Pacira Pharmaceuticals CMO Presents at FDA Advisory Committee Meeting Focused on Assessment of Opioid-Sparing Outcomes in Clinical Trials

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PARSIPPANY, N.J., Nov. 16, 2018 (GLOBE NEWSWIRE) -- Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) today announced that Chief Medical Officer Richard Scranton, M.D., M.P.H., was one of three industry representatives invited to provide insight and perspective during the U.S. Food and Drug Administration's (FDA's) Anesthetic and Analgesic Drug Products Advisory Committee meeting held yesterday, November 15th. The discussion centered on clinical trial design requirements and endpoints needed to demonstrate a clinically meaningful reduction in the use of opioid pain medications (also called "opioid-sparing") when used for acute pain.

During a 20-minute presentation, Dr. Scranton discussed the need to assess a range of clinical and patient-reported outcomes in order to appropriately characterize the clinical benefit of opioid reduction.

In addition to overall decrease in opioid consumption, including opioid-free intervals, Dr. Scranton contended that clinical studies designed to support an opioid-sparing claim should also demonstrate:

- **Adequate pain control** versus the comparator (standard of care) and placebo (opioid) arms for the duration of the study period;
- **Improved functional outcomes**, such as time to ambulation and discharge readiness;
- **Improved patient well-being**, including patient-reported satisfaction scores; and
- **Reduction in opioid-related adverse events**, which can range in severity from nausea and vomiting to urinary retention and respiratory depression and cause a host of negative consequences including delayed return to normal diet and time to mobility that can lengthen hospital stay.

"Yesterday's FDA Advisory Committee meeting was an important step toward advancing our collective goal of understanding and defining the requirements needed to seek important clinical claims related to opioid-sparing and opioid-free analgesia," said Dave Stack, chairman and chief executive officer of Pacira. "We were pleased to add our subject matter insight."

In August, as part of the FDA's ongoing efforts to address the opioid epidemic, Commissioner Scott Gottlieb, M.D. released plans to issue a minimum of four new guidance documents for industry to replace the existing 2014 analgesic guidance document on developing new drugs. One of these documents will set forth recommendations on how sponsors can assess a clinically meaningful reduction in the use of opioid pain medications when used for acute pain.

Key learnings from yesterday's meeting will be considered by the Anesthetic and Analgesic Drug Products Advisory Committee as they develop this updated guidance document.

To access an archived webcast of the meeting, which was held at the FDA White Oak Campus in Silver Spring, Maryland, click here: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm591101.htm

About Pacira
Pacira Pharmaceuticals, Inc. (NASDAQ:PCRX) is a specialty pharmaceutical company dedicated to advancing and improving postsurgical outcomes for acute care practitioners and their patients. The company's flagship product, 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. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit www.pacira.com.

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