Pacira BioSciences Announces PCRX-201 Granted Regenerative Medicine Advance Therapy (RMAT) Designation for the Treatment of Osteoarthritis of the Knee

March 13, 2024

-- PCRX-201 is the first gene therapy product candidate to receive RMAT designation for osteoarthritis --

-- Designation supported by encouraging preliminary data from 72-patient Phase 1 study --

-- 52-Week Data Accepted for Presentation at OARSI 2024 and 104-week data to be submitted for presentation later this year --

TAMPA, Fla., March 13, 2024 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to PCRX-201 (enekinragene inzadenovec), the company's novel, intra-articular helper-dependent adenovirus (HDAd) gene therapy product candidate that codes for interleukin-1 receptor antagonist (IL-1Ra), for the treatment of osteoarthritis of the knee.

"We are honored to receive FDA's first-ever RMAT designation for a gene therapy product candidate in osteoarthritis," said Frank D. Lee, chief executive officer of Pacira BioSciences, Inc. "We continue to be encouraged by the preliminary clinical findings supporting PCRX-201 as a potential disease-modifying therapy for osteoarthritis, and we look forward to presenting additional follow-up data later this year."

The company's RMAT application was supported by the preliminary safety and efficacy findings from a Phase 1 open-label, proof-of-concept, single ascending dose trial that enrolled 72 patients in two three-dose cohorts: a co-administered intra-articular steroid cohort and a cohort that did not receive a steroid. PCRX-201 was well tolerated, with efficacy observed through at least 52 weeks at all doses and cohorts. The highest level of efficacy was achieved in the co-administered steroid group, which showed a greater percentage of patients with at least a 50% improvement in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and stiffness scores, as well as a meaningful improvement in (Knee Injury and Osteoarthritis Outcomes Score) KOOS functional assessment. Preliminary 36-week data were presented at the Osteoarthritis Research Society International (OARSI) 2023 World Congress, the premier annual international forum in osteoarthritis research and treatment. The 52-week data have been accepted for presentation at OARSI 2024 taking place in Vienna, Austria in April 2024 and the company expects to present 104-week efficacy and safety data later this year.

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the development and review processes for promising therapies, including genetic therapies, that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the drug or therapy has the potential to address an unmet medical need.

RMAT designation provides the benefits of intensive FDA guidance on efficient drug development, including the ability for early interactions with 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 PCRX-201

PCRX-201 was acquired from GQ Bio Therapeutics GmbH, a privately held biopharmaceutical company headquartered in Hamburg, Germany. GQ Bio's product candidates are next-generation gene transfer vehicles. These gene therapy vectors are highly efficient in entering joint cells to confer multi-year clinical benefit. In PCRX-201, the high-capacity adenoviral gene therapy vector codes for the expression of IL-1Ra, a cytokine inhibitor that plays a central role in blocking inflammation and catabolic processes that are associated with pain and disease progression in osteoarthritis. Its unique design includes an inducible promoter so that, only in the presence of inflammation signaling, the vector turns joint cells into factories to produce sustained therapeutic levels of IL-1Ra to manage pain and mitigate osteoarthritis-related joint damage while remaining localized to the joint space.

About Pacira

Pacira BioSciences, Inc. (Nasdaq: PCRX) is committed to providing a non-opioid option to as many patients as possible to redefine the role of opioids as rescue therapy only. 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 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. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, 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 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, patent terms, development of products, strategic alliances and intellectual property 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; 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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