Pacira Receives European Commission Approval for EXPAREL® (bupivacaine liposome injectable suspension) for the Treatment of Postsurgical Pain

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--Approval based on four pivotal studies showing EXPAREL reduced pain scores and opioid use following surgery--

--EXPAREL is the first long-acting non-opioid option for field block and brachial plexus or femoral nerve block approved in Europe--

PARSIPPANY, N.J., Nov. 18, 2020 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (NADSAQ: PCRX), the leading global provider of non-opioid pain management options, today announced that the European Commission has granted marketing authorization for EXPAREL 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.

“We are pleased to see news of the European Commission’s approval of EXPAREL and look forward to the opportunity to bring a safe and effective opioid alternative to surgical patients across Europe,” said Dave Stack, Chief Executive Officer and Chairman of Pacira BioSciences. “Europe has long been at the forefront of enhanced recovery after surgery – or ERAS – models of care. With the European Commission’s broad approval for EXPAREL across a wide variety of surgical settings and administration techniques, we see a well-defined position for EXPAREL to play an integral role in further optimizing postsurgical protocols and accelerating postoperative recovery.”

The European Commission approval was based on the results of four pivotal Phase 3 studies that demonstrated improvements in pain reduction and opioid use. These studies include:

- **Lower Extremity Nerve Block Study:** This study assessed the safety and efficacy of EXPAREL as a femoral nerve block in patients undergoing total knee arthroplasty. Results demonstrated that EXPAREL resulted in a significant reduction in cumulative pain scores over 72 hours compared to placebo. A higher percentage of patients who received EXPAREL were pain-free, consumed fewer opioids and reported higher satisfaction with their pain control compared with placebo.
- **Upper Extremity Nerve Block Study:** This study assessed the safety and efficacy of EXPAREL as an interscalene brachial plexus nerve block in patients undergoing total shoulder arthroplasty or rotator cuff repair. Results demonstrated that EXPAREL significantly improved pain control and reduced opioid consumption through 48 hours compared with placebo and a standardized pain management protocol alone.
- **Hard Tissue Infiltration Study:** This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing bunionectomy. Results demonstrated that EXPAREL significantly reduced pain and opioid consumption compared with placebo over the first 24 hours following surgery than patients administered placebo.
- **Soft Tissue Infiltration Study:** This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing hemorrhoidectomy. Results demonstrated that EXPAREL significantly reduced pain compared to placebo at all time points, including a 30 percent reduction in the cumulative pain scores at 72 hours. Patients who received EXPAREL consumed significantly fewer opioids than patients administered placebo.

The European Commission decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. Commercial planning is underway, with an anticipated launch in the second half of 2021. EXPAREL was initially approved in the United States for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Since its launch, EXPAREL has been used in over seven and a half million patients.

About Pacira BioSciences
Pacira BioSciences, Inc. is the leading provider of non-opioid pain management and regenerative health solutions dedicated to advancing and improving outcomes for health care practitioners and their patients. 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 for single-dose infiltration in adults to produce postsurgical local analgesia and 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 for Patients
EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies where EXPAREL was injected into the wound, the most common side effects were nausea, constipation, and vomiting. In studies where EXPAREL was injected near a nerve, the most common side effects were

nausea, fever, and constipation. EXPAREL is not recommended to be used in patients younger than 18 years old or in pregnant women. Tell your healthcare provider if you have liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from your body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL: can affect your nervous system and your cardiovascular system; may cause an allergic reaction; may cause damage if injected into your joints.

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