Zogenix Announces FDA Advisory Committee Review of Zohydro(TM) ER for the Management of Chronic Pain

November 8, 2012

SAN DIEGO, Nov. 8, 2012 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, today announced that the U.S. Food and Drug Administration's (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) will review the Company's New Drug Application (NDA) for Zohydro™ ER (hydrocodone bitartrate extended-release capsules) on December 7, 2012. Zohydro ER is Zogenix's lead investigational product candidate for the management of moderate-to-severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Details of the meeting agenda will be available in the Federal Register.

The Prescription Drug User Fee Act (PDUFA) date for completion of the review by the FDA is March 1, 2013. If approved, Zohydro ER will be classified as a Drug Enforcement Agency (DEA) Schedule II drug, subject to stricter prescribing and dispensing rules compared to the currently prescribed hydrocodone products. Zogenix has included in the NDA a comprehensive Risk Evaluation and Mitigation Strategy (REMS) that is consistent with current FDA and industry-wide guidelines for extended-release opioid products. The REMS is intended to control inappropriate prescribing, misuse and abuse of extended-release opioids while maintaining patient access to essential pain medications.

About Anesthetic and Analgesic Drug Products Advisory Committee

The AADPAC reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human anesthetic and analgesic drug products and makes appropriate recommendations to the Commissioner of Food and Drugs. The AADPAC provides FDA with independent expert advice and recommendations; however, the final decision regarding approval is made by FDA.

About Zohydro ™ER

Zohydro ER is an investigational oral, novel extended-release formulation of hydrocodone without acetaminophen for the management of moderate to severe chronic pain in patients requiring continuous, around the clock opioid therapy for an extended period of time. If approved, Zohydro ER could be the first extended-release novel formulation (without acetaminophen) hydrocodone therapy for pain, avoiding the potential for liver injury associated with the use of acetaminophen in high doses or over long periods of time.

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.

About Chronic Pain

Chronic pain is defined as ongoing or recurrent pain that adversely affects an individual's well-being. An estimated 116 million people in the United States are burdened with chronic pain, at an estimated national economic cost of $560 billion to $635 billion annually. Chronic pain can be managed with both immediate-release and extended-release opioids. Currently marketed hydrocodone products are only immediate-release and contain an analgesic combination ingredient, primarily acetaminophen. Acetaminophen may cause liver injury when used in high dosages, over long periods of time or in accidental overdoses due to multiple acetaminophen products being taken at once.

About Zogenix

Zogenix, Inc., with offices in San Diego and Emeryville, California, is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Zogenix's first commercial product, SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead investigational product candidate, Zohydro™ ER (hydrocodone bitartrate) is an oral, novel extended-release formulation of various strengths of hydrocodone without acetaminophen intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. Zogenix's second DosePro investigational product candidate, Relday™, is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER and an Investigational New Drug Application for Relday. The FDA assigned a PDUFA target action date of March 1, 2013 for the Zohydro ER NDA.

For additional information, please visit www.zogenix.com.

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 AADPAC meeting and the timing thereof, the target action date for the FDA to complete its review of the Zohydro ER NDA; the potential for Zohydro ER to be the first approved oral extended-release formulation of hydrocodone without acetaminophen and the timing thereof; and 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. 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 release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the potential for the FDA to delay the PDUFA target action date of March 1, 2013 due to the FDA's internal resource constraints or other reasons; the uncertainty of the FDA approval process and other regulatory requirements; the top-line data Zogenix has reported for Zohydro ER is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial, and may also change in connection with the continued review of such data as part of the FDA's review of the NDA for Zohydro ER; the potential for delays associated with any additional data required to be submitted by Zogenix in support of the NDA; the potential for Zohydro ER to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro ER to delay or prevent regulatory approval or commercialization; the impact of any inability to raise sufficient capital to fund ongoing operations; and other risks described in Zogenix's 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 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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