Pain Therapeutics, Inc.

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**FOR IMMEDIATE RELEASE**

# Pain Therapeutics Announces Positive Top-Line Results from Human Abuse Potential Study with REMOXY

## REMOXY Meets Both Primary Endpoints with Statistical Significance ($p$<0.0001)

**AUSTIN, TX** – May 12, 2015 – Pain Therapeutics, Inc., (Nasdaq:PTIE) today announced top-line results of an FDA Category 3 Human Abuse Potential Study with REMOXY Extended-Release Capsules CII, its lead drug candidate that is specifically designed to discourage certain common methods of drug tampering and misuse. This study demonstrated with statistical significance ($p$<0.0001) that both intact and chewed REMOXY were less "liked" than immediate-release oxycodone on the two primary endpoints, Drug Liking and Drug High. The Abuse Potential study was conducted in non-dependent, recreational opioid users, as recommended by FDA guidelines.

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"We believe today's results demonstrate abuse-deterrent properties of the REMOXY formulation against a common, and often lethal, form of oral drug abuse", said Nadav Friedmann, PhD, MD., Pain Therapeutics' Chief Medical Officer.

**Study Design**

Pain Therapeutics' former corporate partner for REMOXY had sole responsibility for this FDA Category 3 Human Abuse Potential Study with REMOXY. This study was conducted in accordance with draft FDA Guidance to Industry on Abuse Deterrent Opioids and interactions between the study sponsor and FDA. The study was randomized, double-blind, placebo and active controlled, using a 4-way crossover design in healthy, non-dependent recreational opioid users. Nearly 60 subjects completed this study, with an average age of 27 years. The study's primary objective was to measure the abuse potential of chewed and intact 40mg REMOXY compared to 40mg immediate-release (IR) oxycodone when taken orally. Study subjects were instructed to chew REMOXY capsules vigorously for up to 5 minutes, but none were able to do so in light of REMOXY's high viscosity, texture or taste. Pharmacodynamic measures of the primary endpoints, Drug Liking and Drug High, included use of a standard 0-100 point Visual Analogue Scale (VAS) in the initial two hours post-dose ($AUC_{02h}$), as recommended by FDA to assess a formulation's abuse potential. The sponsor generated study tables for this Abuse Potential Study in December 2014. Pain Therapeutics has not performed an independent analysis of study results.

**Top-line Study Results**

Clinical and statistical highlights include:

- On the co-primary endpoint of Drug Liking, scores were significantly lower for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0001) compared to IR oxycodone.

- On the co-primary endpoint of Drug High, scores were significantly lower for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0001) compared to IR oxycodone.

- On the secondary endpoint of Good Drug Effects, scores were significantly lower for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0001) compared to IR oxycodone.

- On the secondary endpoint of Bad Drug Effects, scores were significantly higher for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0079) compared to IR oxycodone.

- On the secondary endpoint of Pupil Constriction, scores were significantly lower for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0001) compared to IR oxycodone.

- On the secondary endpoint of Nausea, scores were significantly lower for intact REMOXY ($p$<0.0001) and for chewed REMOXY ($p$<0.0143) compared to IR oxycodone.

- On the secondary endpoint of Feel Sick, scores were significantly lower for intact REMOXY ($p$<0.0002) and for chewed REMOXY ($p$<0.039) compared to IR oxycodone.

"We believe results of today's study speak to the clinical and commercial potential of REMOXY", said Remi Barbier, President & CEO of Pain Therapeutics. "REMOXY's high viscosity is intended to deter injection and snorting. We believe this feature, coupled to today's data on oral abuse, contributes to an overall assessment of abuse potential that supports a label-claim for REMOXY".

## CONFERENCE CALL

Pain Therapeutics will host a conference call today, Tuesday, May 12th at 4:30 pm Eastern Time to discuss progress across its portfolio of drug candidates and to respond to questions.

**To participate in the conference call, please dial 1-877-407-4018** prior to the start of the call. Those interested in listening to the conference call live via the internet may do so by visiting the Company's website at www.paintrials.com.

A playback of the call will be available for about 7 days after the live event. To access the playback, please dial 1-877-870-5176 (or international toll-free number 1-858-384-5517) and enter code 1360-9974.

**About REMOXY®**

We own world-wide commercial rights to our lead drug candidate, REMOXY Extended-Release Capsules CII, which is a unique, twice-a-day formulation of oral oxycodone. REMOXY's intended indication is for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time and for which alternative treatments are inadequate. We specifically developed REMOXY to discourage certain common methods of drug tampering and misuse. The REMOXY NDA is supported by multiple clinical trials, including a successful Phase III efficacy program conducted under a Special Protocol Assessment.

**About Pain Therapeutics, Inc.**

Pain Therapeutics, Inc. is a clinical-stage biopharmaceutical company that develops novel drugs. The FDA has not approved our drug candidates for commercial sale. For more information, please visit www.paintrials.com.

***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 potential resubmission of an NDA for REMOXY with the U.S. Food and Drug Administration, or FDA; the sufficiency of data and other information to support the resubmission and approval of an NDA for REMOXY and support for a label claim for abuse deterrence; the scope of target markets for REMOXY; and statements regarding the benefits of REMOXY. 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, difficulties or delays in development, testing, regulatory approval, production and marketing of our drug candidates, including REMOXY; unexpected difficulties or delays in the submission and regulatory review of an NDA for REMOXY; unexpected adverse side-effects or inadequate therapeutic efficacy of our drug candidates and other factors that could slow or prevent, development, product approval or market acceptance (including the risk that current and past results of clinical trials and studies may be found to be insufficient for marketing approval); developments of products or technologies by current or future competitors, and the development of competing or alternative therapies. 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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