



## **Pacira Receives Positive CHMP Opinion for EXPAREL® for the Treatment of Postsurgical Pain in Children Aged 6 or Older**

September 20, 2022

**-- European Commission decision on the Marketing Authorization Application (MAA) expected in November 2022 --**

TAMPA, Fla., Sept. 20, 2022 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NASDAQ: PCRX), the leading global provider of non-opioid pain management options, announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for an expanded indication of EXPAREL to include use in children aged 6 years and older as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds.

"This positive CHMP opinion brings Pacira one step closer to realizing another milestone on our corporate mission to provide an opioid alternative to as many patients as possible," said Dave Stack, Chief Executive Officer and Chairman of Pacira BioSciences. "We look forward to the potential to offer a non-opioid option to children across Europe, while giving clinicians another tool to help optimize clinical outcomes."

The European Commission approval was based on the results of the Phase 3 PLAY study of EXPAREL infiltration in pediatric patients undergoing spinal or cardiac surgeries. Overall findings were consistent with the pharmacokinetic and safety profiles for adult patients with no safety concerns identified at a dose of 4 mg/kg. The PLAY study enrolled 98 patients to evaluate safety and the pharmacokinetics of EXPAREL for two patient groups: patients aged 12 to less than 17 years and patients aged 6 to less than 12 years.

The European Commission decision is applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein. The data is still under review in the United Kingdom. EXPAREL was initially approved by the European Commission in November 2020 as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults.

### **About Pacira BioSciences**

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. The company is also developing innovative interventions to address debilitating conditions involving the sympathetic nervous system, such as cardiac electrical storm, chronic pain, and spasticity. 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 acetanide 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](http://www.pacira.com).

### **About EXPAREL®**

EXPAREL (bupivacaine liposome injectable suspension) is indicated in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia, and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. Since its launch, EXPAREL has been used in over nine million patients. EXPAREL utilizes the company's proprietary multivesicular liposomal drug delivery technology composed of a honeycomb of numerous, non-concentric, internal aqueous chambers containing bupivacaine. After injection, bupivacaine is released over time, as the lipid membranes are absorbed, prolonging the duration of action. EXPAREL is the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. A single dose of EXPAREL provides significant reductions in cumulative pain scores with up to a 78 percent decrease in opioid consumption; the clinical benefit of the opioid reduction was not demonstrated. Additional information is available at [www.EXPAREL.com](http://www.EXPAREL.com).

### **Important Safety Information about EXPAREL for Patients**

EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies in adults where EXPAREL was injected into a wound, the most common side effects were nausea, constipation, and vomiting. In studies in adults where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. In the study where EXPAREL was given to children, the most common side effects were nausea, vomiting, constipation, low blood pressure, low number of red blood cells, muscle twitching, blurred vision, itching, and rapid heartbeat. EXPAREL can cause a temporary loss of feeling and/or loss of muscle movement. How much and how long the loss of feeling and/or muscle movement depends on where and how much of EXPAREL was injected and may last for up to 5 days. EXPAREL is not recommended to be used in patients younger than 6 years old for injection into the wound, for patients younger than 18 years old for injection near a nerve, and/or in pregnant women. Tell your health care provider if you or your child has liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from the body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL can affect the nervous system and the cardiovascular system; may cause an allergic reaction; may cause damage if injected into the joints; and can cause a rare blood disorder.

### **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 the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements related to the acquisition of Flexion Therapeutics, Inc. and the costs and benefits thereof, our growth and future operating results and trends, our strategy, plans, objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, anticipated product portfolio, development programs, strategic alliances, patent terms 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: risks associated with acquisitions, such as the risk that the 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; the possibility that if we do not achieve the perceived benefits of the Flexion acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of our shares could decline; the impact of the COVID-19 pandemic on elective surgeries, our manufacturing and supply chain, global and United States economic conditions, and our business, including our revenues, financial condition and results of operations; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL, ZILRETTA and iovera® and 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 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 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 construct an additional EXPAREL manufacturing suite in San Diego, California; our ability to successfully complete a ZILRETTA capacity expansion project in Swindon, England; the outcome of any litigation; the ability to successfully integrate Flexion or any future acquisitions into our existing business; the recoverability of our deferred tax assets; and 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. 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. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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