Pacira Pharmaceuticals, Inc. Announces FDA Extension of EXPARELâ„¢ PDUFA Target Date by Three Months

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PARSIPPANY, N.J., June 14, 2011 /PRNewswire/ -- Pacira Pharmaceuticals, Inc., (Nasdaq: PCRX [1]), an emerging specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) for EXPAREL™ (Bupivacaine Extended-Release Liposome Injection) by three months. The new PDUFA goal date is October 28, 2011.

The FDA requested additional information from Pacira, which the company has submitted. The FDA determined that this information constituted a major amendment. The agency has the option to extend the PDUFA goal date when a sponsor submits a major amendment to an NDA within three months of the PDUFA goal date to provide the FDA time to complete the review.

About Pacira

Pacira Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company focused on the development, manufacture and commercialization of novel pharmaceutical products, based on its proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. In December 2010, Pacira announced that its New Drug Application (NDA) for EXPAREL, the company's most advanced investigational product candidate, had been accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of October 28, 2011 for the review of the EXPAREL NDA. EXPAREL is a bupivacaine-based product and has completed extensive Phase 3 clinical development for postoperative analgesia by infiltration. EXPAREL consists of bupivacaine encapsulated in DepoFoam, which is designed to address the limitations of widely used medications by enhancing their dosing and/or administration profile. Additional information about Pacira is available at www.pacira.com<
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