

## **Pernix Announces the Issuance of Zohydro ER with BeadTek Formulation Patent**

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*Issuance of U.S. Patent Number 9,132,096 covering the Zohydro ER with BeadTek formulation extends exclusivity to 2034; To be added to FDA's Orange Book.*

**MORRISTOWN, NJ** – September 24, 2015 – Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced that the central patent for Zohydro® ER with BeadTek™, U.S. Patent Number 9,132,096, has issued. The patent covers a formulation of a combination of inactive beads with BeadTek abuse deterrent technology and active hydrocodone beads and expires in September 2034. In addition, Zohydro ER with BeadTek will be added to the U.S. Food and Drug Administration's (FDA) *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book"), which identifies drug products approved on the basis of safety and effectiveness by the FDA.

"The issuance of this patent comes after the launch of Zohydro ER with BeadTek on May 4, 2015 and will be a valuable addition to the growing Zohydro ER patent estate," said Doug Drysdale, Chairman and CEO of Pernix Therapeutics. "This patent further supports the Pernix commitment to the introduction of products promoting the safe use of opioids for appropriate patients."

BeadTek is a technology that encompasses an indistinguishable mix of inactive beads, active immediate release hydrocodone beads and active extended-release hydrocodone beads. Zohydro ER with BeadTek was approved on January 30, 2015 by the FDA. Zohydro ER with BeadTek delivers an extended release of hydrocodone that provides 12-hour dose duration. When the medication is taken as directed, the inactive beads contained in Zohydro ER with BeadTek remain inert. The inactive beads dissolve independently of the active hydrocodone beads and are designed not to change the 12-hour release properties of the medication. However, when crushed and dissolved in liquids or solvents, the inactive beads are designed to immediately form a viscous gel.

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 of acetaminophen. Zohydro ER with BeadTek is available in strengths 10mg, 15 mg, 20mg, 30 mg, 40mg, and 50mg.

### **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 114 million prescriptions in 2014. 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](http://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 therefor; our ability to obtain regulatory approval of our product candidates; 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](http://www.pernixtx.com).*

### **Pernix Therapeutics Holdings Inc. Contact**

#### **Media Relations**

Marianne Lambertson, (800) 793-2145 ext. 1012  
Vice President, Strategic Development  
[mlambertson@pernixtx.com](mailto:mlambertson@pernixtx.com)

#### **Investor Relations**

Lisa Wilson, (212) 452-2793  
In-Site Communications  
[lwilson@insitecony.com](mailto:lwilson@insitecony.com)

Or

Sanjay Patel, (800) 793-2145 ext. 1009  
Chief Financial Officer  
[spatel@pernixtx.com](mailto:spatel@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 ( $\geq 2\%$ ) 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.