Zogenix Achieves Zohydro(TM) Long-Term Safety Database for NDA

September 30, 2011

NDA Submission Remains on Track for Early 2012

SAN DIEGO, Sep 30, 2011 (GlobeNewswire via COMTEX) --

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 obtained the required long-term clinical exposure data from its Phase 3 open label safety study (Study 802) of Zohydro(TM) (hydrocodone bitartrate) extended-release capsules. The safety database of at least 300 patients on therapy with Zohydro for six months and at least 100 patients on therapy with Zohydro for one year is a requisite component of the 505(b)(2) New Drug Application (NDA) for Zohydro to the U.S. Food and Drug Administration (FDA), which remains on track for submission in early 2012.

Roger Hawley, Chief Executive Officer of Zogenix, said, "Following on the recent announcement of positive top-line results from our pivotal Phase 3 efficacy study (Study 801) for Zohydro, we are pleased to announce that we have now obtained the long-term safety dataset required for the Zohydro NDA submission. We are now focused on analyzing the results of the two Phase 3 studies and preparing the data for submission to the FDA. We have our pre-NDA meeting scheduled with the FDA during the fourth quarter and we believe we remain on track to submit the Zohydro NDA in early 2012. In addition, our recently priced secondary offering provides us with the resources to advance Zohydro through potential FDA approval."

Zohydro is being evaluated 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 could be the first extended-release hydrocodone therapy available without acetaminophen, which is associated with an increased risk of liver toxicity when used in high doses over time.

Hydrocodone pain products represent the largest prescription drug category in the United States, with over 128 million prescriptions filled in 2010. The Company believes Zohydro's ability to consistently deliver hydrocodone over an extended period of time, without exposure to acetaminophen, will position the product well in this large market.

About Zohydro

Zohydro is a novel, oral, single entity (without acetaminophen) extended-release capsule formulation of hydrocodone bitartrate. When used in high dosages over time, acetaminophen can cause liver toxicity. If approved, Zohydro could be the first single-entity hydrocodone therapy available. Zohydro uses Alkermes' patented Spheriodal Oral Drug Absorption System (SODAS(R)) drug delivery technology, which serves to enhance the release profile of hydrocodone to provide consistent 12-hour pain relief relative to existing immediate release combination products. Capsule strengths utilized in the Phase 3 study included 10, 20, 30, 40 and 50 mg capsules.

About Chronic Pain

The American Pain Society estimated in 1999 that 9% of the U.S. adult population suffers from moderate to severe non-cancer related chronic pain. Chronic pain can be treated with both immediate-release and extended-release opioids. Marketed hydrocodone products are the most commonly prescribed pharmaceuticals in the U.S., generating $3.2 billion in sales during the 12 months ended December 2010 (Wolters Kluwer Pharma Solutions, Source Pharmaceutical Audit Suite Retail, January 2010 -- December 2010). All of these hydrocodone products contain an analgesic combination ingredient, primarily acetaminophen. Acetaminophen may cause liver toxicity when used in high dosages over time.

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(R) DosePro(R) (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead product candidate, Zohydro(TM) (hydrocodone bitartrate), is a novel, oral, single-entity (without acetaminophen) extended-release capsule formulation currently in Phase 3 clinical trials for the management of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. Zogenix's second DosePro product candidate, Relday(TM), is a proprietary, long-acting injectable formulation of risperidone for the treatment of 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, and timing of, an NDA submission for Zohydro; the potential for Zohydro to be the first approved oral, single-entity extended-release formulation of hydrocodone; the size of the opioid pain market and the potential of Zohydro to be well positioned in that market; and the resources required to advance Zohydro through FDA approval. 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 top-line data Zogenix has reported for Zohydro 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 Zogenix's planned submission and the FDA's review of the NDA for Zohydro; the progress and timing of Zogenix's clinical trials; the potential that earlier clinical trials may not be predictive of future results; the potential for Zohydro to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to Zohydro to delay or prevent regulatory approval or commercialization; the impact of any inability to raise sufficient capital to fund ongoing operations; the ability of Zogenix and its licensors to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its products and product candidates and the ability to operate its business without infringing the intellectual property rights of others; 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.

SOURCE: Zogenix

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

MEDIA:
Victoria Aguiar | The Ruth Group
646.536.7013 | vaguiar@theruthgroup.com