



Pacira BioSciences Announces Publication of Positive Two-Year Phase 1 Data For PCRX-201 in *Annals of the Rheumatic Diseases*

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—A single locally administered intra-articular injection of PCRX-201 into the knee was well tolerated in patients with moderate-to-severe knee osteoarthritis —

—Exploratory clinical outcome measures showed improvements out to two years in pain, stiffness, and function across all doses and groups —

—Phase 2 ASCEND trial of PCRX-201 in knee osteoarthritis advancing with first topline read out on track for year-end 2026 —

BRISBANE, Calif., Aug. 06, 2026 (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 the publication of positive two-year results from its Phase 1 clinical trial evaluating PCRX-201 (enekenragene inzadenovec), the company's investigational locally administered gene therapy for knee osteoarthritis (OA). Published in the [*Annals of the Rheumatic Diseases*](#), the study showed that PCRX-201, when administered as a single local administration via intra-articular injection into the knee, was well tolerated in patients with moderate to severe knee osteoarthritis. Through two years of follow-up, exploratory outcome measures showed improvements in pain, stiffness, and function across all dose cohorts among patients who remained in the study.

"Publication in *Annals of the Rheumatic Diseases* highlights the quality and importance of these findings," said Stanley Cohen, M.D., board-certified rheumatologist and Co-Medical Director of the Metroplex Clinical Research Center in Dallas, Texas, and lead investigator of the study. "The safety profile and the improvements observed across exploratory outcome measures over two years in this study provide a strong scientific rationale for the advancement of PCRX-201 into later-stage clinical development which is currently underway."

Study Design

The Phase 1 clinical trial was a two-part open-label study that enrolled 72 adults ranging in age from 30 to 80 years old with symptomatic, radiographically confirmed moderate-to-severe knee OA. In Part 1, 36 participants received a single injection of PCRX-201 at a low, middle, or high dose. In Part 2, 36 participants received methylprednisolone immediately before PCRX-201 administration to improve tolerability and evaluate whether glucocorticoid pretreatment could enhance vector transduction. The primary endpoint was safety; secondary and exploratory endpoints included systemic biodistribution and clinical outcomes measuring pain, stiffness, and function, with follow-up through 104 weeks. ([See press release for full results.](#))

"Publication of these two-year Phase 1 data marks an important milestone for our gene therapy program and reinforces our belief in PCRX-201's potential to change the treatment landscape for knee osteoarthritis," said Jonathan Slonin, MD, MBA, chief medical officer of Pacira BioSciences. "We are encouraged by the results observed to date, which, if confirmed in future studies, could meaningfully exceed the three-to-six-month duration of current therapies and deliver a treatment effect lasting one year or more, representing a potentially transformative advancement for patients. We look forward to building on these findings through our ongoing Phase 2 ASCEND trial."

Glucocorticoid pretreatment, which was associated with a lower rate of joint effusion and greater improvement in clinical outcomes, has been incorporated into the company's ongoing Phase 2 ASCEND study of PCRX-201 (NCT06884865). The company recently announced that it has initiated enrollment in Part B of the Phase 2 ASCEND study and has implemented a successful transition of PCRX-201 to a scalable manufacturing process.

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

About PCRX-201 (enekenragene inzadenovec)

PCRX-201 (enekenragene inzadenovec) features an innovative design based on the company's proprietary high-capacity adenovirus vector platform. It is currently being studied as a potential treatment for the underlying biomechanical and inflammatory processes that lead to 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 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.

Given the promising Phase 1 results, Phase 2 of the two-part multicenter ASCEND study for PCRX-201 is underway. To learn more about PCRX-201 and the company's clinical development program, please visit www.Pacira.com

About the High-capacity Adenovirus Vector Platform

Pacira's proprietary novel high-capacity adenovirus (HCAAd) 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 HCAAd 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 HCAAd 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 HCAAd platform can be administered locally and have the potential for redosing at appropriate therapeutic 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 HCAAd platform are expected to have a commercially attractive and viable cost of goods profile.

Beyond PCRX-201, the company is evaluating several other HCAAd product candidates.

About Pacira

Pacira delivers innovative, non-opioid pain therapies to transform the lives of patients. Pacira has two 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 acetate extended-release injectable suspension), an extended-release, intra-articular injection indicated for the management of osteoarthritis knee pain. The company is also advancing a pipeline of clinical-stage assets for musculoskeletal pain and adjacencies. Its most advanced product candidate, PCRX-201 (enenkinragene inzaadenovect), is a novel locally administered gene therapy, is in Phase 2 clinical development for osteoarthritis of the knee. 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: the ability to realize the anticipated benefits of the divestiture of Iovera®; '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, 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 those 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 acquired businesses and/or assets 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; risks associated with divestitures; 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 and ZILRETTA; the rate and degree of market acceptance of EXPAREL and ZILRETTA; the size and growth of the potential markets for EXPAREL and ZILRETTA and our ability to serve those markets; our plans to expand the use of EXPAREL and ZILRETTA to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL, ZILRETTA and any of our other product candidates, including, but not limited to, PCRX-201 and PCRX-2002; the commercial success of EXPAREL and ZILRETTA; 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 high-capacity adenovirus ("HCAAd") vector platform; the approval of the commercialization of our products in other jurisdictions (by either us or our partners); clinical trials in support of an existing or potential HCAAd-based product candidate; 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; 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 (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 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.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in the "Risk Factors" of our most recent Annual Report on Form 10-K and in other filings that we periodically make with the SEC.

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