



Pacira BioSciences Announces Settlement of U.S. Patent Litigation for EXPAREL

April 07, 2025

-- Fresenius Kabi licensed to sell volume-limited amounts of generic bupivacaine liposome injectable suspension in the U.S. no earlier than a confidential date in 2030 --

-- Fresenius also licensed to sell generic bupivacaine liposome injectable suspension in the U.S. without volume limitations beginning in 2039 --

BRISBANE, Calif., April 07, 2025 (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 settled its litigations with Fresenius Kabi USA, LLC (Fresenius), Jiangsu Hengrui Pharmaceuticals Co., Ltd., and eVenus Pharmaceuticals Laboratories, Inc. related to patents for EXPAREL® (bupivacaine liposome injectable suspension).

As part of the settlement, the parties will file Consent Judgments with the United States Court of Appeals for the Federal Circuit and the United States District Courts for the District of New Jersey and the Northern District of Illinois that enjoin Fresenius from marketing generic bupivacaine liposome injectable suspension before the expiration of the patents-in-suit, except as provided for in the settlement described below.

In settlement of all outstanding claims in the litigations, Pacira has agreed to provide Fresenius with a license to Pacira's patents required to manufacture and sell certain volume-limited amounts of generic bupivacaine liposome injectable suspension in the United States beginning on a confidential date that is sometime in early 2030. The license will permit entry of generic bupivacaine liposome injectable suspension before the July 2, 2044 expiration date of the last-to-expire of Pacira's Orange Book-listed patents for EXPAREL.

While the agreed-upon volume-limited percentages are confidential, they begin at a high-single-digit percentage of the total volumes distributed in the U.S. market and increase gradually in each 12-month period following the volume-limited entry date until reaching a percentage in the low thirties in 2033 and increasing modestly in each of the next two 12-month periods before reaching a maximum percentage in the high thirties of the total volumes distributed in the U.S. for the final three years of the agreement. In addition, Pacira has agreed to provide Fresenius with a license to Pacira's patents required to manufacture and sell an unlimited quantity of generic bupivacaine liposome injectable suspension in the U.S. beginning no earlier than 2039.

"We remain confident in our EXPAREL intellectual property portfolio and believe this settlement agreement appropriately recognizes the strength of our patents and provides clarity around EXPAREL exclusivity," said Frank D. Lee, chief executive officer of Pacira. "With the litigation resolved, we look forward to focusing on advancing our 5x30 strategy and building upon our leadership position in musculoskeletal pain and adjacencies by developing new treatments that address the significant unmet needs of millions of Americans living with chronic pain."

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®, 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 "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 settlement described herein, '5x30', our growth and business strategy; 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 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 failure to realize the anticipated benefits and synergies from the acquisition of GQ Bio Therapeutics GmbH; 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 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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