Pain Therapeutics Appeals FDA Decision on REMOXY

November 12, 2018

AUSTIN, Texas, Nov. 12, 2018 (GLOBE NEWSWIRE) -- Pain Therapeutics, Inc. (Nasdaq: PTIE), a biopharmaceutical company, today announced that it has petitioned the Food & Drug Administration (FDA) regarding a Complete Response Letter (CRL) for REMOXY issued August 2018. The FDA and the Company have agreed to meet in-person on January 31, 2019 to discuss this matter.

REMOXY is the proposed 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, compared to marketed extended-release oxycodone products.

"The opioid crisis rages on, yet deficiencies of certain prescription opioid drugs are still with us," said Remi Barbier, President & CEO of Pain Therapeutics. "It's a matter of national interest to address these deficiencies head-on, even if it means taking certain opioid drugs off the market. We don't need regulatory runarounds. We need comprehensive and humanitarian solutions to the opioid crisis, including taking steps to stop drug abuse, curb unneeded opioid prescriptions, and reduce the risk of opioid use disorder in pain patients."

Pain Therapeutics disagrees with recent FDA comments and conclusions regarding REMOXY's abuse-deterrent properties and the drug's overall risk/benefit profile. Based on the totality of scientific evidence, the Company believes:

- When corrected for math errors, material mistakes and misrepresentations made by FDA during a June 2018 Advisory Committee, REMOXY has properties that may deter against common methods of abuse, such as injection abuse;
- 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;
- Excipients in REMOXY may pose a lower risk of health problems and possess a higher margin of safety compared to marketed extended-release oxycodone products; and
- REMOXY meets all evidentiary standards for drug approval and its proposed indication.

For these and other reasons, Pain Therapeutics is requesting a neutral re-examination of its data, further discussion and a fair resolution of this matter.

About REMOXY®ER (extended-release oxycodone capsules CII)
REMOXY has a thick, sticky, high viscosity gel formulation that abusers cannot cut, grate or divide into smaller discrete particle sizes. The drug's gel formulation resists syringe-ability, injection, and rapid extraction in ingestible solvents. Unlike certain marketed opioid drugs, REMOXY is *not* formulated with excipients that are implicated as being toxic when injected by abusers.

REMOXY intends to address the public health epidemic around prescription opioids by advancing the science of abuse deterrence, providing an additional treatment option for physicians and patients, and increasing the range of available abuse deterrent technologies.

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.
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.*

For More Information Contact:
Eric Schoen

Chief Financial Officer
Pain Therapeutics, Inc.
IR@paintrials.com
(512) 501-2450

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