Pacira Announces 104-Week Safety and Efficacy Data Following Local Administration of PCRX-201 for Moderate to Severe Osteoarthritis of the Knee

November 14, 2024

-- Poster to be presented at ACR Convergence annual meeting --

PARSIPPANY, N.J., Nov. 14, 2024 (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 new data demonstrating its gene therapy for osteoarthritis candidate, PCRX-201 (enekinragene inzadenovec), provided sustained improvements in knee pain, stiffness, and function to 104 weeks following local administration, with a well-tolerated safety profile. The data, which indicate a potential for sustained clinical efficacy in patients with moderate to severe osteoarthritis of the knee (OAK), will be presented during a poster session at the American College of Rheumatology's annual ACR Convergence meeting on Sunday, November 17 from 10:30 am – 12:30 pm EST.

"The results of this large phase 1 study demonstrate durable pain relief across all levels of disease severity for at least 2 years following a single injection. This is promising, considering traditional pain management interventions provide an average of three to six months of effect," said Stanley Cohen, MD, a board-certified rheumatologist and Co-Medical Director of the Metroplex Clinical Research Center in Dallas, TX, who was lead investigator in this trial and primary author on the poster presentation. "Unlike other treatments that temporarily alleviate symptoms, PCRX-201 addresses a root cause of osteoarthritis knee pain—inflammation—to help control patients' pain for years rather than months."

The new data is derived from an open-label, phase 1 trial investigating the safety and efficacy of PCRX-201 administered via ultrasound-guided intraarticular injection in 72 patients with OAK graded at 2, 3, or 4 on the Kellgren-Lawrence scale, a semiquantitative method for evaluating the severity of osteoarthritis on a scale of 0-4.

Participants were broken into two cohorts. The first cohort received one of three doses of PCRX-201. The second cohort received concurrent pretreatment with an intraarticular corticosteroid (methylprednisolone 40 mg), a technique common in gene therapy dosing to improve tolerability and gene transfer.

Pain and function benefits were observed at all doses and across both cohorts over the full 104 weeks studied, with patients in the second cohort achieving greater pain reduction and fewer adverse events (AEs). Additional results in the pretreated cohort, across all doses, include:

- **48%-65% improvement in pain** from baseline, as measured by the Western Ontario and McMaster Universities Arthritis Index-A (WOMAC-A)
- **53%-72% improvement in stiffness** from baseline, as measured by WOMAC-B
    - **Improvements in function from baseline**, as measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) Activities of Daily Living (ADL) scale, that were similar to improvements in WOMAC-A and WOMAC-B
- **By 16 weeks more than 70% of participants** achieved greater than 50% reductions from baseline pain.

No serious treatment-emergent AEs related to the treatment or procedure were reported regardless of steroid pretreatment or dose level administered. Treatment-related joint effusions (swelling) were the most common AE, occurring in 36% of patients who received steroid pretreatment vs 61% of patients who were not pretreated. The majority of effusions were mild to moderate in severity and resolved in a median of 33 days among patients in the pretreated group.

"We look forward to continuing to advance the clinical investigation of PCRX-201 following these promising results, with a Phase 2, double-blind, active-controlled study planned for 2025," said Frank D. Lee, chief executive officer of Pacira BioSciences. "Unlike traditional gene therapies, which are administered systemically and have primarily been limited to the treatment of rare diseases, we believe PCRX-201 holds the broad potential to provide a long-term pain management solution for the 14 million U.S. patients suffering from the negative impacts of osteoarthritis of the knee. With a local administration that delivers relief directly to the source—the knee joint capsule—PCRX-201 is on the leading edge of what could be possible for gene therapies and offers patients the hope for a long-lasting pain management solution that improves their ability to comfortably engage in activities of daily living, like climbing stairs and exercising."

PCRX-201 is a locally administered gene therapy, designed to produce interleukin-1 receptor antagonist (IL-1Ra), a naturally occurring, anti-inflammatory protein with a proven mechanism of action that reduces interleukin-1 (IL-1) signaling, a known factor in the development and progression of osteoarthritis of the knee. Unlike systemically administered gene therapies, PCRX-201 delivers the medicine where it matters to reduce pain and disability and potentially slow structural progression at the site of the disease. PCRX-201 uses 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 IL-1Ra expression once inflammation is quelled.

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.

About Pacira BioSciences
Pacira BioSciences 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, interscalene brachial plexus nerve block in adults, sciatic nerve block in the popliteal fossa in adults, and adductor canal block in adults 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. The company is also advancing the development of PCRX-201, 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 our future outlook, our intellectual property and patent terms, our growth and future operating results and trends, our strategy, plans, objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, including our plans with respect to the repayment of our indebtedness, anticipated product portfolio, development programs, development of products, strategic alliances, plans with respect to the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act 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 those indicated by such forward-looking statements as a result of various important factors, including risks relating to, among others: the integration of our new chief executive officer; risks associated with acquisitions, such as the risk that the acquired 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 U.S. economic conditions (including inflation and rising interest rates), and our business, including our revenues, financial condition, cash flow 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 and iovera°; the commercial success of EXPAREL, ZILRETTA and iovera°; the related timing and success of U.S. 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 ability to successfully integrate any future acquisitions into our existing business; 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.

Investor Contact: Susan Mesco, (973) 451-4030 susan.mesco@pacira.com Media Contact: Sara Marino, (973) 248-7005 Sara.marino@pacira.com