



Pacira BioSciences Advances PCRX-201 Development Program with Successful Transition to Scalable Commercial Manufacturing Process

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— First patient enrolled in Part B of Phase 2 ASCEND study enabled by availability of drug product from new manufacturing process —

— Topline data from Part A of Phase 2 ASCEND study remains on track for end of year —

BRISBANE, Calif., July 27, 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 that it has successfully transitioned PCRX-201 (enekinragene inzadenovec), its investigational locally administered gene therapy for osteoarthritis of the knee, to a U.S.-based scalable commercial manufacturing process intended to support future registrational development and commercialization. With drug product from the new manufacturing process now available, the first patient has been enrolled in Part B of the Phase 2 ASCEND study. Enrollment in Part A of ASCEND concluded in June, with topline data expected by the end of 2026.

This milestone supports Pacira's 5x30 growth strategy by advancing one of the company's most promising pipeline programs while further demonstrating the scalability of the proprietary high-capacity adenovirus (HCAd) platform. Together with PCRX-201's Regenerative Medicine Advanced Therapy (RMAT) designation and encouraging Phase 1 results, the manufacturing transition further supports the program's progression toward late-stage development. Importantly, the manufacturing transition was completed without delaying the ongoing Phase 2 ASCEND program.

"Successfully incorporating our intended commercial manufacturing process into our Phase 2 ASCEND study represents an important milestone for the PCRX-201 development program and a testament to the clinical development and manufacturing capabilities of our team," said Frank D. Lee, chief executive officer of Pacira BioSciences. "By generating controlled clinical data with product manufactured using our new process we expect to utilize in later-stage development and commercialization, we are reducing development risk, advancing operational readiness, and strengthening the foundation for potential future registrational studies."

"Advancing Part B of the ASCEND study is an important step in evaluating the potential of this investigational gene therapy for patients living with osteoarthritis of the knee," said Jonathan Slonin, MD, MBA, chief medical officer of Pacira BioSciences. "This milestone reflects years of rigorous scientific and clinical work, including the foundational collaboration with the Brendan Lee Lab at Baylor College of Medicine, whose expertise helped inform the development of this locally administered gene therapy approach."

About the ASCEND Study

The two-part, multicenter ASCEND study will involve approximately 135 patients between the ages of 45-80 years old with painful OA of the knee and a Kellgren-Lawrence (K-L) Grade of 2, 3 or 4. The study is evaluating 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 and stratified by K-L Grade, a semiquantitative method for evaluating the severity of OA on a scale of 0-4. 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 of the study randomized 49 patients, and Part B will randomize approximately 90 patients. The study's 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 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 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 a pipeline of clinical-stage assets for musculoskeletal pain and adjacencies. Its most advanced product candidate, PCRX-201 (enekinragene inzadenovec), is a novel locally administered gene therapy 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 "believes," "anticipates," "plans," "estimates," "expects," "intends," "may," "will," "would," "could," "can" 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 anticipated consummation of the divestiture of iovera® to Zimmer Biomet Holdings, Inc., or Zimmer Biomet, and the timing and benefits thereof; the ability to realize the anticipated benefits of the divestiture of iovera®; Zimmer Biomet's ability to unlock the full potential 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, 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 but not limited to 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 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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