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Pfizer Inc. Continues Development Program For Remoxy® (oxycodone) Extended-Release Capsules CII

Tuesday, October 22, 2013 - 04:00am

Pfizer Inc. (NYSE: PFE) announced today that, having achieved technical milestones related to manufacturing, it will continue the development program for Remoxy® (oxycodone) Extended-Release Capsules CII. Following guidance received from the U.S. Food and Drug Administration (FDA) earlier this year, Pfizer will proceed with the additional clinical studies and other actions required to address the Complete Response Letter received in June 2011. These new clinical studies will include, in part, a pivotal bioequivalence study with the modified Remoxy formulation to bridge to the clinical data related to the original Remoxy formulation, and an abuse-potential study with the modified formulation. As previously disclosed, the complete response submission is not expected to occur prior to mid-2015.

Remoxy is an investigational extended-release oral formulation of oxycodone for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Remoxy was initially developed by Pain Therapeutics, Inc. (NASDAQ: PTIE) using DURECT Corporation's (NASDAQ: DRRX) ORADUR® technology, which is designed to discourage common methods of tampering. In 2005, King Pharmaceuticals, Inc. entered into an agreement with Pain Therapeutics, Inc. to develop and commercialize Remoxy. Pain Therapeutics, Inc. filed the initial new drug application (NDA) for Remoxy in June 2008 and received a Complete Response Letter in December 2008. King Pharmaceuticals, Inc. assumed full control of the development of Remoxy in March 2009 and filed a resubmission of the Remoxy NDA in December 2010. Pfizer obtained rights to Remoxy as part of its acquisition of King Pharmaceuticals, Inc. in February 2011.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of October 22, 2013. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about an investigational medicine, Remoxy, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates as well as the possibility of unfavorable clinical trial results; the timing of Pfizer's submission of a response to the June 2011 Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to Remoxy, and whether Pfizer will be able to address to the FDA's satisfaction the issues raised in the Complete Response Letter; whether and when any applications may be filed with regulatory authorities in the U.S. or any other jurisdictions for Remoxy for the management of moderate-to-severe pain, and whether and when regulatory authorities may approve any such applications, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

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