Pacira BioSciences Receives FDA 510k Clearance for New iovera° SmartTip to Manage Chronic Low Back Pain via Long-lasting Medial Branch Nerve Block

January 07, 2025

PARSIPPANY, N.J., Jan. 07, 2025 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in the delivery of innovative, non-opioid pain therapies to transform the lives of patients, announced today that it has received clearance from the U.S. Food & Drug Administration (FDA) to market a new Smart Tip designed to access the medial branch nerves to manage chronic low back pain.

The iovera° system is an innovative, FDA-cleared, drug-free treatment that relieves pain via cryoneurolysis—a process whereby focused cold therapy is applied to a targeted nerve, temporarily interrupting its ability to transmit pain signals. Pain relief is typically experienced immediately after treatment, with the effects lasting for months as the nerve gradually regenerates.

To date, the iovera° portfolio has consisted of either a three-pronged Smart Tip featuring 8.5-mm long 27-gauge needles to treat superficial nerves or a single, 90-mm long, 20-guage Smart Tip ideally suited to treat deeper nerves. It is most commonly used to treat knee pain, but frequently used to manage pain in the hip, shoulder, chest, foot and ankle, and more.

Now, this new, 25-gauge 180-mm Smart Tip will allow for the treatment of deeper nerves, such as the medial branch nerve and is specifically designed so that it can relieve chronic low back pain associated with facet mediated pain. This longer-needle Smart Tip is uniquely designed for use through a cannula or introducer, providing the ability for ice ball formation at deeper peripheral nerves.

Chronic low back pain remains a pervasive health challenge in the United States:

- Back pain is the leading cause of disability nationwide.
- It is also the most common reason for extended work absences.
- Chronic back pain is the number one indication for opioid prescriptions, often leading to dependency and abuse.
- Annually, 28 to 30 million Americans seek treatment for chronic back pain, yet only 2 to 3 million undergo interventional procedures.

With the introduction of this new iovera° Smart Tip, Pacira aims to address these gaps and elevate the standard of care. This FDA-cleared innovation offers a compelling alternative to conventional treatments such as radiofrequency ablation (RFA) ablation, which has substantial limitations. With RFA, patients may not get the effects of pain relief until 1-2 weeks after treatment, further the intense heat can damage surrounding tissue and blood vessels, and tissue damage may lead to painful neuritis (inflammation in the nerves).

A single-center randomized pilot study conducted by Interventional Pain Management and Physical Medicine and Rehabilitation (PM&R) Specialist Martin Ferrillo, DO, of Albany and Saratoga Centers for Pain Management, compared iovera° cryoneurolysis to RFA for facet-mediated chronic back pain.

The findings underscore the significant advantages of the iovera° system:

- Patients treated with iovera° reported pain scores that were more than 2 points lower at 180 and 360 days compared to those treated with RFA on the 0-10 NRS Pain scale.
- At 360 days, patients in the iovera° group showed statistically and clinically significant improvements in functional outcomes, as evidenced by average Oswestry Disability Index (ODI) scores improving from moderate disability to minimal disability.
- More iovera° patients expressed satisfaction with their pain management compared to those receiving RFA.
- No serious adverse events were observed over the course of the study.

“The FDA clearance of this new iovera° Smart Tip is a pivotal step forward, offering patients an innovative, drug-free solution that delivers meaningful and lasting pain relief” said Jonathan Slonin, MD, Chief Medical Officer of Pacira BioSciences. “This achievement reflects our dedication to improving quality of life for the millions of Americans living with chronic back 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 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.

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. When stimulation compatible components are used, the iovera° system can also facilitate targeting nerve location by conducting electrical nerve stimulation from a compatible 3rd party nerve stimulator. The iovera° system is not indicated for treatment of central nervous system tissue.

Important Safety Information

- Do not receive treatment with iovera° if you experience hypersensitivity to cold or have open and/or infected wounds near the treatment site.
- You may experience bruising, swelling, inflammation and/or redness, local pain and/or tenderness, and altered feeling at the site of application.
- In treatment area(s), you may experience damage to the skin, skin darkening or lightening, and dimples in the skin.
- You may experience a temporary loss of your ability to use your muscles normally outside of the treatment area.
- Talk to your doctor before receiving treatment with iovera°.

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.

Investor Contact: Susan Mesco, (973) 451-4030 susan.mesco@pacira.com Media Contact: Sara Marino, (973) 370-5430 sara.marino@pacira.com