Zohydro(R) ER Demonstrates Sustained 12-Hour Pain Relief

September 2, 2014

No Additional Nighttime Dosing and No End-of-Dose Failure, in Most Patients, According to Post-Hoc Analysis Presented at PAINWeek

SAN DIEGO, Sept. 2, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related and central nervous system (CNS) disorders, today announced new post-hoc analysis data showing that the indicated 12-hour dose of Zohydro® ER, (hydrocodone bitartrate) Extended-Release Capsules, CII, provided durable pain relief over the entire dosing interval. This finding is important because a major concern for all extended-release pain medications is the potential for lack of consistent pain relief throughout the entire day, especially at the end of the dosing.

"In this study, we saw that most of the chronic pain patients taking Zohydro ER achieved effective pain relief for the entire duration of 12 hours for each administered dose. In particular, most patients did not experience dose failures during the night, meaning they did not wake up to take additional medication for their pain," said Srinivas Nalamachu, MD, President and Medical Director, International Clinical Research Institute, Overland Park, Kansas.

The goal of extended-release opioids is to provide sustained delivery of medication and continuous pain relief over the entire dosing interval, reducing or eliminating the need to take rescue pain medication. Chronic pain patients experiencing interruptions in sleep frequently have higher degrees of pain and reduced functioning the following day. [1]

These data will be presented at PAINWeek, the national conference on pain for clinicians specializing in pain management taking place this week in Las Vegas.

"Zohydro ER was developed specifically for the subset of severe chronic pain patients currently managing their pain with short-acting hydrocodone/acetaminophen medication but who need true sustained 12-hour pain relief and are at risk for acetaminophen toxicity. These data further support that Zohydro ER fulfills this medical need," said Bradley Galer, MD, chief medical officer of Zogenix. "This analysis of our pivotal Phase 3 data demonstrated that pain relief with Zohydro ER was durable throughout the entire 12-hour dosing interval without any observation of end of dose failure. This finding, coupled with the lack of the need to wake up at night to take rescue pain medication, is particularly important, since minimizing the amount of rescue medication and providing around-the-clock pain relief are often overlooked factors in the effective treatment of severe chronic pain."

Zohydro® ER 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 is the first and only extended-release hydrocodone for around-the clock management of severe chronic pain without acetaminophen, lowering the risk for liver toxicity due to overexposure of acetaminophen, which can be fatal or require a liver transplant.

About the PAINWeek Presentation

"Single-entity, extended-release hydrocodone bitartrate: effective pain relief during 12-hour dosing"

Poster 60, Thursday, September 4, 6:30 pm – 8:30 pm

The multi-center, enriched enrollment, randomized withdrawal study evaluated the efficacy and safety of Zohydro ER in opioid-experienced subjects with moderate-to-severe chronic low back pain. This new analysis examined the durability of pain relief throughout the 12-hour dosing interval by examining patterns of rescue medication utilization in patients with chronic low back pain. The study began with an open-label, conversion/titration phase (≤6 weeks) in which 150 subjects with moderate-to-severe chronic low back pain were converted from their current opioid to Zohydro ER dosed every 12 hours. After the conversion/titration phase, subjects were randomized in a double-blind fashion to Zohydro ER or placebo for the 12-week treatment phase. Rescue medication was permitted up to twice daily.

Key findings include:

- During more than 75% of dosing days, rescue medication was not needed after the evening dose of Zohydro ER suggesting that patient sleep was not interrupted due to the need to take rescue pain medicine
- Less than 10% of rescue doses were taken during the last 4 hours of nighttime dosing and less than 20% of rescue doses were taken during the last 4 hours of daytime dosing showing no pattern of end of dose interval failure
- Zohydro ER provides an effective option for patients using immediate-release opioid medication chronically who are at risk for acetaminophen-induced liver injury

About Zohydro® ER

INDICATION

Zohydro® ER 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 click here to see the Zohydro ER professional product labeling 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.**
- **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.**
- **Accidental ingestion of Zohydro ER, especially in children, can result in a fatal overdose of hydrocodone.**

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 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.

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

Forward-Looking Statements

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "indicates," "will," "intends," "suggests," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding: the effectiveness of Zohydro ER, including the duration of relief. Actual results may differ from those set forth in this release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: Zogenix's ability to achieve broad market acceptance and generate revenues from sales of Zohydro ER; the potential that the post-hoc analysis may not be predictive of future efficacy results of Zohydro ER; and other risks detailed in Zogenix's prior press releases as well as in public periodic filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

[1]Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Institute for Clinical Systems Improvement. Assessment and Management of Chronic Pain. Updated November 2013.

Zohydro® ER is a registered mark of Zogenix, Inc.

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