



Pain Therapeutics, Inc.

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Pain Therapeutics Announces FDA Advisory Committee Meeting for REMOXY®

- August 5th is FDA's Tentative Date for Advisory Committee Meeting -

- No Change to PDUFA Date -

AUSTIN, Texas, May 19, 2016 – Pain Therapeutics, Inc. (Nasdaq: PTIE) announced today that an Advisory Committee of the U.S. Food and Drug Administration (FDA) will review the REMOXY® New Drug Application (NDA), tentatively scheduled for Friday, August 5, 2016. This is intended to be a joint meeting of the FDA's Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee.

“This could be a prime opportunity to showcase the abuse-deterrence and other properties of our lead drug candidate, REMOXY,” said Remi Barbier, President & CEO of Pain Therapeutics. “We look forward to sharing our data with the FDA, Committee members and the general public.”

FDA also advised us that the Prescription Drug User Fee Act (PDUFA) date for the REMOXY NDA, September 25, 2016, is unchanged.

About REMOXY ER (oxycodone capsules CII)

REMOXY ER is a proprietary, abuse-deterrent, extended-release oral formulation oxycodone (CII). 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’s thick, sticky, high viscosity formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking. REMOXY ER targets the \$2.5 billion marketplace for long-acting oxycodone. We own exclusive, worldwide rights to REMOXY ER.

The FDA has not yet established the safety or efficacy of 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® is a trademark of Pain Therapeutics, Inc.

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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 the tentatively scheduled date of the advisory committee meeting, the PDUFA target action date; potential marketing clearance, and any potential timing for regulatory approval, for REMOXY; the proposed indication for REMOXY; and the potential for REMOXY to deter unapproved routes of administration. 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 gaining full regulatory approval for REMOXY; unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates; the uncertainty of patent protection for our intellectual property or trade secrets; unanticipated additional research and development, litigation and other costs; the potential for abuse-deterrent pain medications or other competing products to be developed by competitors; and results of our clinical or pre-clinical studies with REMOXY not supporting further development. 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.

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