

Pernix Launches Zohydro® ER with BeadTek™

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New Formulation Maintains 12-Hour Efficacy to Treat Patients Suffering from Chronic Pain

MORRISTOWN, NJ – (BUSINESS WIRE) – May 04, 2015 – Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced that the new formulation of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, with BeadTek™ is now available in U.S. pharmacies. On January 30, 2015, the U.S. Food and Drug Administration (FDA) approved this updated formulation that features BeadTek, a technology encompassing an indistinguishable mix of inactive beads, active immediate-release hydrocodone beads and active extended-release hydrocodone beads. Zohydro ER with BeadTek delivers an extended release of hydrocodone that provides 12-hour dose duration. When 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 when taken as directed. However, when crushed and dissolved in liquids or solvents, the inactive beads are designed to immediately form a viscous gel.

“Zohydro ER with BeadTek represents an advancement for clinicians and their patients living with, chronic pain, demonstrating effective relief over the 12-hour dose duration.” said Srinivas Nalamachu, MD, president and medical director, International Clinical Research Institute, Overland Park, Kansas and lead author of a clinical study evaluating the long-acting pain relief of Zohydro ER. “Research demonstrated significant rates in pain reduction with no pattern of end-of-dose failure, as well as significantly improved disability scores in patients taking Zohydro ER with BeadTek.”

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 will be available in strengths 10 mg, 15mg, 20mg, 30mg, 40 mg and 50 mg.

“Zohydro ER is an ideal strategic fit for Pernix, having tremendous synergy with our existing CNS franchise. It also represents a major step forward in our strategy to expand our commercial reach, and we expect it to create significant value for our shareholders,” said Douglas Drysdale, Chairman, President and Chief Executive Officer of Pernix Therapeutics. “Adding Zohydro ER with BeadTek strengthens our specialty product portfolio and brings the proven clinical benefits of Zohydro ER to patients suffering with chronic pain in need of around-the-clock opioid therapy.”

As part of the acquisition, announced on March 10, 2015, Pernix has retained key members of Zogenix’s commercial team, who will oversee the sales and marketing of Zohydro ER with BeadTek, most notably the approximately 100-person sales team. The new Pernix Pain Management sales team will immediately promote both Zohydro ER with BeadTek and Silenor®. Approximately two-thirds of patients experiencing chronic pain report having poor or unrefreshing sleep. Silenor, the only non-scheduled, non-addictive prescription medication for insomnia, provides a valuable option for patients already taking a scheduled medication for pain relief.

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

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.

INDICATION

Zohydro® ER (hydrocodone bitartrate) is an extended-release opioid agonist 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.

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, or 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 inhibitors 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.

About Silenor

Silenor is a prescription sleep medicine that is used to treat people with insomnia who have trouble staying asleep. Staying asleep is the number one reported sleep problem of people with insomnia. Instead of putting you to sleep, Silenor helps you stay asleep during the night. It also helps to keep you from waking too early in the morning. Silenor does this by working with the wake-promoting mechanism of your body's natural sleep-wake cycle. Silenor is the only nonscheduled, non-addictive prescription medicine indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. Silenor has minimal next-day residual effects, even in elderly patients and has shown no evidence of physical dependence or withdrawal symptoms.

For more information on Silenor including important safety information and the full prescribing information, visit www.silenor.com

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.

Zohydro® ER is a registered trademark of Pernix Ireland Pain Limited.

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Pernix Therapeutics Holdings, Inc.

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