Zogenix Announces Appointment of David Brushwood, J.D., R.Ph., to External Safe Use Board

July 17, 2014

Board Commends Comprehensive Surveillance Program, Educational Efforts for Zohydro(R) ER

SAN DIEGO, July 17, 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 that David Brushwood, J.D., R.Ph., recently-retired Professor Emeritus of Pharmaceutical Outcomes and Policy at the University of Florida, College of Pharmacy, has joined the company's External Safe Use Board. This group of independent experts is responsible for providing thorough feedback and recommendations regarding the use of Zohydro® ER (hydrocodone bitartrate) Extended-Release Capsules, CII. Zohydro ER is the first and only extended-release formulation of hydrocodone without acetaminophen and 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.

Professor Brushwood will provide expertise and guidance on pharmacy-level education, training and surveillance. His research interests are in the areas of regulating for outcomes, medication error prevention and pain management policy. Professor Brushwood graduated from the schools of pharmacy and law at the University of Kansas and practiced both professions before entering academia more than 30 years ago. Professor Brushwood is the recipient of several prestigious awards for his contributions in healthcare and pharmacy ethics, and he is a frequent contributor to pharmacy and law journals.

"The work Zogenix is doing with pharmacy education is very innovative for a pharmaceutical company. I am pleased to be serving as a member of this independent board of distinguished experts," said Professor Brushwood.

Board members have been participating in monthly meetings to review a variety of data inputs and discuss the benefit/risk profile of Zohydro ER, effectiveness of the current surveillance tools, current education and prevention programs, and identify opportunities to enhance signal detection or risk mitigation activities.

"Zogenix has instituted a compelling and comprehensive surveillance program that is setting a new industry standard in the pain community," said 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. "The data to date are very encouraging, and demonstrate emerging positive trends around the appropriate use of Zohydro ER."

In addition to Professor Brushwood, the following experts serve on the External Safe Use Board:

Jeffrey Gudin, MD – Chairperson; Pain Management Specialist
Director of Pain Management and Palliative Care at Englewood Hospital and Medical Center in New Jersey

John J. Burke – Law Enforcement Specialist
President of National Association of Drug Diversion Investigators; Owner and President of Pharmaceutical Diversion Education Inc.

Debra Gordon, RN, DNP, FAAN – Patient Advocate
Teaching Associate with the Department of Anesthesiology & Pain Medicine at the University of Washington, Seattle

Herbert Neuman, MD, MBA – Pharmacovigilance Expert
President of R3xperts LLC

Scott Novak, PhD – Surveillance Expert
Senior Developmental Epidemiologist at RTI International

Steven Passik, PhD – Addiction Specialist
Director of Clinical Addiction Research and Education at Millennium Laboratories

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 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 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) 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," "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 of the External Safe Use Board to provide expertise and guidance on pharmacy-level education, training and surveillance; and the potential for preliminary data to demonstrate the appropriate use of Zohydro ER. 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 market opportunity for Zohydro ER may suffer from general public concern regarding the safety of opioids as well as negative publicity and political influences relating to the regulation of opioids in general and Zohydro ER in particular; Zogenix may be unable to achieve broad market acceptance and generate significant revenues from sales of Zohydro ER; 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.

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

FPR

CONTACT: Investors
Zack Kubow |The Ruth Group
646.536.7020 | zkubow@theruthgroup.com

Media
David Polk | Chandler Chicco Companies
310.309.1029 | DPolk@chandlerchiccocompanies.com

Zogenix