Zogenix Provides Update on Zohydro(TM) ER (hydrocodone bitartrate) Launch Readiness Plans

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Zogenix in Final Preparations for Early March Market Launch

SAN DIEGO, Feb. 11, 2014 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of pain-related conditions and central nervous system disorders, today announced it has made significant progress in preparing for the market launch of Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, approved by the U.S. Food and Drug Administration in October 2013. Zohydro ER, the first and only extended release hydrocodone without acetaminophen, is indicated for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. For patients managing chronic pain with an immediate release hydrocodone combination product, an extended release formulation without the risks associated with acetaminophen may be beneficial. Zohydro ER may also be an alternative for people living with chronic pain who have developed opioid tolerance or are experiencing side effects with other long-acting opioids.

In preparation for commercial launch, the company has completed a significant organizational expansion, increasing its employee footprint to approximately 250. Zogenix has recruited professionals with extensive experience in the pain management marketplace to contribute to a full range of commercial operations including sales and marketing, managed markets and trade team. Zogenix has also assembled an impressive medical affairs leadership team as announced in December 2013. All 150 territory representative positions have been filled and comprehensive training began February 3rd, and will continue throughout the month. Manufacturing of Zohydro ER has also been completed and the product is ready for shipment to wholesalers. The company believes that adequate inventory is in place to meet anticipated launch demand for the product.

These preparations place Zohydro ER's commercial launch on track for early March.

About Zohydro ER

INDICATION

Zohydro™ ER is an opioid agonist, extended-release, oral formulation of hydrocodone bitartrate 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 for use 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 EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME and INTERACTION WITH ALCOHOL

- **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 consumption of Zohydro ER, especially in children, can result in fatal overdose of hydrocodone.**
- **For patients who require opioid therapy while pregnant, be aware that infants may require treatment for neonatal opioid withdrawal syndrome. Prolonged use during pregnancy can result in life-threatening neonatal opioid withdrawal syndrome.**
- **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.**

IMPORTANT SAFETY INFORMATION

Zohydro ER is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma or hypercarbia; known or suspected paralytic ileus; and hypersensitivity to hydrocodone bitartrate or any other ingredients in Zohydro ER.

Zohydro ER contains hydrocodone, a Schedule II controlled substance. As an opioid, Zohydro ER exposes users to the risks of addiction, abuse, and misuse. As modified-release products, such as Zohydro ER, deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of hydrocodone present.

Potential serious adverse events caused by opioids include respiratory depression, potential for misuse and abuse, CNS depressant effects, prolonged gastric obstruction, and severe hypotension. 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.

For more information about Zohydro ER, please visit: http://www.zohydroer.com

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX), with offices in San Diego and Emeryville, California, is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with pain-related conditions and central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. Zogenix developed and commercialized the first needle-free subcutaneous injection, SUMAVEL® DosePro® (sumatriptan injection), for migraine and cluster

headache. Zogenix received FDA approval for Zohydro ER (hydrocodone bitartrate) extended-release capsules, the first extended-release oral formulation of hydrocodone without acetaminophen. The development pipeline for Zogenix includes a once-monthly subcutaneous injection for schizophrenia.

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," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "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 timing of the launch of Zohydro ER, the potential of Zohydro ER to provide a significant new management alternative within the chronic pain market, and the company's ability to ensure an adequate and continued supply of Zohydro ER to successfully launch commercial sales or meet anticipated market demand. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the timing and success of the commercial launch of Zohydro ER; Zogenix's ability to successfully launch and drive market demand for Zohydro ER; Zogenix's ability to obtain additional financing as needed to support its operations; the scope and validity of patent protection for Zohydro ER and Zogenix's ability to commercialize Zohydro ER without infringing the patent rights of others; unexpected adverse side effects or inadequate therapeutic efficacy of Zohydro ER that could limit commercialization, or that could result in recalls or product liability claims; competition from other pharmaceutical or biotechnology companies; other difficulties or delays relating to the development, testing, manufacturing and marketing of and obtaining regulatory approval for Zogenix's products; 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.

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