Pernix Therapeutics Files Citizen Petition Following Issuance of U.S. Patent Number 9,265,760 (‘760 Patent) Covering Safety Information Related to Dosing Patients with Zohydro ER® with BeadTek™ CII

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Pernix Therapeutics Holdings, Inc. files a Citizen Petition requesting the FDA refrain from approving any application for Generic Zohydro ER that proposes to omit from labeling important safety information protected by the ‘760 patent.

Morristown, NJ, March 02, 2016 (GLOBE NEWSWIRE) -- Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced their submission of a Citizen Petition to the Commissioner of Food and Drugs pursuant to section 505(q) of the Federal Food, Drug and Cosmetic Act (“FDC Act”). Under this petition, Pernix has requested that the FDA refuse to approve any Abbreviated New Drug Application (“ANDA”) or any relevant 505(b)(2) New Drug Application citing Zohydro ER as a listed drug and seeking to omit from its proposed labeling safety-related information contained in the prescribing information for Zohydro ER and protected by the ’760 patent. Pernix has asserted that the labeling information protected by the ’760 patent cannot be omitted from the label of any proposed generic version of Zohydro ER with BeadTek. Pernix believes that omission of such patent-protected information would render a generic drug product deficient of important safety information, depriving physicians and patients of critical information regarding the safe administration of the drug product, and would put patients at risk.

This Citizen Petition follows the February 23, 2016 announcement by Pernix of the issuance of the ‘760 patent, which covers important safety information related to dosing patients with Zohydro ER with BeadTek. The ‘760 patent is broadly directed to a method of dosing patients with hepatic impairment with hydrocodone where no adjustment in start dose is needed for patients with mild or moderate hepatic impairment.

“Pernix puts patients and its customers at the center of everything that we do.” said Doug Drysdale, Chairman and CEO of Pernix Therapeutics. “We decided to take action following the issuance of U.S. Patent ‘760 by submitting a Citizen Petition to protect the critical information regarding safe administration of Zohydro ER with BeadTek.”

The ‘760 patent, solely owned by Pernix, expires July 25, 2033 and is the second patent to be listed in the last six months as covering Zohydro® ER with BeadTek in the United States Food and Drug Administration’s (FDA) *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*.

Zohydro ER with BeadTek is indicated 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. Zohydro ER does not contain acetaminophen, unlike many immediate-release hydrocodone products, reducing the risk for potential liver toxicity due to overexposure to acetaminophen. As covered by the ‘760 patent, no adjustment in starting dose for Zohydro ER is required for patients with mild or moderate hepatic impairment. Zohydro ER with BeadTek is available in strengths 10mg, 15 mg, 20mg, 30 mg, 40mg, and 50mg.

To reference the press release issued by Pernix Therapeutics related to U. S. Patent Number 9,265,760 (‘760 Patent) Covering Safety Information Related to Dosing Patients with Zohydro ER® with BeadTek™ CII, please click here: http://www.pernixtx.com/news/pernix-therapeutics-announces-the-issuance-of-new-orange-book-patent-for-zohydro-er-with-beadtek-cii/

About Zohydro ER with BeadTek

Zohydro ER with BeadTek is an extended-release form of hydrocodone indicated 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. Zohydro ER with BeadTek does not contain acetaminophen, unlike many immediate-release hydrocodone products, reducing the risk for potential liver toxicity due to overexposure of acetaminophen. The active ingredient, hydrocodone, is the most commonly prescribed opioid in the U.S., with over 90 million prescriptions in 2015. Zohydro

ER with BeadTek is an opioid agonist, extended-release, oral formulation of hydrocodone bitartrate containing technology that contains an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents.

For more information on Zohydro ER with BeadTek including important safety information and the full prescribing information, visit www.zohydroer.com.

About BeadTek™

BeadTek technology was developed using safe, well-known excipients and proprietary manufacturing processes to create an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents. All of the beads within the medication capsule are indistinguishable in color, shape, density and size, and do not impact the drug release profile when taken as directed.

Forward-Looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's current expectations, and are subject to known and unknown uncertainties and risks. Actual results could differ materially from those discussed due to a number of factors, including, but not limited to: the success of our clinical trials, including the timely recruitment of trial subjects and meeting the timelines therefore; our ability to obtain regulatory approval of our product candidates; our ability to have third parties manufacture our products; competitive factors; our ability to find and hire qualified sales professionals; general market conditions; and other risk factors described in Pernix Therapeutics' filings with the United States Securities and Exchange Commission. Pernix assumes no obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by law.

About Pernix Therapeutics

Pernix Therapeutics is a specialty pharmaceutical business with a focus on acquiring, developing and commercializing prescription drugs primarily for the U.S. market. The Company targets underserved therapeutic areas such as CNS, including neurology and pain management, and has an interest in expanding into additional specialty segments. The Company promotes its branded products to physicians through its two Pernix sales forces and markets its generic portfolio through its wholly owned subsidiaries, Macoven Pharmaceuticals, LLC and Cypress Pharmaceutical, Inc.

To learn more about Pernix Therapeutics, visit www.pernixtx.com.

Investor Relations Sanjay Patel, (800) 793-2145 ext. 1009 Chief Financial Officer spatel@pernixtx.com

Media Relations Marianne Lambertson, (800) 793-2145 ext. 1012 Vice President, Strategic Development mlambertson@pernixtx.com

LIMITATIONS OF USE

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Zohydro ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

Zohydro ER is not indicated as an as needed (prn) analgesic.

Please see the Zohydro ER full prescribing information for the complete boxed warning and safety information.

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION;

ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; INTERACTION WITH ALCOHOL; and CYTOCHROME P450 3A4 INTERACTION

See full prescribing information for complete boxed warning.

- **ZOHYDRO ER exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor regularly for development of these behaviors or conditions.**

- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow ZOHYDRO ER whole to avoid exposure to a potentially fatal dose of hydrocodone.**

- **Accidental ingestion of ZOHYDRO ER, especially in children, can result in a fatal overdose of hydrocodone.**

- **Prolonged use of ZOHYDRO ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.**

- **Instruct patients not to consume alcohol or any products containing alcohol while taking ZOHYDRO ER because co-ingestion can result in fatal plasma hydrocodone levels.**

- **Initiation of CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of hydrocodone from ZOHYDRO ER.**

IMPORTANT SAFETY INFORMATION

Zohydro ER is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma, known or suspected paralytic ileus, and hypersensitivity to hydrocodone bitartrate.

Zohydro ER has warnings for: interactions with CNS depressants; elderly, cachectic, debilitated patients, and those with chronic pulmonary disease; hypotensive effects; patients with head injury or increased intracranial pressure; and concomitant use of CYP3A4 may increase opioid effects. Please see full prescribing information for the complete warning information.

Potential serious adverse events caused by opioids include addiction, abuse, and misuse; life-threatening respiratory depression; neonatal opioid withdrawal syndrome; interactions with other CNS depressants; hypotensive effects; gastrointestinal conditions, and seizures. The most common adverse reactions associated with Zohydro ER (≥2%) include constipation, nausea, somnolence, fatigue, headache, dizziness, dry mouth, vomiting, pruritus, abdominal pain, peripheral edema, upper respiratory tract infection, muscle spasms, urinary tract infection, back pain, and tremor. With intravenous abuse, the inactive ingredients in Zohydro ER can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

PERNIX THERAPEUTICS

Pernix Therapeutics Holdings, Inc.