Zogenix Announces New Efficacy and Safety Data on ZX008 for Treatment of Seizures in Dravet Syndrome

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Patient and Caregiver Sleep Quality and Quality of Life Data Reported for First Time

New Clinical Data Presented at 14th International Child Neurology Congress on the Use of Low-Dose Fenfluramine in Managing Seizures Associated With Dravet Syndrome

EMERYVILLE, Calif., May 05, 2016 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of central nervous system (CNS) disorders, today announced new data which continues to demonstrate the sustained effectiveness and cardiovascular safety of ZX008 (low-dose fenfluramine) as an adjunctive therapy for seizures associated with Dravet syndrome. In addition, for the first time, data were presented on patient and caregiver sleep quality and quality of life. The podium presentation was given at the 14th International Child Neurology Congress (ICNC), taking place this week in Amsterdam, The Netherlands. ZX008 is designated as an orphan drug in both the U.S. and Europe, and recently received Fast Track designation in the U.S., for the treatment of Dravet syndrome.

The data presented highlighted the updated results from the new patient cohort, which now includes 9 Dravet syndrome patients. All of these patients began add-on treatment with low-dose fenfluramine (5 mg to 20 mg per day) at various starting points between 2010 and the end of January 2016. Median treatment duration was 1.5 years (range 0.3 to 5.1 years). During the 90-day run-in period prior to initiating low-dose fenfluramine treatment, the median frequency of major motor seizures (defined as tonic, clonic, tonic-clonic, atonic, and myoclonic seizures lasting >30 seconds) was 15.0 per month (range 0.4 to 39.7). Over the entire observation period, the median frequency of major motor seizures was reduced to 1.5 per month, and the median decrease was 75% (range 28-100%). Six of the 9 patients had at least a 70% reduction in major motor seizures.

In addition, parents/caregivers were asked to rate both their child's and their own sleep quality and quality of life using 0-10 scales where 0 = extremely bad and 10 = very good. At the most recent visit, mean sleep quality reported for patients and parents was 8.1/10 and 7.9/10, respectively, while mean Quality of Life scores were 7.4/10 for both groups.

In this new cohort of patients, treatment with low-dose fenfluramine continued to be generally well-tolerated, and did not result in any echocardiographic or clinical signs of cardiac valve abnormalities, pulmonary hypertension or any other cardiovascular abnormalities. The most common treatment-emergent adverse events were mild-to-moderate somnolence (n=6), diminished appetite (n=4), mood changes (n=2), and non-convulsive status epilepticus (n=2). There were no fenfluramine discontinuations due to adverse events or lack of effect.

"The continued meaningful reduction in seizure frequency and sustained cardiovascular safety demonstrated in these updated results for the new cohort of patients further support our confidence in the potential of ZX008 as a safe and effective treatment for seizures associated with Dravet syndrome," said Bradley Galer, M.D., Chief Medical Officer of Zogenix. "We believe the relatively high levels of sleep quality and quality of life reported reflect the seizure control in these patients. Our Phase 3 program for ZX008 in Dravet syndrome is currently enrolling patients in the U.S., and will begin enrolling patients in Europe shortly."

The observed effectiveness, tolerability and cardiovascular-related safety with add-on, low-dose fenfluramine in this new cohort of Dravet syndrome patients further extends the findings initially reported for the original twelve subjects in 2012 and the initial report from this new cohort in December of 2015.

About the ZX008 Phase 3 Program
The Zogenix study entitled, "A Trial of Two Fixed Doses of ZX008 (Fenfluramine HCl) in Children and Young Adults With Dravet Syndrome", is being conducted for patients with Dravet syndrome whose seizures are not adequately controlled on their current seizure medication. For more information, please visit www.clinicaltrials.gov listing (NCT02682927).

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 improve their 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," "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 the commencement of the second Phase 3 clinical study for ZX008 and ZX008's potential as a treatment for seizures associated with Dravet syndrome. 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 ZX008, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies may not be predictive of future results; Zogenix's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; Zogenix's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; Fast Track designation may not result in an expedited regulatory review process; 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.

CONTACT: Investors: Andrew McDonald
Founding Partner, LifeSci Advisors LLC
646-597-6987 | Andrew@lifesciadvisors.com

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Zogenix, Inc.