# Zogenix Announces U.S. Food and Drug Administration (FDA) Acceptance for Review of Zohydro ER(TM) New Drug Application (NDA) for Treatment of Chronic Pain

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SAN DIEGO, July 16, 2012 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for Zohydro ER™ (hydrocodone bitartrate extended-release capsules), Zogenix's lead investigational product candidate for the treatment of moderate to severe chronic pain. Under the Prescription Drug User Fee Act (PDUFA), the goal for a standard review of an NDA is 10 months from NDA submission, and the FDA has assigned a target action date of March 1, 2013 for the Zohydro ER NDA.

Zohydro ER is an oral, single-entity (without acetaminophen) novel extended-release formulation of various strengths of hydrocodone intended for administration every 12 hours for continuous, around-the-clock management of moderate to severe chronic pain for an extended period of time. If approved, Zohydro ER could be the first hydrocodone product to offer the benefit of less frequent dosing and the ability to treat patients with chronic pain without the risk of acetaminophen-related liver injury. Currently, hydrocodone is only available in immediate-release, combination products, most commonly with the analgesic acetaminophen, and requires dosing every 4 to 6 hours. Based on a recent discussion with the FDA, we anticipate the agency will convene an advisory committee for Zohydro ER during the PDUFA review period. The advisory committee provides the FDA with independent expert advice and recommendations; however, the final decision regarding approval is made by the FDA.

"We are pleased with the decision by the FDA to accept our submission for filing and look forward to working with them throughout the regulatory process," said Stephen Farr, Ph.D., president and chief operating officer of Zogenix. "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. In addition, the Risk Evaluation and Mitigation Strategy (REMS) for Zohydro ER will be consistent with the recently introduced FDA-approved REMS for Extended Release and Long Acting Opioids. We are supportive of these measures to reduce the inappropriate prescribing and misuse of opioid products which, by including the hydrocodone class, creates consistent controls across all extended release opioid products. The approval of Zohydro ER would allow appropriate DEA registered physicians to treat chronic pain patients using hydrocodone for moderate to severe pain while avoiding acetaminophen-related liver injury."

The NDA submission is based on data from more than 1,100 patients with chronic pain participating in the pivotal Phase 3 efficacy study (Study 801) and an open-label Phase 3 safety study (Study 802) of Zohydro ER. Study 801 successfully met its primary efficacy endpoint, demonstrating that Zohydro ER resulted in significantly (p=0.008) improved chronic pain relief compared to placebo. The two key secondary endpoints in this study (the proportion of patients with at least 30% improvement in pain intensity and the improvement of overall satisfaction of medication) were also met. Additional study endpoints were supportive of the efficacy of Zohydro ER compared to placebo. The most commonly reported adverse events (≥2%) in the placebo-controlled pivotal Phase 3 efficacy Study 801 in opioid-experienced patients were consistent with those typically seen with chronic opioid therapy and were constipation, nausea, somnolence, fatigue, headache, dizziness, dry mouth, vomiting and pruritus. Study 802, in which patients received Zohydro ER for up to 12 months, demonstrated that the incidence of adverse events with Zohydro ER for up to 12 months was consistent with that seen in the pivotal Phase 3 efficacy study.

About Zohydro ER

Zohydro ER is an oral, single-entity, 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 single-entity 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 treated 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, single-entity (without acetaminophen) novel extended-release formulation of various strengths of hydrocodone 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 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, single-entity extended-release formulation of hydrocodone and the timing thereof; and the size of the chronic pain market and the potential of Zohydro ER to provide a significant new treatment 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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