



Pain Therapeutics, Inc.

December 20, 2016

## **Pain Therapeutics to Discuss REMOXY® ER with FDA**

### **FDA Meeting Set for February 13, 2017**

AUSTIN, Texas, Dec. 20, 2016 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE) today announced it plans to meet with the U.S. Food and Drug Administration (FDA) in person on Monday, February 13, 2017 to discuss the regulatory path forward for REMOXY ER. The Company will provide details of this FDA meeting after receipt of final meeting minutes.

Pain Therapeutics is committed to working with the FDA to gain regulatory approval of REMOXY ER. During its upcoming meeting with the FDA, the Company plans to open a scientific dialogue around the intranasal (snorting) route of abuse. REMOXY ER is a gel formulation that is not suitable for deep inhalation. The Company believes REMOXY ER's thick, sticky, high-viscosity drug mass is a key feature of its abuse deterrent properties, recognizing that no drug can be made abuse-proof.

#### **About REMOXY ER (extended-release oxycodone capsules CII)**

REMOXY ER is a proprietary, abuse-deterrent, extended-release oral formulation of oxycodone. The proposed indication for this drug candidate is for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." We developed REMOXY ER to make oxycodone difficult to abuse yet provide 12 hours of steady pain relief when used appropriately by patients. In particular, REMOXY ER's thick, sticky, high-viscosity gel formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking. REMOXY ER targets the multi-billion marketplace for long-acting oxycodone.

We own exclusive, worldwide commercial rights to REMOXY ER.

#### **About Opioid Abuse**

Opioid drugs such as oxycodone are an important treatment option for patients with severe chronic pain. However, oxycodone abuse and diversion remains a serious, persistent problem. Nearly 19,000 people died from opioid overdose in 2014, according to the National Institute on Drug Abuse. For over a decade, Pain Therapeutics has pioneered Abuse-Deterrent Formulations (ADFs) to help in the fight against prescription drug abuse. ADFs attempt to raise the bar on prescription drug abuse by making it difficult, longer or aversive to tamper with long-acting opioid formulations, recognizing that no drug can be made abuse-proof.

#### **About Pain Therapeutics, Inc.**

We develop proprietary drugs that offer significant improvements to patients and physicians. Our expertise consists of developing new drugs and guiding these through various regulatory and development pathways in preparation for their eventual commercialization. We generally focus our drug development efforts around disorders of the nervous system, such as chronic pain. The FDA has not yet established the safety or efficacy of our drug candidates.

NOTE: REMOXY® ER is a trademark of Pain Therapeutics, Inc.

***Important 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, statements regarding potential discussions with the FDA and the abuse-deterrent properties and potential benefits of REMOXY ER. Such statements are based on management's current expectations but actual results may vary materially due to various factors, many of which are beyond the control of management. Drug development involves substantial risks and uncertainties, including but not limited to those risks and uncertainties relating to successfully completing the activities required to address the issues raised by the FDA in the September 2016 Complete Response Letter for REMOXY ER and the time required to do so, including the time required to reach resolution with the FDA on the scope of the appropriate actions to be undertaken and the possibility that the FDA may raise additional issues in the future that were not raised in the past. In addition, the development of abuse-deterrent drug products is a young and still emerging area of drug development, with regulatory guidance that may be inconsistent, unclear or still in development. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. For further information regarding these and

*other risks related to our business, investors should consult our filings with the U.S. Securities and Exchange Commission.*

For More Information Contact:

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