Zogenix Provides Update on Zohydro(TM) ER Regulatory Review

February 27, 2013

SAN DIEGO, Feb. 26, 2013 (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 it has been informed by the U.S. Food and Drug Administration (FDA) that Zogenix is unlikely to receive an action letter for its New Drug Application (NDA) for Zohydro™ ER (hydrocodone bitartrate extended-release capsules) by the Prescription Drug User Fee Act (PDUFA) goal date of March 1, 2013. Under the performance goals set by the FDA under PDUFA, the agency can miss the prescribed goal date for approximately ten percent of the NDAs that are submitted each year and still meet the performance goals for review of priority and standard applications.

The FDA has not provided Zogenix with information as to the reason for the possible delay, but has indicated that the delay would likely be brief and may last only several weeks. Zogenix has not been informed of any deficiencies in the application during the review process to date.

"We are confident in the Zohydro ER program and our NDA submission and are committed to working with the FDA while it completes its review," said Stephen Farr, Ph.D., president and chief operating officer of Zogenix. "We believe there is an important medical need for an extended-release hydrocodone medicine without acetaminophen and that Zohydro ER can fill this need based on its safety and efficacy profile. We also understand the public health concerns regarding the misuse and abuse of all opioids and intend to be a proactive leader by implementing our proposed efforts to assure safe and appropriate use."

If approved, Zohydro ER will be classified as a Drug Enforcement Agency (DEA) Schedule II drug, making it subject to stricter prescribing and dispensing rules, compared to the hydrocodone-acetaminophen combination products, which are classified as Schedule III drugs. The Schedule II designation recognizes the potential for abuse and dependence, and is an important measure in the effort to promote appropriate use and minimize the potential of abuse or diversion of hydrocodone products. Zohydro ER will also have a Risk Evaluation and Mitigation Strategy (REMS) consistent with the recently introduced FDA-approved REMS for Extended Release (ER) and Long Acting (LA) Opioids.

About Zohydro ER

Zohydro ER is an 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 hydrocodone therapy without acetaminophen for the management of chronic 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 100 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. (Nasdaq:ZGNX), 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, 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. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER. Zogenix's second investigational product candidate, Relday™, is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia; an investigational new drug application was submitted to the FDA in May 2012.

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 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 press release due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the potential for the FDA to further delay the PDUFA target action date due to the FDA's internal resource constraints or other reasons; the FDA following its advisory committee's recommendation to not approve the Zohydro ER NDA; the uncertainty of the FDA approval process and other regulatory requirements; the potential for additional safety and abuse deterrence studies and REMS requirements and the related delay in approval of the Zohydro ER NDA and/or commercialization of this product candidate; 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 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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