Zogenix Establishes External Safe-Use Board

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Experts to Provide Independent Oversight and Recommendations

SAN DIEGO, Feb. 12, 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 the formation of an External Safe-Use Board. The Board will be a key part of the company's comprehensive approach supporting the appropriate use of Zohydro™ ER (hydrocodone bitartrate) extended-release capsules, the first and only extended-release 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. The areas of expertise of the standing members of the Board are matched to ensure Zogenix will receive timely, independent and thorough feedback and recommendations regarding the use of Zohydro ER after launch in early March. The Board will meet regularly to review a variety of data inputs regarding the medication's prescribing and use.

"Instituting the External Safe-Use Board is another example of our commitment to responsible commercialization of our products," said Roger Hawley, chief executive officer of Zogenix. "The important role of this Board serves to report independent assessments, interpretations and recommendations regarding the use of Zohydro ER directly to the Board of Directors of Zogenix and to me. Our intentions are to proactively share this information with the Food & Drug Administration (FDA). This will be the first time that a Schedule II opioid product will have launched with an expert, independent safety review board in place from the first day of product availability."

Chairperson of the External Safe-Use Board, Jeffrey Gudin, MD, Director of Pain Management and Palliative Care at Englewood Hospital and Medical Center in New Jersey, said, "This type of voluntary initiative on the part of Zogenix, will allow external, highly experienced specialists, to provide valuable insight and advice about the impact of introducing this new pain treatment to the community and, if needed, to recommend specific actions needed to ensure that the risk of abuse, misuse and diversion is minimized. The creation of this Board exemplifies Zogenix's commitment to the appropriate use of Zohydro ER."

The members of the External Safe-Use Board consist of widely recognized experts in pain management, risk management, pharmacovigilance, surveillance, addiction, patient care and law enforcement. The Board members will meet quarterly and have responsibility for interpreting and identifying the assessment of the benefit/risk profile of Zohydro ER, effectiveness of the current surveillance tools, current education and prevention programs, and identification of opportunities to enhance signal detection or risk mitigation activities.

Zogenix is committed to promoting the appropriate use of Zohydro ER through a comprehensive suite of voluntary initiatives, which include integrated educational resources for patients, prescribers and pharmacists, surveillance programs to identify misuse, abuse and diversion, commercial activity focused on selected prescribers experienced with managing pain using Schedule II extended-release opioids, education and training requirements for Zogenix territory representatives who will be compensated on achieving educational goals during launch year and provision of safe storage mechanisms for prescription medicines.

In addition, Zogenix is fully engaged in developing an abuse deterrent formulation of Zohydro ER, as announced in November 2013, consistent with the Food & Drug Administration's (FDA) draft guidance for the industry on the evaluation and labeling of abuse deterrent opioids.

External Safe-Use Board

Jeffrey Gudin, MD – Chairperson; Pain Management Specialist

Dr. Gudin is currently Director of Pain Management and Palliative Care at Englewood Hospital and Medical Center in New Jersey, an affiliate of the Mount Sinai School of Medicine. His clinical and research focus includes the safe use of controlled substances for the treatment of pain, preemptive analgesia, and increasing clinician awareness of pain management and palliative care. He is board certified in Pain Medicine, Anesthesiology, Addiction Medicine and Hospice and Palliative Care.

John J. Burke – Law Enforcement Specialist

Commander Burke has been a law enforcement officer for over 43 years. He is the president of the non-profit organization, National Association of Drug Diversion Investigators, and is the owner and president of Pharmaceutical Diversion Education Inc., a company which provides education and consulting work on a wide variety of prescription drug abuse issues to law enforcement, health professionals, and the pharmaceutical industry.

Debra Gordon, RN, DNP, FAAN – Patient Advocate

Dr. Gordon is a Teaching Associate with the Department of Anesthesiology & Pain Medicine at the University of Washington (UW), Seattle. She works in conjunction with the inpatient and outpatient Pain Relief Services, clinics and hospital staff to collaborate on improving systems of care and designing outcome evaluations that benefit patients and populations across the continuum of care. She has also been involved in a number of national and international projects focused on improving the quality and safety of pain management.

Herbert Neuman, MD, MBA – Pharmacovigilance Expert

Dr. Neuman, President of R3xperts LLC, has Dr. Neuman, President of R3xperts LLC, has designed global drug safety and risk management systems for multiple companies and advises healthcare firms on a broad range of product safety issues. He has experience working with the FDA to understand and mitigate important drug safety and risk management issues.

Scott Novak, PhD – Surveillance Expert

Dr. Novak, Senior Developmental Epidemiologist at RTI International, holds research interests in the causes, correlates, and consequences of substance use, including the behavioral and psychiatric sequelae. He currently directs the program of research on prescription drug abuse within RTI's behavioral health epidemiology program. He is also active in studies investigating the epidemiology of new synthetic/designer drugs of abuse in the United States and internationally.

Steven Passik, PhD – Addiction Specialist

Dr. Passik is the Director of Clinical Addiction Research and Education at Millennium Laboratories and is a Professor of Psychiatry and Anesthesiology at Vanderbilt University Medical Center in Nashville, Tennessee. He has served on the editorial board of several peer-reviewed pain management journals, and was the president of the Indiana Cancer and AIDS Pain Initiative and the editor in chief of the National Cancer Institute's PDQ Supportive Care Editorial Board.

Joseph Pergolizzi, Jr., MD – Risk Management Expert

Dr. Pergolizzi is a senior partner in the Naples Anesthesia and Physician Associates Group and Chairman of the Board of the Association of Chronic Pain Patients. He has served as a member of various medical and scientific societies and acted on a number of institutional committees including the Medical Errors Committee and Pharmacy and Therapeutics Committee, and is also a participant of the FDA's Safe Use Initiative Roundtable.

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: www.ZohydroEr.com or the Zohydro ER REMS website at www.ZohydroERREMS.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 CNS 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 ability to ensure that the risk of abuse, misuse and diversion of Zohydro ER is minimized and the potential to develop an abuse deterrent formulation of Zohydro ER. 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: Zogenix's ability to adequately ensure that the risk of abuse, misuse and diversion of Zohydro ER is minimized; risks and uncertainties associated with the development and regulatory approval of an abuse deterrent formulation of Zohydro ER; 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 an abuse deterrent formulation 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.

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