Zogenix Provides Update on Zohydro(TM) ER NDA

October 1, 2013

SAN DIEGO, Oct. 1, 2013 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system disorders and pain, announced that it has been informed today by the U.S. Food and Drug Administration (FDA) that an action letter on the New Drug Application (NDA) for Zohydro™ ER (hydrocodone bitartrate) extended-release capsules could follow after a further delay of short duration. The FDA had previously informed the company that it expected to issue an action letter over the summer. The original PDUFA goal date was March 1, 2013.

On September 10, 2013, the FDA announced safety labeling changes and post-marketing requirements for extended-release (ER) and long-acting (LA) opioid analgesics. Previously, the FDA had indicated a decision on the Zohydro ER NDA could follow after a significant class-wide action on ER/LA opioid analgesics. Following the announcement, Zogenix and the FDA have completed the final labeling and reached agreement on the post-marketing requirements for Zohydro ER. The FDA has also reconfirmed there are no deficiencies in the NDA. While the FDA indicated its intent to take prompt action on the Zohydro ER NDA, the timing for a decision may be impacted by the current government shutdown. The FDA indicated earlier today that agency activities funded by PDUFA user-fees remain operational.

If approved, Zohydro ER will be classified as a Drug Enforcement Agency (DEA) Schedule II drug, making it subject to strict prescribing and dispensing rules, compared to the hydrocodone-acetaminophen combination products, which are classified as Schedule III controlled substances. The Schedule II designation 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 FDA approved REMS for ER/LA opioids.

If approved, Zohydro ER is expected to be the first extended-release formulation hydrocodone therapy without acetaminophen. The use of products containing acetaminophen in high doses over long periods of time has the potential for causing liver injury. Acetaminophen overdose is a leading cause of acute liver failure in the United States, with 63 percent of unintentional acetaminophen overdoses attributed to the use of hydrocodone-acetaminophen combination products.[i]

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 CNS and pain-related conditions 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 has a new drug application pending with the FDA for Zohydro ER (hydrocodone bitartrate) extended-release capsules. 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 potential for Zohydro ER to be the first approved oral extended-release formulation of hydrocodone without acetaminophen and the timing thereof. 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 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.

[i] Michna, E, Duh, MS, Korves, C, Dahl, JL. Removal of opioid/acetaminophen combination prescription pain medications: assessing the evidence for hepatotoxicity and consequences of removal of these medications. *Pain Medicine.* 2010; 11: 369-378.

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