Pacira BioSciences Announces Positive Topline Data from Phase 3 Study of EXPAREL as a Single-dose Sciatic Nerve Block in the Popliteal Fossa for Bunionectomy

September 21, 2022

-- Second Phase 3 study achieves primary and key secondary endpoints; safely demonstrating statistically significant reductions in postsurgical pain and opioid consumption through 96 hours --

-- Company on track to submit supplemental New Drug Application in first quarter of 2023 --

TAMPA, Fla., Sept. 21, 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 sciatic nerve block in the popliteal fossa for postsurgical regional analgesia in patients undergoing bunionectomy. EXPAREL achieved the study's primary endpoint by demonstrating a statistically significant reduction in cumulative pain scores from 0 to 96 hours compared with bupivacaine HCl ($p<0.00001$). EXPAREL also achieved statistical significance for reduction in postsurgical opioid consumption ($p<0.00001$) and percentage of opioid-free subjects ($p<0.001$) through 96 hours compared with bupivacaine HCl, which were key secondary endpoints. EXPAREL was well tolerated with a safety profile consistent with bupivacaine HCl.

"With the successful readout of our second Phase 3 study, we now have an overwhelmingly positive body of data supporting EXPAREL as the first and only single-dose product to safely demonstrate four days of superior pain control versus bupivacaine," said Dave Stack, chairman and chief executive officer of Pacira BioSciences. "EXPAREL-based nerve and field blocks are fueling a revolution in regional aesthesia. With these positive data sets, we believe we are well positioned to broaden the EXPAREL label to include two additional nerve block indications for prolonged pain management across a wide variety of lower extremity procedures. This will help physicians improve their patients' outcomes by providing better pain control, while minimizing opioids, accelerating recovery times, and migrating procedures to outpatient settings."

Pacira plans to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) early next year to expand the EXPAREL label to include sciatic nerve blocks in the popliteal fossa, as well as femoral nerve blocks in the adductor canal. Earlier this month, Pacira announced positive results from a Phase 3 study of EXPAREL as a single-dose femoral nerve block in the adductor canal for total knee arthroplasty. A sciatic nerve block in the popliteal fossa is used for anesthesia and analgesia for foot, ankle, achilles tendon, and other lower leg surgeries. A femoral nerve block in the adductor canal is used for anesthesia and analgesia for surgery of the knee, medial lower leg, and ankle surgeries.

"These results from our second Phase 3 study of EXPAREL as a lower extremity nerve block, demonstrate safe, effective and clinically meaningful superiority against the active comparator bupivacaine," said Roy Winston, MD, chief medical officer of Pacira BioSciences and a board-certified anesthesiologist. "We look forward to the regulatory process with the FDA with the goal of providing clinicians with two new routes of administration that have safely demonstrated superior efficacy to the current standard in consecutive studies involving lower extremity surgeries."

About the Phase 3 Study

The Phase 3, randomized, double-blind, active-controlled, multicenter study was designed to evaluate the efficacy, safety, and pharmacokinetics of EXPAREL versus bupivacaine HCl administered as a sciatic nerve block in the popliteal fossa. The study was conducted in two parts, with Part A completed and analyzed before enrollment in Part B was initiated.

In total, the study randomized 185 subjects. In Part A, 66 subjects undergoing bunionectomy were randomized 1:1:1 to receive a sciatic nerve block in the popliteal fossa with a single dose of EXPAREL 266 mg, EXPAREL 133 mg or 0.25% bupivacaine HCl (50 mg). In part B, an additional 119 subjects undergoing bunionectomy were randomized 1:1 to receive a sciatic nerve block in the popliteal fossa with a single dose of EXPAREL 133 mg or 0.25% bupivacaine HCL (50 mg). All subjects in Part A and Part B received a Mayo field block with 20 mL 0.5% bupivacaine HCl after study drug administration in the operating room immediately prior to surgical incision.

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