Zogenix Reports Positive Top-Line Results From Relday(TM) Phase 1b Multi-Dose Clinical Trial

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Product Candidate Now Phase 3 Ready

Company Initiates Efforts to Secure Global Development and Commercialization Partner

SAN DIEGO, Sept. 30, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today announced positive top-line pharmacokinetic results from its Phase 1b multi-dose clinical trial of Relday ™, a proprietary, once-monthly subcutaneous investigational formulation of risperidone for the treatment of schizophrenia. If approved, Relday has the potential to be the first subcutaneous antipsychotic product that achieves therapeutic drug levels on the first day of administration, allows for once-monthly dosing and does not require reconstitution. Zogenix has retained Locust Walk Partners of Cambridge, MA, a transaction advisory firm for life sciences companies, to provide transaction advisory and support services for Relday, and has now initiated efforts to secure a global strategic development and commercialization partner for Relday.

The Phase 1b multi-dose parallel group clinical trial enrolled 60 subjects comprised of three cohorts of patients receiving four monthly injections of Relday, at dose levels of either 60, 90 or 120 mg of risperidone per month. A fourth cohort received five bi-weekly intramuscular injections of Risperdal® Consta®. Risperdal Consta requires oral supplementation for the first three weeks following dosing initiation, and requires at least four doses to reach steady state. The results for Relday demonstrated that risperidone plasma concentrations in the therapeutic range were achieved on the first day of dosing, reached steady state levels following the second dose and consistently maintained therapeutic levels throughout the four-month period. In addition, dose proportionality was confirmed across the dose range intended for clinical practice (60 to 120 mg). Relday was generally safe and well-tolerated, with results consistent with the profile of risperidone and the Company's previous Phase 1 single-dose clinical trial.

"With the positive top-line results from the Phase 1b multi-dose trial, Relday is now well-positioned to begin a Phase 3 program once a development and commercialization partner is secured," said Stephen Farr, Ph.D., President and CEO of Zogenix. "Our market research indicates that Relday, if approved, has the potential to address a medical need within the schizophrenia treatment landscape by becoming the first monthly subcutaneous antipsychotic product that achieves therapeutic drug levels on the first day of administration, thereby eliminating the need for loading dose regimens upon therapy initiation or following a missed dose."

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 injectable formulation of risperidone, Risperdal Consta, requires twice-a-month dosing, oral supplementation during therapy initiation, intramuscular injection and drug reconstitution prior to use.

About Relday™

If approved, Relday has the potential to be the first subcutaneous antipsychotic product that allows for once-monthly dosing and achieves therapeutic drug levels on the first day of administration. Zogenix believes that Relday will offer an improved pharmacokinetic (PK) profile, significant reduction in injection volume and a simplified dosing regimen (e.g., no need for loading dose) 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 1b multi-dose clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 60 patients with chronic, stable schizophrenia or schizoaffective disorder across a dose range of 60, 90 and 120 mg, and included a comparator arm of Risperdal Consta.

About Zogenix

Zogenix, Inc. (Nasdaq:ZGNX) is a pharmaceutical company committed to developing and commercializing CNS therapies that address specific clinical needs for people living with orphan and other CNS disorders who need innovative treatment alternatives to help them return to normal daily functioning.

For more information, 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, the viability of Relday, initiation of a multi-dose clinical trial and Phase 3 development studies for Relday, Zogenix's ability to secure a global strategic development partner for rest-of-world development and commercialization of Relday, Zogenix's ability to initiate a Phase 3 clinical trial for Relday based on results from the Phase 1b clinical trial, 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; potential delays in the initiation of a Phase 3 program for Relday or the requirement that Zogenix conduct additional development activities prior to initiating such Phase 3 program; 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 terms of any development or commercialization partnership for Relday may not be favorable, and the partner may not perform as expected; the market potential for anti-psychotics, and Zogenix's ability to compete within that market; Zogenix's 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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Zogenix, Inc.