Pain Therapeutics, Inc.

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Pain Therapeutics Reports Positive Top-line Results from Nasal Abuse Potential Study with REMOXY™

- Study Meets Primary Endpoint (p<0.01) -

- REMOXY NDA Remains On-Track for Resubmission in Q1 2018 -

AUSTIN, TX – January 9, 2018 – Pain Therapeutics, Inc. (Nasdaq: PTIE) today announced positive results from a human abuse potential study of its late-stage drug candidate, REMOXY. Study results indicate that in non-dependent, recreational opioid users, nasal administration of REMOXY resulted in significantly lower abuse potential compared to immediate-release (IR) oxycodone. All study subjects reported reduced 'Drug Liking' 'Take Drug Again' and 'Drug High' for REMOXY compared to oxycodone IR. In addition, nasal administration of REMOXY showed lower exposure to oxycodone, lower peak concentrations (C_{max}) and longer time to peak drug concentration (T_{max}) against comparator drugs, suggesting comparatively lower abuse potential.

"We believe these data indicate REMOXY may have limited nasal abuse potential relative to comparator drugs," said Remi Barbier, President & CEO. "We have now successfully completed all studies necessary to resubmit the REMOXY NDA to the FDA, and plan to do so shortly."

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Design & Methods:
This Category 3 nasal abuse potential study was conducted in accordance with the U.S. Food and Drug Administration's (FDA) Guidance for Industry for Abuse-Deterrent Opioids. In a randomized, double-blind, active- and placebo-controlled, single-dose, 4-way crossover study, 38 recreational opioid users with a history of intranasal drug abuse were enrolled in the study. The primary endpoint was 'Drug Liking'. Secondary endpoints included 'Take Drug Again', 'Drug High' and pupil size. There were four treatment arms: REMOXY 40 mg intact; REMOXY 40 mg microwaved; oxycodone IR 40 mg; and placebo. All treatments were administered nasally. Thirty-six subjects completed the study. In addition, the first 20 subjects who completed the double-blind portion of the study also participated in a supplemental FDA Category 2 treatment arm to measure pharmacokinetic parameters following the nasal administration of 40 mg crushed OxyContin®.

Top-Line Study Results:
REMOXY intact and microwaved each demonstrated lower VAS scores on the primary endpoint, Drug Liking ($p<0.01$) versus oxycodone IR, indicating that oxycodone IR was significantly preferred over REMOXY.

On secondary endpoints, REMOXY intact and microwaved each demonstrated lower scores versus oxycodone IR on Take Drug Again, Drug High and pupil size (each $p<0.001$ or better).

On all pharmacokinetic parameters, REMOXY resulted in significantly lower exposure to oxycodone compared to oxycodone IR and crushed OxyContin. Peak oxycodone concentrations (C_{max}) were at least 4-fold lower for REMOXY, microwaved or intact, compared to crushed OxyContin or oxycodone IR. Additionally, time to reach peak oxycodone concentrations was 3.5 times as long for REMOXY compared to crushed OxyContin. The C_{max} values for nasally administered REMOXY, microwaved REMOXY, crushed OxyContin and oxycodone IR were 14.9, 11.9, 63.6 and 64.7 ng/ml, respectively. T_{max} values were 3.1, 3.1, 0.88 and 1.6 hours, respectively.

Finally, the Abuse Quotient ($AQ=C_{max}/T_{max}$) is an essential measurement of abuse potential, with lower scores suggesting comparatively lower potential for abuse.

In this study, AQ measurements were:

<5.0 for REMOXY, intact or microwaved
72.3 for OxyContin crushed
40.4 for oxycodone IR

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 – 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-DX – 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.*

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