Pain Therapeutics Announces Two New Peer-Reviewed Publications for REMOXY

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AUSTIN, Texas, Jan. 07, 2019 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq:PTIE), a clinical-stage drug development company, today announced two new publications for its drug candidate, REMOXY ER (extended-release oxycodone). The studies are published in *Journal of Opioid Management* (Vol 14, No 6), a medical journal whose editorial review board consists of the world's leading experts in the field.

REMOXY is the trade name for a new type of abuse-deterrent, twice-daily capsule gel formulation of oxycodone. REMOXY has physical/chemical properties intended to deter abuse.

"For years, opioid drugs were heavily marketed, inappropriately prescribed and lightly regulated, creating ideal conditions for an opioid epidemic," said Remi Barbier, President & CEO. "Considering the staggering consequences, and the need to balance potential solutions with appropriate access to pain meds, FDA's resistance to REMOXY remains a bit of a mystery. We hope for clarity and answers when we meet with FDA on January 31st to discuss this matter."

The first publication is titled "*Abuse-Deterrent Properties of REMOXY ER, a High-Viscosity Extended-Release Oxycodone Formulation"* and examined the complexity, time and effort needed to extract oxycodone in a lab setting. The publication concludes that REMOXY ER demonstrated robust, meaningful abuse-deterrence relative to OxyContin® ER and Xtampza® ER. Specifically, in lab simulations of injection abuse, OxyContin ER released 65-87% of its oxycodone within 10 minutes. Xtampza ER released 96% of its oxycodone within 5 minutes in a simple heated manipulation and released 50-60% in two unheated manipulations in 10 minutes. In contrast, a minimal (5-30%) amount of oxycodone was extracted from REMOXY ER in heated or unheated manipulations in 10 minutes, even with the use of multistep manipulations. Additionally, in lab simulations of oral abuse, OxyContin ER released 77-85% of its oxycodone in 5 minutes in four common ingestible liquids. In contrast, manipulated REMOXY ER released 2-22% of its oxycodone in 20 minutes in five common ingestible liquids. Failure of the REMOXY formulation occurred only following a complex combination of manipulation techniques and extraction conditions that require advanced lab equipment.

The second publication is titled "*A Nasal Abuse Potential Randomized Clinical Trial of REMOXY ER, a High-Viscosity Extended-Release Oxycodone Formulation*" and examined nasal abuse. The publication concludes that REMOXY ER demonstrated significantly lower nasal abuse potential compared to oxycodone immediate-release or OxyContin ER. Specifically, intranasal REMOXY ER led to four-fold lower peak levels of drug (Cmax); a 57-128% longer time to peak levels of drug (Tmax); a >10-fold lower 'Abuse Quotient'; and lower 'Take Drug Again' scores compared to both OxyContin ER and oxycodone IR.

Data from both studies were included in the New Drug Application (NDA) for REMOXY.

Despite these robust data, and a total of over 8,800 meaningful data points, in August 2018 the Food & Drug Administration (FDA) issued a Complete Response Letter (CRL) for REMOXY. Pain Therapeutics disagrees with recent FDA comments and conclusions regarding REMOXY's abuse-deterrent properties. Based on the totality of scientific evidence, the Company believes:

- Based on a fair, neutral and impartial review of data, there is overwhelming evidence that REMOXY may be less abusable than marketed extended-release oxycodone products;
- When corrected for math errors, material mistakes and misrepresentations made by FDA during a June 2018 Advisory Committee Meeting, REMOXY has properties that may deter against common methods of abuse, such as injection abuse; and
- REMOXY meets all evidentiary standards for drug approval and its proposed indication.

For these and other reasons, Pain Therapeutics has requested a neutral re-examination of its data, further discussion and a fair resolution of this matter. The FDA and the Company have agreed to meet in person on January 31, 2019 to discuss this matter.

About Pain Therapeutics, Inc.
Pain Therapeutics, Inc. is a clinical-stage biopharmaceutical company that develops novel drugs. The FDA has not yet established the safety or efficacy of any of our drug candidates. 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 the potential abuse-deterrent properties of REMOXY and the drug candidate's overall risk/benefit profile . 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 potential regulatory approval of opioid drugs. 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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