Pacira BioSciences Announces Positive Topline Data from Phase 3 Study of EXPAREL as a Single-dose Femoral Nerve Block in the Adductor Canal for Total Knee Arthroplasty

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Study achieved primary and key secondary endpoints of statistically significant reductions in postsurgical pain and opioid consumption through 96 hours

TAMPA, Fla., Sept. 07, 2022 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced positive topline results from its Phase 3 study of EXPAREL as a single-dose femoral nerve block in the adductor canal for postsurgical regional analgesia in patients undergoing total knee arthroplasty. EXPAREL achieved the study's primary endpoint demonstrating a statistically significant reduction in cumulative pain scores from 0 to 96 hours compared with bupivacaine HCl ($p<0.01$). EXPAREL also achieved a statistically significant reduction in postsurgical opioid consumption through 96 hours ($p<0.01$) compared with bupivacaine HCl, a key secondary endpoint. EXPAREL was well tolerated with a safety profile consistent with bupivacaine HCl.

With these positive results, Pacira plans to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration early next year seeking expansion of the EXPAREL label to include femoral nerve block in the adductor canal.

"These positive data build on our market-leading position in long-lasting, non-opioid pain control by establishing EXPAREL as the first and only product with positive Phase 3 data safely demonstrating four days of superior postsurgical pain relief compared to bupivacaine," said Dave Stack, chairman and chief executive officer of Pacira BioSciences. "We believe we are now well positioned to broaden the EXPAREL label with an additional nerve block indication and further solidify the role of EXPAREL as a cornerstone in opioid-sparing postsurgical pain management regimens that support accelerated recovery and increased case migration to the 23-hour stay environment. This will help us continue to drive paradigm changes in patient care as we redefine the role of opioids as a last resort rescue medication."

About the Phase 3 Study
The Phase 3, randomized, double-blind, multicenter, active-controlled study was designed to evaluate the efficacy, safety, and pharmacokinetics of EXPAREL admixed with bupivacaine HCl versus bupivacaine HCl administered as a femoral nerve block in the adductor canal block for postsurgical analgesia in subjects undergoing primary unilateral total knee arthroplasty. In total, 166 subjects were randomized 1:1 to receive either 10 mL (133 mg) of EXPAREL admixed with 10 mL (50 mg) 0.5% bupivacaine HCl or 10 mL (50 mg) 0.5% of bupivacaine HCl mixed with 10 mL normal saline.

The study's primary endpoint was the area under the curve, or AUC, of the Numerical Rating Scale pain intensity scores from 0 to 96 hours post-surgery comparing EXPAREL to 0.5% bupivacaine HCl. Secondary endpoints included total postsurgical opioid consumption from 0 to 96 hours comparing EXPAREL to bupivacaine HCl.

Pacira plans to submit the full results from the Phase 3 study for presentation at future scientific conferences and for publication in a peer-reviewed journal.

About Pacira BioSciences

Pacira BioSciences, Inc. (Nasdaq: PCRX) is committed to providing a non-opioid option to as many patients as possible to redefine the role of opioids as rescue therapy only. The company is also developing innovative interventions to address debilitating conditions involving the sympathetic nervous system, such as cardiac electrical storm, chronic pain, and spasticity. Pacira has three commercial-stage non-opioid treatments: EXPAREL® (bupivacaine liposome injectable suspension), a long-acting, local analgesia currently approved for postsurgical pain management; ZILRETTA® (triamcinolone acetonide extended-release injectable suspension), an extended-release, intra-articular, injection indicated for the management of osteoarthritis knee pain; and iovera°®, a novel, handheld device for delivering immediate, long-acting, drug-free pain control using precise, controlled doses of cold temperature to a targeted nerve. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit www.pacira.com.

About EXPAREL®

EXPAREL (bupivacaine liposome injectable suspension) is indicated in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia, and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. Since its launch, EXPAREL has been used in over nine million patients. EXPAREL utilizes the company's proprietary multivesicular liposomal drug delivery technology composed of a honeycomb of numerous, non-concentric, internal aqueous chambers containing bupivacaine. After injection, bupivacaine is released over time, as the lipid membranes are absorbed, prolonging the duration of action. EXPAREL is the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. A single dose of EXPAREL provides significant reductions in cumulative pain scores with up to a 78 percent decrease in opioid consumption; the clinical benefit of the opioid reduction was not demonstrated. Additional information is available at www.EXPAREL.com.

Important Safety Information about EXPAREL for Patients

EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies in adults where EXPAREL was injected into a wound, the most common side effects were nausea, constipation, and vomiting. In studies in adults where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. In the study where EXPAREL was given to children, the most common side effects were nausea, vomiting, constipation, low blood pressure, low number of red blood cells, muscle twitching, blurred vision, itching, and rapid heartbeat. EXPAREL can cause a temporary loss of feeling and/or loss of muscle movement. How much and how long the loss of feeling and/or muscle movement depends on

where and how much of EXPAREL was injected and may last for up to 5 days. EXPAREL is not recommended to be used in patients younger than 6 years old for injection into the wound, for patients younger than 18 years old for injection near a nerve, and/or in pregnant women. Tell your health care provider if you or your child has liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from the body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL can affect the nervous system and the cardiovascular system; may cause an allergic reaction; may cause damage if injected into the joints; and can cause a rare blood disorder.

Forward-Looking Statements

Any statements in this press release about Pacira's future expectations, plans, trends, outlook, projections and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may," "will," "would," "could," "can" and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements related to the acquisition of Flexion Therapeutics, Inc. and the costs and benefits thereof, our growth and future operating results and trends, our strategy, plans, objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, anticipated product portfolio, development programs, strategic alliances, patent terms and intellectual property and other statements that are not historical facts. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. Actual results may differ materially from these indicated by such forward-looking statements as a result of various important factors, including risks relating to, among others: risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur; the possibility that if we do not achieve the perceived benefits of the Flexion acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of our shares could decline; the impact of the COVID-19 pandemic on elective surgeries, our manufacturing and supply chain, global and United States economic conditions, and our business, including our revenues, financial condition and results of operations; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL, ZILRETTA and iovera° and the rate and degree of market acceptance of EXPAREL, ZILRETTA and iovera°; the size and growth of the potential markets for EXPAREL, ZILRETTA and iovera° and our ability to serve those markets; our plans to expand the use of EXPAREL, ZILRETTA and iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL, ZILRETTA and iovera°; the commercial success of EXPAREL, ZILRETTA and iovera°; the related timing and success of United States Food and Drug Administration supplemental New Drug Applications, and premarket notification 510(k)s; the related timing and success of European Medicines Agency Marketing Authorization Applications; our plans to evaluate, develop and pursue additional product candidates utilizing our proprietary multivesicular liposome (pMVL) drug delivery technology; the approval of the commercialization of our products in other jurisdictions; clinical trials in support of an existing or potential pMVL-based product; our commercialization and marketing capabilities, our ability to successfully construct an additional EXPAREL manufacturing suite in San Diego, California; our ability to successfully complete a ZILRETTA capacity expansion project in Swindon, England; the outcome of any litigation; the ability to successfully integrate Flexion or any future acquisitions into our existing business; the recoverability of our deferred tax assets; and assumptions associated with contingent consideration payments; and factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K and in other filings that we periodically make with the Securities and Exchange Commission. 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 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, except as required by law. 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.

Investor Contact: Susan Mesco, (973) 451-4030 susan.mesco@pacira.com Media Contact: Coyne Public Relations Kristin Capone, (973) 588-2108 kcapone@coynepr.com