FDA Accepts REMOXY® NDA for Review, Sets PDUFA Date of August 7, 2018

March 1, 2018

AUSTIN, Texas, March 01, 2018 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE) announced today that the U.S. Food and Drug Administration (FDA) has determined that a New Drug Application (NDA) for REMOXY ER, the Company's lead drug candidate, is sufficiently complete to permit a substantive review.

The FDA has set an action date of August 7, 2018 under the Prescription Drug User Fee Act (PDUFA). The Company believes the FDA will hold an open advisory committee meeting to discuss REMOXY ER, although a date has not yet been determined.

"The acceptance of the REMOXY NDA marks another important milestone for Pain Therapeutics," said Remi Barbier, Chairman, President and Chief Executive Officer of Pain Therapeutics. "We are grateful to everyone who has contributed to the development of REMOXY ER over the years. We now look forward to working closely with the FDA during the regulatory review process."

REMOXY ER is an abuse-deterrent, extended-release, capsule formulation of oxycodone (CII), a prescription drug for severe 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. Pain Therapeutics developed REMOXY ER to make oxycodone difficult to abuse yet provide 12 hours of steady pain relief when used appropriately by patients with pain.

Pain Therapeutics filed the REMOXY NDA through the 505(b)(2) regulatory pathway.

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) capsules) – A proprietary, abuse-deterrent, twice-daily, prescription drug for severe chronic pain, currently under regulatory review with a PDUFA target date of August 7, 2018.

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-125DX – 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 timing of the regulatory review 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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