Zogenix Announces First Patient Dosed in Relday Multi-Dose Clinical Study

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Results Anticipated in Third Quarter 2015, Positioning Zogenix for Potential World-Wide Partnering Opportunities for Relday

SAN DIEGO, March 26, 2015 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:ZGNX), a pharmaceutical company developing and commercializing products for the treatment of central nervous system (CNS) disorders, announced today that dosing has begun in patients enrolled in its Relday™ multi-dose Phase 1b clinical study. Relday is a proprietary, long-acting, subcutaneously injected formulation of risperidone being investigated for the treatment of schizophrenia.

Relday has been designed to provide potentially significant improvements over current long-acting injection treatment options for patients suffering from schizophrenia. In a Phase 1 single-dose clinical study in schizophrenic patients, Relday demonstrated the ability to achieve therapeutic plasma levels of risperidone on the first day of dosing, followed by a controlled release profile over the remaining four-week period. This pharmacokinetic profile of Relday may eliminate the requirement for long-acting risperidone injections to be supplemented with daily oral therapy for several weeks during therapy initiation or when patients are not fully compliant with an injection regimen over the course of long-term therapy. In addition, dose-proportionality for Relday has been established across all doses, as well as the duration of treatment being consistent with once-monthly dosing. Unlike all currently marketed long-acting injectable treatment options which are administered via intramuscular injection, Relday is administered subcutaneously. Moreover, unlike some leading injectable products in the category, Relday does not require reconstitution prior to use.

Fifty-six subjects with schizophrenia or schizoaffective disorder are planned to be enrolled in this open label, multi-dose, safety and pharmacokinetic (PK) study. Subjects will be administered Relday or Risperdal® Consta® (risperidone), an approved long-acting intramuscular injectable with the same active ingredient as Relday. Patients being administered Risperdal Consta will also receive daily oral risperidone supplementation during a three-week initiation period, and will be dosed every two weeks, as required by its prescribing label. Subjects will be followed for up to 20 weeks in order to confirm and compare the time to reach drug concentrations within the therapeutic range and to compare steady state pharmacokinetics for Relday and Risperdal Consta. The Company anticipates that results from the Relday multi-dose study will be available in the third quarter of 2015.

The Company also plans to initiate efforts to secure an ex-U.S. strategic development and commercialization partner for Relday during this development stage and is targeting an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) by early 2016. If completed, these milestones would position the Company to begin a Phase 3 clinical study for Relday in 2016.

Brad Galer, M.D., chief medical officer of Zogenix, stated, "We are pleased to move the Relday development program forward into this next clinical study. We expect the data to continue to demonstrate that Relday's novel formulation has a differentiated product profile amongst currently marketed long-acting injections for the treatment of schizophrenia that should enhance the treatment for this patient population."

In July 2011, Zogenix licensed from DURECT (Nasdaq:DRRX) exclusive global rights to develop and commercialize this proprietary formulation which utilizes DURECT's SABER® depot technology.

About Zogenix

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

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: delivery and dosing benefits of Relday and the potential to demonstrate that Relday has a differentiated product profile amongst currently marketed long-acting injections; timing for the availability of results from the Phase 1b clinical trial, an end-of-Phase 2 meeting with the FDA, and the initiation of a Phase 3 clinical trial for Relday; and the initiation of efforts to secure potential partners for rest-of-world development and commercialization of Relday. 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 risks 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; competition from other pharmaceutical or biotechnology companies; 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 Zogenix's prior press releases as well as in public periodic 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 press 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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