Pain Therapeutics, Inc.

For More Information Contact:
Ruth Araya
Pain Therapeutics, Inc.
IR@paintrials.com
(512) 501-2485

Pain Therapeutics Reports Positive Regulatory Meeting for REMOXY™

- Resubmission of the REMOXY NDA On-Track for Q1 2018 -

AUSTIN, TX – December 18, 2017 – Pain Therapeutics, Inc. (Nasdaq: PTIE), a biopharmaceutical company, today announced that it has successfully concluded a regulatory meeting with the U.S. Food and Drug Administration (FDA) regarding REMOXY, a drug candidate for severe chronic pain. The purpose of this pre-New Drug Application (NDA) meeting was to agree on submission requirements for the REMOXY NDA under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Following a successful conclusion of its meeting with the FDA, Pain Therapeutics intends to resubmit the REMOXY NDA in Q1 2018 with Priority (six-month) Review.

Pain Therapeutics received comments and clarification from the FDA on the acceptability of the data to be included in the REMOXY NDA resubmission, including a recent intranasal study. All questions were clearly and adequately addressed, and summarized in official minutes of the meeting recently issued by the FDA. There are no discrepancies or requests for clarifications following receipt of final meeting minutes.

"We appreciate the FDA's guidance and clarity as we prepare to resubmit the REMOXY NDA," said Remi Barbier, President & CEO of Pain Therapeutics.

-more-

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 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 gel-cap formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking.

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. Drug 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.

Our pipeline of drug assets includes:

REMOXY ER (extended-release oxycodone capsules CII) – Proprietary abuse-deterrent, twice-daily oral oxycodone for severe chronic pain. NDA resubmission planned for Q1 2018.

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

PTI-125 R_x – Proprietary small molecule drug for the treatment of Alzheimer's disease. Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH).

PTI-125 D_x – Blood-based diagnostic/biomarker to detect Alzheimer's disease. 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 planned resubmission of the REMOXY NDA in a timely matter. 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 the ability to resubmit the REMOXY NDA in Q1 2018. 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.*

###