Zogenix Announces Completion of Enrollment in ZX002 Phase 3 12-Month Safety Study

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SAN DIEGO, Nov 30, 2010 (GlobeNewswire via COMTEX) --

Zogenix, Inc. (Nasdaq:ZGNX) today announced completion of enrollment in its open-label Phase 3 safety study (Study 802) of ZX002. ZX002 is a novel, oral, single-entity, controlled-release formulation of hydrocodone for the treatment of moderate to severe pain in patients requiring around-the-clock opioid therapy for an extended period of time. The goal of this 12-month study of ZX002 is to evaluate overall safety in at least 300 patients for six months and at least 100 patients for one year. With successful conclusion of the enrollment of 450 patients for this study, the top-line long-term safety results are anticipated to be available in the second half of 2011.

Zogenix is concurrently conducting a pivotal Phase 3 efficacy study (Study 801) of ZX002. Study 801 is a randomized, 12-week, double-blind, placebo-controlled trial that is continuing to enroll opioid-experienced adult subjects with moderate to severe chronic lower back pain. The primary efficacy endpoint is the mean change in average daily pain intensity scores between ZX002 and placebo. Study 801 is expected to be fully enrolled in early 2011. Initial top-line data from Study 801 are also anticipated in the second half of 2011.

Pending positive Phase 3 clinical results, Zogenix expects to submit an NDA for ZX002 with U.S. Food and Drug Administration (FDA) by early 2012. If approved, ZX002 has the potential to be the first controlled-release version of hydrocodone and also the first hydrocodone product that is not combined with another analgesic.

Stephen J. Farr, Ph.D., President and Chief Operating Officer said, "With the completion of enrollment in our Phase 3 safety study, we believe ZX002 is on track to be the first potential single-entity, controlled-release hydrocodone formulation. Most marketed hydrocodone products contain acetaminophen, an analgesic which can cause liver toxicity at high doses over time. ZX002 is not combined with any other analgesic, and may be suitable for both patients who are using immediate-release opioid products on a chronic basis and patients already using extended-release opioids."

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 United States, generating $3.1 billion in U.S. sales during the 12 months ended June 2010 (Wolters Kluwer Pharma Solutions, Source(R): PHAST Retail). Most of these products contain the analgesic combination ingredient acetaminophen. When used in high dosages over time, acetaminophen can cause liver toxicity.

About ZX002

ZX002 is a novel, oral, single-entity controlled-release formulation of hydrocodone currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy for an extended period of time. ZX002 uses Elan Pharma International Limited's proprietary Spheroidal Oral Drug Absorption System, or SODAS(R) Technology. The SODAS technology serves to enhance the release profile of hydrocodone to provide consistent 12-hour pain relief relative to existing immediate-release combination formulations.

If approved, ZX002 may represent the first available controlled-release version of hydrocodone and also the first hydrocodone product that is not combined with another analgesic. The Phase 3 clinical development program for ZX002 was initiated in March 2010 and initial top-line data are anticipated in the second half of 2011. Pending positive Phase 3 clinical results, Zogenix expects to submit a new drug application (NDA) for ZX002 with U.S. Food and Drug Administration (FDA) by early 2012.

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(TM) (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, ZX002, is a novel, oral, single-entity controlled-release formulation of hydrocodone currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy.

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 timing of results from Study 802, the enrollment and timing of results from Study 801 and the timing of an NDA filing. 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 the Zogenix's business, including, without limitation: the progress and timing of the company's clinical trials; the potential that earlier clinical trials may not be predictive of future results; the potential for ZX002 to receive regulatory approval on a timely basis or at all; the potential for adverse safety findings relating to ZX002 to delay or prevent regulatory approval or commercialization, or result in product liability claims; 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 other risks described in the company'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 news 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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