

# ZOGENIX

## Zogenix Reports Positive Phase 3 Results for Zohydro -- Meets Primary Efficacy Endpoint

August 17, 2011

First Extended-Release Hydrocodone Product Without Acetaminophen  
NDA Submission Expected by Early 2012

### Conference Call and Webcast Today, August 17th, at 8:30 a.m. ET

SAN DIEGO, Aug. 17, 2011 (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 positive top-line results from its pivotal Phase 3 efficacy study (Study 801) of Zohydro(TM) (hydrocodone bitartrate) extended-release capsules. Zohydro is being evaluated for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy for an extended period of time. If approved, Zohydro could be the first extended-release hydrocodone treatment available without acetaminophen, which is associated with an increased risk of liver toxicity when used in high doses over time. The Company plans to submit a New Drug Application (NDA) for Zohydro to the U.S. Food and Drug Administration (FDA) by early 2012, with potential approval and product launch in 2013.

Hydrocodone pain products represent the largest prescription drug category in the United States, with over 131 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.

The trial successfully met the primary efficacy endpoint of the study in demonstrating Zohydro resulted in significantly ( $p=0.008$ ) improved chronic pain relief compared to placebo. The two key secondary endpoints were also met, specifically, the proportion of patients with at least 30% improvement in pain intensity and the improvement of overall satisfaction of medication. Additional study endpoints were supportive of the efficacy of Zohydro compared to placebo. The study demonstrated that Zohydro was safe and well tolerated. The most commonly reported adverse events in patients treated with Zohydro (>5%) were constipation, nausea, and urinary tract infection.

Stephen J. Farr, Ph.D., President and Chief Operating Officer of Zogenix, "We are very encouraged by the study results, which we believe are meaningful for patients suffering from moderate to severe chronic pain. Zohydro will offer hydrocodone for the first time in a convenient 12-hour dose while eliminating acetaminophen. Zohydro may simplify physicians' ability to prescribe the appropriate hydrocodone dose for chronic pain while managing the inadvertent overuse of acetaminophen, which is a common ingredient in combination pain products and over-the-counter medications."

Study 801 is part of the ongoing Phase 3 program for Zohydro. An additional open-label safety study is ongoing in patients with moderate to severe chronic pain (Study 802). This long-term safety data required by the FDA to support an NDA filing will be completed in the third quarter of 2011.

Roger Hawley, Chief Executive Officer of Zogenix, said, "These positive results represent an important step forward in the commercialization of our extended-release hydrocodone. Adding Zohydro as our second commercial product would be transformational for Zogenix's business, given the number of chronic pain patients and the growing physician demand for an acetaminophen-free hydrocodone product. If approved, as planned, we intend to expand our sales force in order to be in a position to educate prescribers about this important new option for chronic pain management and assume a greater promotional responsibility for SUMAVEL DosePro."

Further discussion about the Zohydro phase 3 program will be presented at the Company's investor meeting, scheduled in New York for later this year. Additional details about the Zogenix Investor Meeting will be released in a separate announcement.

#### Conference Call and Webcast

Zogenix will hold a conference call today, August 17, 2011 at 8:30 a.m. ET to discuss the top-line phase 3 results for Zohydro. To participate, please dial 866-788-0544 (U.S.) or 857-350-1682 (International); participant passcode: 60568209. To access the live webcast, please visit the Zogenix Investor Relations website at <http://ir.zogenix.com>.

A replay of the conference call will be available beginning August 17, 2011 at 11:30 AM. ET and ending on September 17, 2011 by dialing 888-286-8010 (U.S.) or 617-801-6888 (International); passcode: 35366758. A replay of the webcast will also be available on the Zogenix Investor Relations website for one month, through September 17, 2011.

Discussion during the conference call may include forward-looking statements regarding such topics as, but not limited to, the Zohydro development program and any comments the Company may make about its future plans or prospects in response to questions from participants on the conference call.

#### About the Phase 3 Efficacy Study (801)

The multi-center randomized, double-blind, placebo-controlled study enrolled opioid-experienced patients aged 18-75 who had an established clinical diagnosis of moderate to severe chronic lower back pain and inadequate pain relief from their existing therapy. The trial consisted of an open-label conversion and titration phase of Zohydro followed by a 12-week placebo-controlled treatment phase comparing Zohydro 20-100 mg every 12 hours to placebo. More than 300 patients were randomized into the double-blind treatment phase.

The primary objective of this study was to evaluate the relative efficacy of Zohydro as measured by the change from baseline to the end of treatment in pain intensity. The protocol specified primary endpoint was the mean change from baseline to the end of 12 weeks of treatment in the average 24-hour pain intensity ratings based on the 0-10 Numerical Rating Scale (NRS) from daily electronic diaries comparing Zohydro and placebo.

#### 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 Elan's 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 is associated with an increased risk of 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 treatment 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. Zogenix expects to begin clinical studies of Relday in early 2012. For additional information, please visit [www.zogenix.com](http://www.zogenix.com).

#### Forward Looking Statements

Zogenix cautions you that statements included in this press release and the conference call 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 for Zohydro to be well positioned in that market; the impact of Zohydro on Zogenix's overall business; the potential expansion of the Zogenix sales force; the timing of the release of results from Study 802 for Zohydro; and the initiation of clinical trials for Relday in early 2012. 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 presentation 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 presentation 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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