Pacira Awarded New U.S. Patent Covering EXPAREL Composition

December 03, 2024

-- First in new family of EXPAREL patents --

-- Expands EXPAREL intellectual property and provides protection into 2044 --

PARSIPPANY, N.J., Dec. 03, 2024 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in the delivery of innovative, non-opioid pain therapies, today announced the receipt of U.S. Patent No. 12,156,940 (the '940 patent) from the U.S. Patent and Trademark Office (the U.S. PTO). The '940 patent, entitled "Manufacturing of Bupivacaine Multivesicular Liposomes" protects the chemical composition of EXPAREL ® (bupivacaine liposome injectable suspension). This patent is the first patent from a new family of patents related to EXPAREL produced by the company's enhanced large-scale manufacturing process in San Diego, which received approval from the U.S. Food and Drug Administration in February 2024. The company expects the '940 patent to provide protection into July 2044.

"This new patent highlights our commitment to building a broad portfolio of intellectual property to protect our EXPAREL franchise by expanding its patent life into 2044," said Frank D. Lee, chief executive officer of Pacira BioSciences. "This patent, the first of a new family of patents, underscores Pacira's deep manufacturing expertise and the team's commitment to innovation. We firmly believe we have a strong portfolio of intellectual property and the EXPAREL franchise is well protected on multiple levels."

Pacira will submit the '940 patent for listing in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). Patents that are eligible for Orange Book listing are those that have claims covering the active ingredient, the drug product (formulation and composition) or the approved method of use. The company continues to prosecute patent applications and anticipates additional patents are forthcoming.

Commitment to Protecting EXPAREL Franchise

With the issuance of the '940 patent, the company intends to file a patent infringement lawsuit against Jiangsu Hengrui Pharmaceuticals Co. LTD., and its U.S. distributor, Fresenius Kabi USA, LLC.

A separate lawsuit is advancing against eVenus Pharmaceutical Laboratories, Inc., its China-based parent company, Jiangsu Hengrui, and Fresenius for infringement of U.S. Patent No. 11,819,574 (the '574 patent) in the U.S. District Court for the District of New Jersey. Pacira is also pursuing an appellate review at the Federal Circuit for the New Jersey Court's finding that the company's U.S. Patent No. 11,033,495 (the '495 patent) is not valid. To be successful commercially, eVenus, Jiangsu Hengrui, and Fresenius will have to overcome each of Pacira's patents.

Expansion of Erucic Acid Family of Patents

The U.S. PTO recently issued U.S. Patent Nos. 12,151,024 (the '024 patent) and 12,144,890 (the '890 patent). The '024 and '890 patents belong to the '574 and '495 family of patents and are listed in the Orange Book with an expiration date of January 21, 2041.

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 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.

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