# Pain Therapeutics Resubmits New Drug Application for REMOXY® ER, an Abuse-Deterrent, Extended-Release Drug Candidate for the Treatment of Chronic Pain

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AUSTIN, Texas, Feb. 13, 2018 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE) announced today the resubmission to the U.S. Food and Drug Administration (FDA) of a New Drug Application (NDA) for REMOXY® ER, its lead drug candidate. The Company expects a six-month review cycle by FDA.

“This NDA resubmission is a milestone that brings us closer to offering a new and different abuse-deterrent treatment option for people with chronic pain,” said Remi Barbier, President & CEO.

Pain Therapeutics developed REMOXY ER as an abuse-deterrent, extended-release, capsule formulation of oxycodone, a prescription drug for severe pain. REMOXY ER is designed to make oxycodone difficult to abuse yet provide 12 hours of steady pain relief when used appropriately by patients with pain. REMOXY ER has a thick, sticky, high-viscosity capsule formulation designed to deter unapproved routes of drug administration, such as injection, snorting or smoking.

The REMOXY NDA was filed through the 505(b)(2) regulatory pathway. Pain Therapeutics expects to be notified by FDA of a Prescription Drug User Fee Act (PDUFA) date within 60 days.

The development program for REMOXY ER was designed to meet regulatory standards of clinical and non-clinical safety, efficacy and abuse-deterrence, including positive results of a recently completed nasal abuse potential study.

**About Opioid Abuse**
Opioid drugs such as oxycodone are an important treatment option for patients with severe chronic pain. However, oxycodone abuse and diversion remain serious, persistent problems. Opioid overdose deaths exceeded 64,000 in 2016, according to the Center for Disease Control (CDC). 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 more 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. The FDA has not yet established the safety or efficacy of our drug candidates.

***We own commercial rights worldwide to all of our drug assets.***

**Pain Therapeutics’ Pipeline of Drug Assets Includes:**

**REMOXY ™ ER** (extended-release oxycodone CII) – A proprietary abuse-deterrent, twice-daily, oral oxycodone capsules for severe chronic pain.

**FENROCK ™** (transdermal fentanyl patch system) – A proprietary abuse-deterrent skin patch for severe pain. FENROCK is an early-stage program, substantially funded by a research grant award from National Institute on Drug Abuse (NIDA).

**PTI-125** – A proprietary small molecule drug candidate for the treatment of Alzheimer’s disease. PTI-125 is a Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH).

**PTI-125-DX** – A blood-based diagnostic/biomarker to detect Alzheimer’s disease. PTI-125DX is an early-stage program, substantially funded by a research grant award from the NIH.

*Note: REMOXY ™ ER and FENROCK ™ are trademarks of Pain Therapeutics, Inc.*

***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 abuse deterrent properties of REMOXY ER; the potential acceptance by the FDA of the REMOXY NDA; and the potential approval by the FDA of REMOXY ER. 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 development and testing of our drug candidates; 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; and the potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others. 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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