Pacira BioSciences Presents Updated Three-Year Data Demonstrating Sustained Efficacy and Safety of PCRX-201 Gene Therapy for Patients with Moderate-to-Severe Osteoarthritis of the Knee

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-- Data demonstrates sustained clinical improvements in pain, stiffness and function for up to 156 weeks following a single administration of PCRX-201 --

BRISBANE, Calif., Oct. 28, 2025 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX), the industry leader in the delivery of innovative, non-opioid pain therapies to transform the lives of patients, today announced updated three-year results and a new subset analyses demonstrating sustained efficacy and safety across all patient subgroups, including varying disease severities, from its open-label Phase 1 clinical trial evaluating PCRX-201 (enekinragene inzadenovec), a novel gene therapy candidate for osteoarthritis of the knee. Results show that a single intra-articular injection of PCRX-201 at each of the three doses tested was well tolerated and produced sustained improvements in pain, stiffness, and function through 156 weeks in patients with osteoarthritis of the knee.

The findings will be presented during a poster session at the American College of Rheumatology (ACR) Convergence 2025 in Chicago, on Tuesday, October 28, from 10:30 a.m. to 12:30 p.m. CT.

“This data is evidence of the potential of PCRX-201 to offer long-term pain relief for patients with osteoarthritis of the knee that could significantly change our approach to treating the condition,” said Stanley Cohen, M.D., board-certified rheumatologist and Co-Medical Director of the Metroplex Clinical Research Center in Dallas, Texas, who was lead investigator on the research. “Unlike our current therapies that treat symptoms and deliver only short-term, limited relief, this gene therapy blocks processes at the cellular level that cause chronic inflammation and lead to pain and loss of function of the knee joint. Having a treatment in our arsenal that could provide effective relief for multiple years after a single injection would be transformative.”

PCRX-201 features an innovative design based on the company’s proprietary high-capacity adenovirus, or HCAd, gene therapy vector platform. It 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 disease-modifying design also features an inducible promoter to mimic the body’s natural response to inflammation by “turning up” the expression of IL-1Ra when inflammation is present in the joint and turning down expression once inflammation is quelled.

Study Details
The open-label, Phase 1 trial investigated the safety and efficacy of PCRX-201 at three different doses administered by ultrasound-guided intra-articular injection to patients aged 30 to 80 with moderate to severe osteoarthritis of the knee who remained in the trial for 156 weeks. A total of 72 patients were enrolled across two cohorts. The first cohort (N=36) was administered one injection of PCRX-201 at a low, middle or high dosage. The second cohort (N=36) received concurrent pretreatment with an intra-articular corticosteroid (methylprednisolone 40 mg) to improve tolerability and gene transfer. Knee pain, stiffness and function were assessed at 156 weeks using the Western Ontario and McMaster Universities Osteoarthritis Index pain score (WOMAC-A), the stiffness score (WOMAC-B), and the Knee Injury Osteoarthritis Outcome Score (KOOS), respectively. Anti-AD5 neutralizing antibody (NAb) titers in serum, which can hinder the effectiveness of treatment and increase adverse reactions, were measured at baseline before PCRX-201 administration and up to 52 weeks.

Key Findings:

- A single injection of PCRX-201 at any dose level tested had an acceptable safety profile and was not associated with any serious treatment-related adverse events.
- Patients experienced sustained, clinically meaningful reductions in pain and stiffness and improvements in function for three years at all three doses.
- Within the corticosteroid pretreated cohort, patients with Kellgren-Lawrence (K/L) grade 2 osteoarthritis demonstrated numerically greater reductions in pain than those with more advanced grades (3–4).
- Pre-existing serum NAbs did not alter the effectiveness of PCRX-201 as determined by pain and stiffness scores.
- The findings support the ongoing Phase 2 ASCEND study strategy of PCRX-201 administered at the 10-fold lower dose (1.4E11 genomic copies [GC]) with corticosteroid pretreatment.

Additionally, a subset analyses presented at ACR Convergence further demonstrated that PCRX-201 maintained consistent efficacy and safety across all structural severity subgroups (K/L grades 2–4). Importantly, the presence of pre-existing neutralizing antibodies did not impact efficacy or safety outcomes at any of the three doses evaluated. These findings reinforce the potential for re-dosing.

No serious treatment-emergent AEs related to the treatment or procedure were reported, regardless of steroid pretreatment or

dose level administered. Treatment-related index joint effusions (swelling) were the most common AE, occurring less frequently in the pretreated group (42%) than in the non-pretreated group (67%).

“Given the tremendous need for better knee osteoarthritis treatments, PCRX-201 has the potential to be a game changer in how we manage a condition that affects approximately 15 million Americans and can be quite debilitating,” said Jonathan Slonin, M.D., MBA, Chief Medical Officer at Pacira BioSciences and co-author of the study. “These three-year results confirm the safety and durability of PCRX-201 and support our ongoing Phase 2 study strategy for dosing and corticosteroid pretreatment.”

In March 2024, PCRX-201 became the first-ever gene therapy product candidate in osteoarthritis to receive Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA).

RMAT designation provides the benefits of intensive FDA guidance on efficient drug development, including the ability for early interactions with the FDA to discuss surrogate or intermediate endpoints, potential ways to support accelerated approval and satisfy post-approval requirements, potential priority review of the Biologics License Application (BLA), and other opportunities to expedite development and review. PCRX-201 was also granted Advanced Therapy Medicinal Products (ATMP) designation by the European Medicines Agency in May 2023.

A Phase 2 study of PCRX-201 (the ASCEND study) for the treatment of osteoarthritis of the knee is currently underway.

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. For more information, visit https://clinicaltrials.gov/study/NCT06884865.

About the High-capacity Adenovirus Vector Platform
In February 2025, in support of the company’s ‘5x30’ growth strategy, Pacira acquired GQ Bio Therapeutics and its novel high-capacity adenovirus (HCAd) vector gene therapy vector platform. This 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, our intellectual property 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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