Pernix Presents Data on Novel Extended Release Formulation of Hydrocodone Bitartrate at PAINWeek

September 9, 2015 2:07 PM ET

Next-Generation Tablet Formulation Resists Physical Manipulation and Extraction of Hydrocodone
In Vitro Data Supports Further Human Abuse Liability Studies

LAS VEGAS, NV – September 9, 2015 (GLOBAL NEWSWIRE) – Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, today announced that a series of studies of ZX007, the Company's next-generation extended release formulation of hydrocodone bitartrate developed in coordination with Altus Formulation, showed the tablet resists both physical manipulation and extraction with typical household solvents commonly used by opioid abusers. The success of the studies supports continued evaluation of the formulation in human abuse liability (HAL) studies. The analysis was accepted as a late-breaking abstract and will be presented as a poster at PAINWeek, the nation's largest pain conference for frontline practitioners taking place this week in Las Vegas.

"The studies were performed using common methods that may be undertaken by opioid abusers to manipulate a controlled release product, as well as ways in which a patient may alter the formulation," said Damon Smith, CEO of Altus Formulation. "In vitro studies of ZX007 demonstrated that the formulation resisted attempts at manipulation and extraction in a wide range of solvents and maintained a controlled release after crushing and grinding."

Studies included attempts to crush tablets using a variety of methods and extraction tests utilizing cold or boiling water, low and high pH media, alcohol, methanol, nail varnish remover and isopropyl alcohol. Manipulation with water and other solvents resulted in the immediate formation of a viscous gel with no supernatant or aqueous extraction solution being formed.

"We are pleased with the promising outcome of these studies. Pernix is committed to introducing abuse-deterrent formulations of hydrocodone to promote the safe use of our products and for the benefit of patients who would otherwise have to endure severe pain," said Doug Drysdale, President, Chairman and CEO of Pernix. "Our aim is to bring this new treatment option to market responsibly, focusing on the patients and helping to reduce the overall burden of opioid misuse and abuse."

Pernix markets Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII, with BeadTek™, which 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 10 mg, 15 mg, 20 mg, 30 mg, 40 mg and 50 mg.

ZX007 is being developed using INTELLILAB™ technology, an innovation of Altus Formulation Inc.

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.

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.

Investor Relations
Sanjay Patel, (800) 793-2145 ext. 1009
Chief Financial Officer
spatel@pernixtx.com
or
Lisa Wilson, (212) 452-2793
In-Site Communications
lwilson@insitecony.com

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

About Altus Formulation

Altus Formulation is a drug formulation and development company using its proprietary and patent protected drug delivery technologies to generate novel, differentiated and cost effective new products for its clients. Altus technologies include the INTELLITAB™ abuse resistant platform, FLEXITAB™ breakable controlled release tablets and PNDS™ micellar technology for increased bioavailability of small and large molecule drugs.

Altus Formulation Inc.

Business Development, (514) 883-3447
bd@altusformulation.com

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 (≥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.