Pacira BioSciences Seeks Court Injunction to Protect Clinical Integrity of EXPAREL in the Face of Scientifically Flawed and Misleading Information Published in Anesthesiology

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Complaint challenges the American Society of Anesthesiologists for promoting biased, analytically misguided studies in its journal, on its website, and through CME activity

PARSIPPANY, N.J., April 14, 2021 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX) today filed a lawsuit against the American Society of Anesthesiologists (ASA) and various other defendants seeking pecuniary damages and the retraction of three articles that create the false and misleading impression that EXPAREL® (bupivacaine liposome injectable suspension) is not an effective analgesic. The articles, included in its official medical journal, *Anesthesiology*, were published in print and on the ASA website under the summary headline, "Liposomal Bupivacaine Is Not Superior to Standard Local Anesthetics." This headline appeared on the cover of the publication's February 2021 print issue.

The Complaint establishes that the ASA published articles that were not only scientifically unsound, but that also failed to disclose that certain authors were accepting payments from competing pharmaceutical or drug device manufacturers. Inaccurate or incomplete financial disclosures are a violation of ethical standards established by the medical and scientific research communities and raise serious questions regarding the objectivity of the published work.

"EXPAREL has been used in more than 8 million U.S. patients and is backed by scores of published studies that demonstrate safe and effective, long-lasting pain control, including decreased opioid requirements, improved patient outcomes, and the migration of surgical cases to outpatient sites of care," said Dave Stack, Chief Executive Officer and Chairman of Pacira. "While pain trials are notoriously difficult to execute, and mixed evidence can be identified for all studied analgesics, the three *Anesthesiology* articles overwhelmingly overlook the positive body of literature that exists for EXPAREL."

Mr. Stack continued, "We cannot allow this misrepresentation of the clinical effectiveness of EXPAREL to continue to be promoted in the journal and on the website of the American Society of Anesthesiologists, at the risk of confusing stakeholders along the patient care continuum about the value of EXPAREL compared to current treatment modalities. Requests for discussion with the ASA and the editor of *Anesthesiology* were repeatedly dismissed. This left us with no choice but to take legal action in order to ensure this false and misleading information is not inappropriately cited as an accurate reference in other scientific manuscripts and cannot be used to limit access to patients and providers who require low- and no-opioid care."

EXPAREL is the only long-acting local analgesic approved for infiltration, field block and interscalene brachial plexus nerve block in adult patients, and the FDA recently approved it as the first and only long-acting local analgesic approved with established safety for local infiltration in children aged six and over.

The product is separately reimbursed by the Centers for Medicaid and Medicare Services when used to treat Medicare surgical patients in the ambulatory surgery center environment, a policy that most major commercial payers have also adopted.

Background on the Complaint
Pacira seeks to address three issues in its complaint:

1. **The published meta-analysis is deeply flawed:** Meta-analyses should only be conducted when the studies included are similar in terms of procedure type, patient population, and outcomes evaluated—this analysis combined a variety of administration techniques which included a variety of off-label uses with the largest subgroup being penile block for penile prothesis implant procedures, for which Pacira does not promote or provide educational support, and employed widely rejected methodologies. When proper methodologies are applied, the results are favorable to EXPAREL
2. **Key financial and commercial conflicts were not disclosed:** Financial and commercial disclosures allow transparency related to any potential bias in the publication process. Three authors and the editor-in-chief failed to disclose previous or current and ongoing relationships—either between themselves or their employers—with manufacturers who make products that could or would compete with EXPAREL, including over $14 million in research funding involving competing treatment modalities.
3. **Educational tools on the ASA website—including a continuing medical education (CME) course and a podcast—restate as a fact, the flawed conclusions of the *Anesthesiology* articles:** Guidelines clearly state the importance of avoiding any commercial bias in CME materials in order to ensure the highest level of scientific credibility.

Pacira seeks a preliminary injunction requiring the ASA to remove materials containing these misleading statements from its website in order to prevent the continued spread of misinformation. Pacira will also file a motion for expedited discovery to enable it to obtain crucial documents exposing the ASA's unconscionable conflicts of interest and anti-EXPAREL bias.

The company's motion for a preliminary injunction, which will be filed subsequent to the complaint, will be supported by several key declarants and experts, including William Rayburn, MD, former president of the Society for Academic Continuing Medical Education and former Associate Dean of Continuing Medical Education and Professional Development at the University of New Mexico School of Medicine, and Thomas Trikalinos, MD, PhD, Director of the Center for Evidence Synthesis in Health at Brown University.

The case, *Pacira v. American Society of Anesthesiologists*, was filed in the United States District Court for the District of New Jersey. Pacira is represented in this lawsuit by Latham & Watkins LLP. Copies of the pleadings and declarations are available at www.pacira.com/legal/ASAComplaint.

About Pacira BioSciences

Pacira BioSciences, Inc. (Nasdaq: PCRX) is the industry leader in its commitment to non-opioid pain management and regenerative health solutions to improve patients' journeys along the neural pain pathway. The company's long-acting local analgesic, EXPAREL ® (bupivacaine liposome injectable suspension) was commercially launched in the United States in April 2012. EXPAREL utilizes DepoFoam®, a unique and proprietary product delivery technology that encapsulates drugs without altering their molecular structure, and releases them over a desired period of time. In April 2019, Pacira acquired the iovera° system, a handheld cryoanalgesia device used to deliver precise, controlled doses of cold temperature only to targeted nerves. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit 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. The product combines bupivacaine with DepoFoam®, a proven product delivery technology that delivers medication over a desired time period. EXPAREL represents the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing 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.

Important Safety Information

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 the company's future expectations, plans, 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: the success of the company's sales and manufacturing efforts in support of the commercialization of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and the company's ability to serve those markets; the company's plans to expand the use of EXPAREL to additional indications and opportunities, and the timing and success of any related clinical trials; the ability to realize anticipated benefits and synergies from the acquisition of MyoScience; the ability to successfully integrate iovera° and any other future acquisitions into the company's existing business; the commercial success of iovera° and other factors discussed in the "Risk Factors" of the company's most recent Annual Report on Form 10-K and in other filings that the company periodically makes with the SEC. In addition, the forward-looking statements included in this press release represent the company's 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 the company anticipates that subsequent events and developments will cause its views to change. However, while the company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date of this press release.

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