# Zogenix Reports Positive Results From Relday(TM) Phase 1 Clinical Trial

January 3, 2013

**Plans to Seek Partner and Accelerate Development of Once-Monthly Subcutaneous Formulation of Risperidone for Schizophrenia**

SAN DIEGO, Jan. 3, 2013 (GLOBE NEWSWIRE) -- Zogenix Inc. (Nasdaq:ZGNX), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, today announced positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday™, an investigational candidate of a proprietary, once-monthly subcutaneous formulation of risperidone for the treatment of schizophrenia. Adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products.

Based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix has extended the current study to include a 100 mg dose of the same formulation. The addition of this dose arm to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Positive results from this study extension would better position Zogenix to begin a multi-dose clinical trial, which would provide the required steady-state PK and safety data prior to initiating Phase 3 development studies. Zogenix expects to complete the extension of the Phase 1 clinical trial during the second quarter of 2013.

Roger L. Hawley, chief executive officer of Zogenix, said, "The positive results from the first Relday study provide proof-of-concept for a novel, long-acting, subcutaneous formulation of an established antipsychotic to provide psychiatrists and their patients with an improved treatment option. Because the PK profile, overall safety results and injection site reactions were all favorable, we can now begin discussions with potential partners for rest-of-world development and commercialization as we continue with the 100 mg single-dose study extension of Relday. We believe the data from all three dosage strengths will allow us to accelerate both the 505(b)(2) development timeline and the potential identification of an appropriate partner prior to starting the multi-dose clinical trial."

Because this approach involves selecting the dose by administering different volumes of the same formulation by a healthcare professional, the development of Relday will first focus on delivery by conventional needle and syringe while accelerating the overall program timeline. The introduction of the DosePro needle-free technology can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals.

Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia in adults and teenagers 13 years of age and older. The global long-acting injectable antipsychotic market was approximately $2 billion in 2011. The leading injectable product in the category requires twice-a-month dosing, intramuscular injection and drug reconstitution prior to use. The combined market for oral and injectable antipsychotic products was estimated at more than $17 billion in 2011.

*About Relday™*

If approved, Relday will be the first subcutaneous antipsychotic product that allows for once-monthly dosing. Zogenix believes that Relday will offer an improved PK profile, significant reduction in injection volume and a simplified dosing regimen due to DURECT's (NASDAQ: DRRX) SABER® controlled-release depot technology. In July 2011, Zogenix licensed from DURECT exclusive global rights to develop and commercialize this proprietary formulation which utilizes DURECT's SABER® depot technology.

The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. The study will be extended to include an additional cohort of 10 patients at a 100 mg dose.

*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, extended-release formulation of various strengths of hydrocodone, without acetaminophen, intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. In May 2012, Zogenix submitted to the FDA a New Drug Application for Zohydro ER and was assigned a PDUFA target action date of March 1, 2013 by the FDA. Zogenix's second investigational product candidate, Relday™, is a proprietary, long-acting injectable formulation of risperidone for the treatment of schizophrenia; an investigational new drug application was submitted to the FDA in May 2012.

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" 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 delivery and dosing benefits of Relday to both the patient and clinician, initiation of a multi-dose clinical trial and Phase 3 development studies for Relday, timing of completion of the extension of the Phase 1 trial, discussions with potential partners for rest-of-world development and commercialization of Relday, Zogenix's steps to accelerate both the 505(b)(2) development timeline and the potential identification of an appropriate partner for Relday, the introduction of DosePro technology and the timing thereof, the ability of such product to address the global anti-psychotic market, and the ability to develop a once-monthly injectable product with improved pharmacokinetics and significant reduction in injection volume,. 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 uncertainties associated with the clinical development and regulatory approval of product candidates such as Relday, including potential delays in enrollment and completion of clinical trials; Zogenix's dependence on its collaboration with DURECT Corporation to develop Relday; inadequate therapeutic efficacy or unexpected adverse side effects relating to Relday that could prevent its development or commercialization; difficulties in identifying, negotiating, executing and carrying out strategic transactions relating to Relday; the market potential for anti-psychotics, and Zogenix's ability to compete within that market; ability to obtain and the validity and duration of patent protection and other intellectual property rights for Relday; and other risks described in the company's prior press releases and 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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