FDA Complete Response Letter Received for REMOXY

Potential Drug Approval Unlikely in Less Than a Year

AUSTIN, Texas, June 27, 2011 (GLOBE NEWSWIRE) -- As previously announced by Pain Therapeutics Inc. (Nasdaq:PTIE), a Complete Response Letter was received on June 23, 2011 from the U.S. Food and Drug Administration (FDA) on the resubmission to the new drug application (NDA) for REMOXY® (oxycodone) Extended-Release Capsules CII.

Based on its review, the FDA has determined that the NDA for REMOXY is not approved.

The FDA’s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during in vitro testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency.

Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA’s Complete Response Letter. In the opinion of Pain Therapeutics, potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

King Pharmaceuticals, Inc. assumed full control of the development of REMOXY in March 2009 and filed a resubmission to the REMOXY NDA on December 23, 2010. Pfizer, Inc. (NYSE:PFE) obtained rights to REMOXY upon the close of its acquisition of King Pharmaceuticals, Inc. on February 28, 2011.

About REMOXY

REMOXY is an investigational extended-release oral formulation of oxycodone for the relief of moderate to severe pain requiring continuous, around-the-clock opioid treatment. It is designed to discourage common methods of tampering. REMOXY was developed by Pain Therapeutics using ORADUR® technology licensed from Durect Corporation (Nasdaq:DRRX).

About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. In addition to REMOXY, we have three drug candidates, including formulations of hydromorphone, hydrocodone and oxymorphone. We are also developing a monoclonal antibody to treat metastatic melanoma and are working on a new treatment for patients with hemophilia, a genetic disorder in which patients are unable to stop bleeding. The FDA has not approved any of our drug candidates for commercial sale.

For more information, please visit www.paintrials.com.

Note Regarding Forward-Looking Statements: This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the “Act”). Pain Therapeutics disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, any statements relating to plans regarding assessment and resolution of the issues set forth in the FDA’s Complete Response Letter concerning REMOXY; estimation of the magnitude of delay with respect to any potential FDA approval with respect to REMOXY; and the potential benefits of REMOXY. Such statements are based on management’s current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing and pursuit of regulatory approval of REMOXY; unexpected adverse side effects or inadequate therapeutic efficacy of REMOXY; potential allocation by Pfizer of inadequate resources for, or potential diversion of resources from, the pursuit of regulatory approval of REMOXY; and the potential for abuse resistant pain medications or other competing products or therapies to be developed by competitors, potential competitors or others. For further information regarding these and other risks related to Pain Therapeutics’ business, investors should consult Pain Therapeutics’ filings with the Securities and Exchange Commission.

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