Centers for Medicare and Medicaid Services (CMS) Establishes Additional Payment for iovera in Outpatient Settings

November 04, 2024

-- Final CMS rule concludes iovera is a qualifying device for separate payment under the NOPAIN Act --

-- Beginning January 1, 2025, providers can receive additional Medicare payment when they use EXPAREL or iovera° via product-specific reimbursement codes --

PARSIPPANY, N.J., Nov. 04, 2024 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NSDQ: PCRX), the industry leader in the delivery of innovative, non-opioid pain therapies to transform the lives of patients, today announced that the Centers for Medicare and Medicaid Services (CMS) issued its final Medicare Hospital Outpatient Prospective Payment System (OPPS) and Medicare Ambulatory Surgical Center (ASC) Payment System rule for 2025, which implements the Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act that mandated separate Medicare payment for qualifying non-opioid drugs and devices. In the final rule, CMS confirmed that both EXPAREL® (bupivacaine liposome injectable suspension) and iovera° qualify as eligible non-opioid pain management products under the NOPAIN Act. Hospital outpatient departments (HOPDs) and ASCs that use these products will receive additional Medicare reimbursement beginning January 1, 2025.

Congress passed the NOPAIN Act as part of the Consolidated Appropriation Act of 2023 to provide better patient access to non-opioid drugs and devices used to manage pain in the HOPD and ASC settings, by providing additional Medicare reimbursement for qualifying non-opioid items.

“We are pleased to have both EXPAREL and iovera° counted among the eleven qualifying drugs and devices under this important reimbursement policy change to increase patient and provider access to non-opioid options,” said Frank D. Lee, Chief Executive Officer of Pacira. “Having invested significant time and effort toward reimbursement reform that ultimately affords more patients the benefit of receiving non-opioid pain management interventions, we are proud to receive separate payment for not one—but two—of our best-in-class products across ASC and HOPD settings.”

The reimbursement rate for EXPAREL equates to 106% of the average sales price (ASP +6%) in the HOPD and ASC environments using the new product-specific J-code (J0666) beginning January 1, 2025.

The separate reimbursement for iovera° will pay up to an additional $255.85 when providers administer iovera° in ASC and HOPD settings, using a new C-code created for the iovera° system (C9809). This new Medicare payment is provided in addition to the current reimbursement available to HOPDs and ASCs when they perform a procedure with the iovera° system.

To view the final rule in its entirety, visit the Federal Register.

About Pacira BioSciences
Pacira BioSciences 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, interscalene brachial plexus nerve block in adults, sciatic nerve block in the popliteal fossa in adults, and adductor canal block in adults 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 for iovera°
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 site. Potential complications: As with any

surgical treatment that uses needle-based therapy and local analgesia, 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. Do not receive treatment with iovera° if you experience hypersensitivity to cold or have open and/or infected wounds near the treatment site. Patients 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. Very rarely, patients can experience a temporary loss of your ability to use your muscles normally outside of the treatment area.

About EXPAREL®

EXPAREL (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older, and postsurgical regional analgesia via an interscalene brachial plexus block in adults, a sciatic nerve block in the popliteal fossa in adults, and an adductor canal block in adults. The safety and effectiveness of EXPAREL have not been established to produce postsurgical regional analgesia via other nerve blocks besides an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, or an adductor canal block. 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 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 "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.

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