American Medical Association* (*JAMA*) found an exceedingly high percentage of patients between 14 and 24 years of age are prescribed opioids for surgical tooth extractions;[1] for many patients, this may be their first exposure to opioids. According to a government report, the highest rates of opioid abuse are seen among 18 to 25 year olds.[2]

“We are pleased to work with the oral surgery community to help make EXPAREL available to patients undergoing third molar extraction and other relevant oral and maxillofacial procedures where long-lasting pain control is required to help patients get through the immediate postsurgical period,” said Dave Stack, Chief Executive Officer and Chairman of Pacira. “We believe the ability to offer patients and their caregivers—often their parents, in the case of third molar extraction patients—a safe and effective non-opioid option will not only help reduce overreliance on opioids, but also mitigate exposure to their unwanted side effects and the potential for long-term safety risks like opioid misuse, abuse, or addiction.”

The formal launch of EXPAREL to the oral surgeon community coincides with the presentation of new data on the safety and efficacy of the product in this patient population, which is occurring this week at the annual meeting of the American Association of Oral and Maxillofacial Surgeons (AAOMS) in Las Vegas, Nevada.

The data were generated from a prospective, randomized, double-blind, placebo-controlled study during which patients having all four wisdom teeth removed were randomized to receive a lidocaine nerve block followed by infiltration with either EXPAREL 133 mg (10 mL; 59 subjects) or placebo (10 mL saline; 30 subjects). A total of 166 subjects were enrolled in the study; 77 subjects were excluded due to protocol deviations.

Patients receiving EXPAREL demonstrated a numerically lower overall mean opioid consumption compared to patients administered placebo. Other key findings included:

- **Significantly lower pain scores at 48 hours** (*P*=0.0226), the primary endpoint of the study. Pain scores were also significantly lower compared to placebo at 24 hours (*P*=0.0192), 72 hours (*P*=0.0469), and 96 hours (*P*=0.0450).
- **No difference in adverse event rates** between the EXPAREL and placebo groups were observed; treatment-emergent adverse events were mild or moderate.

“This preliminary study data provides encouraging support for both the strong safety profile of EXPAREL and its potential to deliver prolonged pain management following oral surgery,” said Stuart Lieblich, DMD, a study investigator and lead author on the AAOMS presentation. “When considering oral surgery procedures, especially third molar extraction, postsurgical pain often ranks among patients’ top concerns so the ability to ease anxiety and offer a non-opioid option that provides ample pain management during the first few days after surgery—when pain is often at its worst—is a real benefit to both clinicians and our patients, alike.”

The study, titled Analgesic Efficacy and Safety of EXPAREL® (bupivacaine liposome injectable suspension) in Subjects Undergoing Third Molar Surgery: Preliminary Results of a Randomized Controlled Study, will be presented from the podium on Friday, September 23, 2016 from 10:00-10:09 AM PDT in the Lagoon EF room at the Mandalay Bay Convention Center.

Other EXPAREL-related events at AAOMS include:

- New Ways of Managing Pain in Your Oral and Maxillofacial Patients, a Pacira-sponsored Learning Expo
  - Date: Wednesday, September 21, 2016
  - Time: 4:30 PM-6:00 PM PDT
  - Place: Mandalay Bay Ballroom L
- Setting New Expectations for Pain Management, a Pacira-sponsored program
  - Date: Thursday, September 22, 2016
  - Time: 12:00 PM-1:00 PM PDT
  - Place: Mandalay Bay Convention Center Exhibit Hall (1200 Aisle)

EXPAREL is indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia in patients 18 years of age and older.

About EXPAREL®

EXPAREL (bupivacaine liposome injectable suspension) is currently 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. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing significant reductions in cumulative pain score with up to a 45 percent decrease in opioid consumption; the clinical benefit of the opioid reduction was not demonstrated. Additional information is available at www.EXPAREL.com.

About Pacira

Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) is a 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 flagship product, EXPAREL® (bupivacaine liposome injectable suspension), indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia, was commercially launched in the United States in April 2012. EXPAREL and two other products have successfully utilized DepoFoam®, a unique and proprietary product delivery technology that encapsulates drugs without altering their molecular structure, and releases them over a desired period of time. Additional information about Pacira is available at www.pacira.com.

Forward Looking Statements

Any statements in this press release about our future expectations, plans, outlook and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may" 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 use of EXPAREL to additional indications and opportunities, and the timing and success of any related clinical trials; the related timing and success of United States Food and Drug Administration supplemental New Drug Applications; the outcome of the U.S. Department of Justice inquiry; our plans to evaluate, develop and pursue additional DepoFoam-based product candidates; clinical studies in support of an existing or potential DepoFoam-based product; our plans to continue to manufacture and provide support services for our commercial partners who have licensed DepoCyt(e); our commercialization and marketing capabilities; our and Patheon UK Limited's ability to successfully and timely construct dedicated EXPAREL manufacturing suites; 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, 2015 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. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, and as such 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.

[1] http://jama.jamanetwork.com/article.aspx?articleid=2503505

[2] https://www.drugabuse.gov/publications/research-reports/prescription-drugs/trends-in-prescription-drug-abuse/adolescents-young-adults

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