Pernix Therapeutics Announces the Issuance of Three New Orange Book Patents for Zohydro® ER with BeadTek™

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Patents cover important safety information related to dosing patients who are prescribed Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules with BeadTek™

MORRISTOWN, N.J., May 25, 2016 (GLOBE NEWSWIRE) -- Pernix Therapeutics Holdings, Inc. (NASDAQ:PTX), a specialty pharmaceutical company, today announced that the United States Patent and Trademark Office has issued U.S. Patent Numbers 9,339,499 (‘499 patent), 9,326,982 (‘982 patent), and 9,333,201 (‘201 patent), covering important safety information related to dosing patients with Zohydro ER with BeadTek. These patents, in addition to the 9,265,760 patent (‘760 patent) which issued February 23, 2016, are 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. The ‘760, ‘499, ‘982 and ‘201 patents expire July 25, 2033.

“The ‘499, ‘982, and the ‘201 patents, solely owned by Pernix, are a significant addition to the Orange Book, bringing the total number of Orange Book listed patents covering Zohydro ER with BeadTek to seven,” said John Sedor, Chairman and Interim CEO of Pernix Therapeutics. “We continue to invest in this brand and currently have a half dozen more patent applications pending relating to Zohydro ER with BeadTek.”

In addition to these three new Orange Book listed patents, Pernix Therapeutics also filed a Citizen Petition in early March 2016, requesting that the FDA refrain from approving an Abbreviated New Drug Application (“ANDA”) or any relevant 505(b)(2) New Drug Application citing Zohydro ER with BeadTek as a listed drug and seeking to omit from its proposed labeling safety-related information contained in the prescribing information for Zohydro ER with BeadTek. Within the petition, Pernix urges the FDA that the labeling information protected by the ’760 patent (and now the ‘499, ‘982, and ‘201 patents) cannot be omitted from the labeling of a 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 safe administration of the drug product, and will put patients at risk. To view Pernix’s press release regarding this Citizen’s Petition in its entirety, please click here: http://ir.pernixtx.com/phoenix.zhtml?c=84041&p=irol-newsArticle&ID=2145184

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. As covered by the ‘760, ‘499, ‘982, and the ‘201 patents, 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.

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

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: our ability to negotiate attractive fees and rebates with managed-care, pharmacy benefit and other organizations, our ability to grow sales of our products; our ability to repay outstanding indebtedness; our ability to access capital markets; the successful development of next generation products; the successful resolution of outstanding litigation and other disputes; 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.

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