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Zogenix Receives FDA Approval for Zohydro(TM) ER (hydrocodone bitartrate) Extended-Release Capsules

Conference Call and Webcast on Monday, October 28, at 8:30 a.m. ET

SAN DIEGO, Oct. 25, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system disorders and pain, today announced that the U.S. Food and Drug Administration (FDA) has approved Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, 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. Zogenix expects to launch Zohydro ER in approximately four months.

Zohydro ER is the first extended-release formulation hydrocodone therapy without acetaminophen. The use of products containing acetaminophen in high doses over long periods of time has the potential for causing liver injury. Acetaminophen overdose is a leading cause of acute liver failure in the United States, with 63 percent of unintentional acetaminophen overdoses attributed to the use of hydrocodone-acetaminophen combination products.[1]

"Zohydro ER fulfills a critical need among people living with chronic pain who meet the criteria for therapy with extended release opioids. It is the first extended-release hydrocodone medicine that is acetaminophen-free. Also, a significant proportion of patients on existing forms of immediate-release hydrocodone-acetaminophen combination treatments have liver disease or risk factors, and the availability of an acetaminophen-free formulation encompassing a range of hydrocodone doses is an important therapeutic option for these patients," said Dr. Srinivas Nalamachu, M.D., a pain specialist at the International Clinical Research Institute, Overland Park, Kansas and investigator in the clinical trials of Zohydro ER.

Zogenix is committed to supporting appropriate use of opioid pain treatments for patients suffering from chronic pain. Zogenix will implement the Risk Evaluation and Mitigation Strategy (REMS) for Extended Release (ER) and Long Acting (LA) Opioids required by the FDA for all the products in the class. In addition, Zogenix will participate in the design and implementation of post-marketing studies, as recently outlined by the FDA. NDA sponsors of ER/LA opioids are now required to conduct studies to assess the serious risks associated with long-term use.

"In addition to the REMS, Zogenix has voluntarily developed a series of safe use initiatives to support the appropriate use of Zohydro ER," said Stephen Farr, Ph.D., president of Zogenix. "As part of these initiatives, we will provide state-of-the-art integrated educational resources for patients, physicians and pharmacists and leverage surveillance programs to monitor for misuse and abuse. Further, Zogenix has also started the development of an abuse deterrent formulation of Zohydro ER and we are committed to advancing the program as rapidly as possible."

Zohydro ER capsules will be available in six dosage strengths ranging from 10 mg to 50 mg with dosing every 12 hours. Zohydro ER is classified as a Drug Enforcement Agency (DEA) Schedule II drug, making it subject to stricter prescribing and dispensing rules compared to the immediate-release hydrocodone-acetaminophen combination products, which are currently classified as Schedule III drugs. On October 24, 2013, the FDA announced its intention to submit a formal recommendation to Health and Human Services by early December to reclassify hydrocodone combination products from DEA Schedule III to Schedule II, however, the date of implementation is currently unknown.

Zohydro ER was studied in over 1,100 people living with chronic pain who participated in the pivotal Phase 3 efficacy study or an open-label Phase 3 long-term safety study. The efficacy study that enrolled over 500 subjects with chronic low back pain met the primary endpoint in demonstrating that treatment with Zohydro ER resulted in significantly improved chronic pain relief compared to placebo. The key secondary endpoint was also achieved: a significantly higher number of subjects experienced at least 30% improvement in pain intensity from screening to end of study (67.5%, Zohydro ER versus 31.1%, placebo). The safety profile of Zohydro ER in both Phase 3 studies was consistent with other opioids in that the most frequent treatment emergent adverse events were constipation, nausea, drowsiness (somnolence), fatigue, headache, dizziness, dry mouth, vomiting and itching (pruritus).

Zohydro ER uses Alkermes Pharma Ireland Limited's patented Spheroidal Oral Drug Absorption System (SODAS®) drug delivery technology, which serves to enhance the release profile of hydrocodone to provide extended-release pain relief

relative to existing immediate-release combination products.

Conference Call and Web Cast

Zogenix will hold a conference call on Monday, October 28, 2013 at 8:30 a.m. ET to discuss the FDA approval of Zohydro ER.

To participate, please dial (866) 202-0886 (U.S.) or (617) 213-8841 (International); participant passcode: 35082590. To access the live webcast please visit the Zogenix Investor Relations website at http://ir.zogenix.com.

A replay of the conference call will be available beginning October 28, 2013 at 9:00 p.m. ET until November 4, 2013, by dialing (888) 286-8010 (U.S.) or (617) 801-6888 (International); passcode: 29176780. A replay of the webcast will also be accessible on the Investor Relations website for one month, through November 28, 2013.

Discussion during the conference call may include forward-looking statements regarding such topics as, but not limited to, the Company's commercial activities relating to Zohydro ER and SUMAVEL DosePro, the Company's financial status and any comments the Company may make about its future plans or prospects in response to questions from participants on the conference call.

About the voluntary safe use initiatives for Zohydro ER

To support the appropriate use of Zohydro ER, Zogenix is committed to responsible management of product distribution and commercialization with the following voluntary safe use initiatives:

1. ***Integrated broad-ranging educational resources*** *for patients, physicians and pharmacists, that complement and build upon the ER/LA opioid analgesics REMS, including assessment tools and case-based simulated training*
2. ***Ongoing surveillance and monitoring*** *of key measures from the date of launch which are intended to detect potential misuse, abuse and diversion of Zohydro ER*
3. ***Commercial activity focused on selected*** *physicians who are experienced in the prescribing of Schedule II extended-release opioids, as well as proactive medical outreach to those who have expressed an interest in prescribing Zohydro ER*
4. ***Certification of Zogenix territory representatives*** *of completion of education and training on all REMS and voluntary safe use initiatives for Zohydro ER*
5. ***Incentive compensation based exclusively on achieving safe use goals*** *rather than prescription sales volume for Zogenix territory representatives throughout the launch year*
6. ***Distribution of safe storage mechanisms*** *to encourage patients to practice at-home safekeeping of their prescribed quantity of Zohydro ER*

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.

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 CNS and pain-related conditions 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 recently 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 size of the chronic pain market and the potential of Zohydro ER to provide a significant new management alternative and be well positioned in that market, and the FDA's proposal to change the schedule for hydrocodone combination products from Schedule III to Schedule II under the Controlled Substances Act. 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 any subsequent 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.

[1] Michna, E, Duh, MS, Korves, C, Dahl, JL. Removal of opioid/acetaminophen combination prescription pain medications: assessing the evidence for hepatotoxicity and consequences of removal of these medications. *Pain Medicine.* 2010; 11: 369-378.

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