Pain Therapeutics, Inc.

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Pain Therapeutics Announces Positive Regulatory Guidance for REMOXY™ ER

- Company Will Host Conference Call on Tuesday, March 21st, at 8am Eastern Time -

AUSTIN, Texas – March 20, 2017 – Pain Therapeutics, Inc. (Nasdaq: PTIE) today announced positive regulatory guidance from a recent meeting with the U.S. Food and Drug Administration (FDA) regarding REMOXY (extended-release oxycodone capsules CII), its lead drug candidate. The Company will host a conference call tomorrow morning at 8am EST to discuss REMOXY, and to present a corporate update around partnership discussions and advances to its pipeline.

"In recent weeks we have worked closely with the FDA," said Remi Barbier, President & CEO. "We appreciate their guidance, we understand their new requirements and we believe we're now on track to make expeditious progress toward a resubmission of the REMOXY NDA."

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Pain Therapeutics and the FDA met on February 13, 2017, to discuss REMOXY. During this meeting, agreement was reached on additional studies that are needed for REMOXY's approval. We expect to complete these studies by year-end 2017, at a cost of approximately $3-4 million. Following completion of these studies, we intend to have a pre-NDA meeting with the FDA, followed by resubmission of the REMOXY NDA, with anticipated Priority Review, under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Final Minutes of our FDA discussions confirm two requirements are needed for the resubmission of the REMOXY NDA:

- To conduct a clinical abuse potential study via the intranasal route of abuse; and
- To conduct a non-clinical abuse potential study using household solvents.

CLINICAL (INTRANASAL) ABUSE POTENTIAL STUDY

REMOXY has a sticky, high-viscosity gel formulation that cannot be snorted. Therefore, our intranasal study will ask human volunteers to self-administer into their nostrils REMOXY, placebo or an active comparator. Positive data in one intranasal study is adequate to support a label claim against the intranasal route of abuse. We previously generated positive results using REMOXY under similar test conditions in a large animal model.

NON-CLINICAL ABUSE POTENTIAL STUDY

REMOXY's sticky, high-viscosity formulation cannot be pulled through a normal size syringe. This feature makes it difficult to abuse REMOXY via simple injection. Therefore, we will conduct an abuse potential study in a lab using thin films of REMOXY smeared on glass plates to assess how household solvents affect the formulation. We plan to generate these data against comparator products. Positive data in this study is adequate to support a label claim against the injection route of abuse. We previously generated positive results using REMOXY under similar test conditions.

Our recent discussions with the FDA did not raise any issues around safety, drug efficacy, manufacturing, stability or other drug development topics.

Conference Call

We will host a conference call on Tuesday, March 21st, at 8am Eastern time to discuss REMOXY, and to present a corporate update around partnership discussions and advances to its pipeline. To participate in this conference call in the U.S. please dial toll-free 1-877-407-4018 or international 1-201-689-8471.

To hear the conference call live via the internet please visit www.paintrials.com. About two hours following the live call, a replay of the conference call will be available by phone through Friday, March 31, 2017. To listen to a replay of the call, in the U.S. please dial toll-free 1-844-512-2921, or international 1-412-317-6671, and press replay number 13658173.

About REMOXY ER (extended-release oxycodone capsules CII)

REMOXY 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. REMOXY's thick, sticky, high-viscosity gel formulation may deter unapproved routes of drug administration, such as injection, snorting or smoking. REMOXY targets the multi-billion dollar marketplace for long-acting oxycodone.

We own exclusive, worldwide commercial rights to REMOXY.

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. Nearly 19,000 people died from opioid overdose in 2014, according to the National Institute on Drug Abuse. 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 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, such as chronic pain. The FDA has not yet established the safety or efficacy of our drug candidates.

NOTE: REMOXY is a trademark of Pain Therapeutics, Inc.

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Important 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 discussions with the FDA; the abuse-deterrent properties and potential benefits of REMOXY; progress towards a resubmission plan for the REMOXY NDA; and timing or estimated costs of studies and actions needed to resubmit the REMOXY NDA to the FDA. Such statements are based on management's current expectations but actual results may vary materially due to various factors, many of which are beyond the control of management. Drug development involves substantial risks and uncertainties, including but not limited to those risks and uncertainties relating to successfully completing the activities required to address the issues raised by the FDA in the September 2016 Complete Response Letter for REMOXY ER and the time required to do so, including the time required to conduct the studies and activities to be undertaken and the possibility that the FDA may raise additional issues in the future that were not raised in the past. In addition, the development of abuse-deterrent drug products is a young and still emerging area of drug development, with regulatory guidance that may be inconsistent, unclear or still in development. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. 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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