Pacira Files Lawsuit Against eVenus for Patent Infringement

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TAMPA, Fla., Nov. 08, 2021 (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 it has filed a lawsuit in the United States District Court for the District of New Jersey against eVenus Pharmaceutical Laboratories, Inc. for patent infringement of U.S. Patent Number 11,033,495. The '495 patent is related to EXPAREL® (bupivacaine liposome injectable suspension) and has an expiration date of January 22, 2041. The complaint is seeking an injunction to prevent the infringing manufacture, use, and sale of a potential generic product described in an Abbreviated New Drug Application (ANDA) that eVenus filed with the U.S. Food and Drug Administration in August 2021. The filing of the lawsuit triggered a 30-month stay of final approval of eVenus' ANDA under the Hatch Waxman Act.

The '495 patent was listed in the U.S. Food and Drug Administration (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) on July 30, 2021. This patent marks the first deliverable from the company's comprehensive patent strategy. eVenus's Paragraph IV challenge does not account for several additional Pacira patents that are forthcoming, including another application that recently received an Issue Notification from the U.S. Patent and Trademark Office (USPTO). After the USPTO issues this patent, Pacira will submit it for listing in the Orange Book. Once listed, FDA guidelines require the amendment of an existing ANDA application to provide an additional appropriate patent certification or statement to the newly listed patent.

EXPAREL utilizes the company's unique and proprietary multivesicular liposome delivery technology that encapsulates drugs without altering their molecular structure and releases them over a sustained period. In February 2018, the FDA published rigorous guidance for proving bioequivalence to multivesicular liposomal bupivacaine. Matching comparative characteristics must be conducted on at least three batches of an ANDA product with at least one batch manufactured at commercial scale and include liposome composition, internal aqueous environment of the liposome, and *in vitro* drug release rates. Unlike traditional liposomes, multivesicular liposomes consist of a non-lamellar honeycomb structure.

Pacira intends to vigorously defend its intellectual property rights relating to EXPAREL.

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 the company's unique and proprietary multivesicular liposome 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 multivesicular liposomes, 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 multivesicular liposome 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 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.

About iovera°®

The iovera° system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. In one study, the majority of the patients suffering from osteoarthritis of the knee experienced pain and system relief beyond 150 days. The iovera° system's "1×90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. The iovera° system is not indicated for treatment of central nervous system tissue.

Important Safety Information

The iovera° system is contraindicated for use in patients with the following: Cryoglobulinemia; Paroxysmal cold hemoglobinuria; cold urticaria; Raynaud's disease; open and/or infected wounds at or near the treatment line. Potential complications: As with any surgical treatment that uses needle-based therapy, there is potential for temporary site-specific reactions, including but not limited to: bruising (ecchymosis); swelling (edema); inflammation and/or redness (erythema); pain and/or tenderness; altered sensation (localized dysesthesia). Typically, these reactions resolve with no physician intervention. Patients may help the healing process by applying ice packs to the affected sites, and by taking over-the-counter analgesics.

Forward-Looking Statements

Any statements in this press release about the company'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 strength and efficacy of our intellectual property protection, the ultimate eligibility of another product composition patent for Orange Book eligible listing and other statements that are not historical facts. 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 impact of the worldwide COVID-19 (Coronavirus) pandemic and related global economic conditions on our business and results of operations; the success of the company's sales and manufacturing efforts in support of the commercialization of EXPAREL and iovera°; the rate and degree of market acceptance of EXPAREL and iovera°; the size and growth of the potential markets for EXPAREL and iovera° and the company's ability to serve those markets; the company's plans to expand the use of EXPAREL and iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL and iovera°; the ability to successfully integrate any future acquisitions into the company's existing business; the recoverability of our deferred tax assets; 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 Securities and Exchange Commission. 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, except as required by law. 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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