



Pain Therapeutics, Inc.

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Pain Therapeutics Announces Results of FDA Advisory Committee Meeting for REMOXY ER

AUSTIN, Texas – June 26, 2018 – Pain Therapeutics, Inc. (Nasdaq: PTIE), a drug development company, today announced that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 14 to 3 against the approval of REMOXY ER (oxycodone extended-release capsules) 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.

REMOXY ER, the Company's lead product candidate, is an abuse-deterrent, extended-release, oral formulation of oxycodone, a widely prescribed opioid medication. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of August 7, 2018 for completion of its review of the New Drug Application (NDA) for REMOXY ER.

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About REMOXY ER (extended-release oxycodone capsules CII)

REMOXY ER is in registration with the US Food and Drug Administration (FDA) as a new type of abuse-deterrent, twice-daily, capsule gel formulation of oral oxycodone, a strong opioid drug. REMOXY ER has physical/chemical properties intended to deter abuse and still provide 12 hours of steady pain relief when properly prescribed by physician and used appropriately by patients.

Studies were extensive. The clinical efficacy of REMOXY ER was established in a Phase III study conducted under a Special Protocol Assessment. In total, over 2,400 subjects were exposed to REMOXY ER in 30 clinical studies. 9,000 unique data points were generated from 11 lab studies. The assessment of REMOXY ER's abuse deterrence is supported by data from FDA Category 1 (lab), Category 2 (pharmacokinetic) and Category 3 (human abuse potential) studies. In addition, in November 2017 the Company and FDA held a pre-NDA meeting to confirm the sufficiency of data included in the REMOXY ER NDA resubmission.

REMOXY ER has a thick, sticky, high viscosity, hydrophobic, gel formulation that abusers cannot cut, grate or divide into smaller discrete particle sizes. The gel formulation resists syringe-ability, injection, and rapid extraction in ingestible solvents. REMOXY ER's high viscosity and adhesive properties also cause it to stick to tools and equipment used for abuse. When exposed to heat, REMOXY ER releases an irritant to the eyes and lungs. REMOXY ER resists dose-dumping when challenged by alcohol and common physical and chemical manipulations.

We are requesting marketing approval of REMOXY ER as an analgesic drug with properties that can be expected to deter against injection, snorting and inhalation/smoking routes of abuse.

REMOXY ER intends to address the public health epidemic related to 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.

Our Pipeline of Drug Assets Includes:

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

PTI-125 – This proprietary, small molecule drug candidate is aimed at the treatment of Alzheimer’s disease. PTI-125 is a Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH).

PTI-125DX – This is a proprietary blood-based test to detect Alzheimer’s disease. PTI-125DX is an early-stage program, substantially funded by a research grant award from the NIH.

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.

NOTE: REMOXY™ ER and FENROCK™ are trademarks of Pain Therapeutics, Inc.

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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 abuse deterrent properties of REMOXY ER; the timing of the regulatory review by the FDA of the REMOXY NDA; the potential approval by the FDA of REMOXY ER; or the therapeutic and commercial value, if any, of our pipeline of drug assets. The Company cautions that forward-looking statements are inherently uncertain. 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 development and testing of our drug candidates; unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates; the uncertainty of patent protection for our intellectual property or trade secrets; unanticipated additional research and development, litigation and other costs; the need to raise additional funding from time-to-time, and the potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release. 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 (SEC), which are available on the SEC's website at www.sec.gov.

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