Pacira BioSciences Concludes Patient Enrollment in Part A of Phase 2 Study Evaluating Safety and Efficacy of PCRX-201 for the Treatment of Osteoarthritis of the Knee

November 05, 2025

-- Milestone advances two-part study evaluating novel, locally administered gene therapy designed to increase anti-inflammatory IL-1Ra production in the knee joint --

BRISBANE, Calif., Nov. 05, 2025 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to deliver innovative, non-opioid pain therapies to transform the lives of patients, today announced that it has concluded patient enrollment in Part A of its Phase 2 ASCEND study evaluating PCRX-201 (enekinragene inzadenovec) for the treatment of osteoarthritis (OA) of the knee. This milestone marks the first stage of a two-part, multicenter trial designed to evaluate the safety and efficacy of PCRX-201, the company's novel, locally administered gene therapy candidate for osteoarthritis of the knee. The company expects to report topline results from Part A of the study near the end of 2026.

PCRX-201 is injected locally into the knee joint to boost cellular production of interleukin-1 receptor antagonist (IL-1Ra), and block interleukin-1 pathway activation to improve chronic inflammation, pain, and function. PCRX-201's unique design also features an inducible promoter to mimic the body's natural response to inflammation by "turning on" the expression of IL-1Ra when inflammation is present in the joint and turning off expression once inflammation is quelled.

"Concluding enrollment in Part A of the ASCEND study for PCRX-201 represents a significant milestone in our Phase 2 development program," said Jonathan Slonin, M.D., MBA, Chief Medical Officer at Pacira BioSciences. "Building on encouraging results from our Phase 1 study, this accomplishment underscores the strategic execution of our clinical team and the growing recognition of the potential of PCRX-201 to provide sustained relief, addressing the underlying inflammatory drivers of OA through local administration."

Study Design
The two-part, multicenter ASCEND study will involve approximately 135 patients, 45 to 80 years old with painful OA of the knee at a Kellgren-Lawrence (K-L) Grade of 2, 3 or 4. Subjects are randomly assigned to a treatment dose group and stratified by K-L Grade, a semiquantitative method for evaluating the severity of OA on a scale of 0-4.

Part A of the study randomizes approximately 45 patients and will evaluate two doses of PCRX-201: Dose A (1.4×10^{10} genome copies [GC]) and Dose B (1.4×10^{11} GC). Patients are randomized 1:1:1 to Dose A, Dose B, or saline. All cohorts receive pretreatment with an intra-articular corticosteroid (methylprednisolone 40 mg) to improve tolerability and gene transfer, a common technique in gene therapy dosing.

Part A will inform dose selection and manufacturing readiness for Part B, which will randomize approximately 90 patients. The drug product used in Part B of the study will be manufactured using the company's proprietary commercial scale manufacturing process intended for commercial scale-up. Pacira expects to report topline results from Part A of the study before the end of 2026.

For both Parts A and B, the primary endpoint is the number and percentage of treatment-emergent adverse events, adverse events of special interest, and serious adverse events for PCRX-201 plus steroid pretreatment versus saline plus steroid pretreatment from Week 1 through Week 52. Secondary and exploratory endpoints include efficacy assessments such as changes in pain and physical function from baseline at Weeks 38 and 52, measured by the Numerical Rating Scale (NRS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Injury and Osteoarthritis Outcome Score (KOOS). Biomarkers, immunogenicity, biodistribution, and structural endpoints will also be evaluated. All participants will be followed for five years.

To learn more about the ASCEND study, visit clinicaltrials.gov.

About PCRX-201 (enekinragene inzadenovec)
PCRX-201 (enekinragene inzadenovec) features an innovative design based on the company's proprietary high-capacity adenovirus vector platform. It is currently being studied in the fundamental, underlying chronic inflammatory processes that contribute to "wear and tear" over time in osteoarthritis of the knee, a condition that affects more than 15 million individuals in the U.S. today.

In June 2025, Pacira reported data from its ongoing clinical development program showing that PCRX-201 continues to demonstrate durable and clinically meaningful improvements in knee pain, stiffness, and function through three years following local administration, with a well-tolerated safety profile. PCRX-201 has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration and Advanced Therapy Medicinal Products (ATMP) designation from the European Medicines Agency. PCRX-201 is the first gene therapy to achieve these clinical results and earn these

regulatory designations in osteoarthritis of the knee – a testament to its promise and potential.

About the High-capacity Adenovirus Vector Platform
Pacira's proprietary novel high-capacity adenovirus (HCAd) gene therapy vector platform solves many of the challenges in the field of gene therapy that have prevented its utilization in treating common diseases, such as osteoarthritis.

Key features include:

- The HCAd vector is much more efficient at delivering genes into cells compared to many other gene therapies that rely on adenovirus associated virus, or AAV, vectors. As a result, the desired effect can be achieved with much smaller doses.
- The vector used in the HCAd platform can carry up to 30,000 base pairs of DNA, which enables gene therapy with multiple or larger genes compared to AAV vectors.
- Genetic medicines based on the HCAd platform can be administered locally and have the potential for redosing at therapeutically appropriate intervals.
- Lower dose levels and efficient delivery of genes into cells means that thousands of doses can be produced in a single batch. As a result, therapies built on the HCAd platform are expected to have a commercially attractive and viable cost of goods profile.

Beyond PCRX-201 and other product candidates in preclinical development, the company has identified numerous well-validated cytokines that could also be the basis for locally administered genetic therapies using the HCAd platform.

About Pacira
Pacira delivers innovative, non-opioid pain therapies to transform the lives of patients. Pacira has three commercial-stage non-opioid treatments: EXPAREL® (bupivacaine liposome injectable suspension), a long-acting local analgesic currently approved for infiltration, fascial plane block, and as an interscalene brachial plexus nerve block, an adductor canal nerve block, and a sciatic nerve block in the popliteal fossa 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®º, a novel, handheld device for delivering immediate, long-acting, drug-free pain control using precise, controlled doses of cold temperature to a targeted nerve. The Company is also advancing the development of PCRX-201 (enekinragene inzadenovec), a novel, locally administered gene therapy with the potential to treat large prevalent diseases like osteoarthritis. To learn more about Pacira, visit www.pacira.com.

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 "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "will," "would," and similar expressions, constitute forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to: '5x30', our growth and business strategy, our future outlook, the strength and efficacy of our intellectual property protection and patent terms, our future growth potential and future financial and operating results and trends, our plans, objectives, expectations (financial or otherwise) and intentions, including our plans with respect to the repayment of our indebtedness, anticipated product portfolio and product development programs, strategic alliances, plans with respect to the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act, the expected cost savings and benefits of a July 2025 reduction in force and any 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: the failure to realize the anticipated benefits and synergies from the acquisition of GQ Bio Therapeutics GmbH; 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; our manufacturing and supply chain, global and United States economic conditions (including tariffs, inflation and rising interest rates), and our business, including our revenues, financial condition, cash flows and results of operations; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL, ZILRETTA and iovera°; 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, iovera° and any of our other product candidates, including PCRX-201; 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 complete capital projects; the outcome of any litigation; the recoverability of our deferred tax assets; assumptions associated with contingent consideration payments; assumptions used for estimated future cash flows associated with determining the fair value of the Company and the anticipated funding or benefits of our share repurchase program. 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. Except as required by applicable law, we undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, and readers should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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