Zogenix Announces Initiation of Phase 3 Trial for ZX008 in Lennox-Gastaut Syndrome

November 29, 2017

EMERYVILLE, Calif., Nov. 29, 2017 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of rare central nervous system (CNS) disorders, today announced that the first child has enrolled in the Phase 3 clinical trial for the Company's lead investigational therapy, ZX008, as an adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS).

"LGS is a rare, devastating form of epilepsy that disrupts the lives of patients and their families, who are usually unable to control their seizures despite treatment with a number of existing therapeutic options," said Associate Professor Kelly Knupp, M.D., MSCS, FAES of Children's Hospital Colorado, and Principal Investigator of the U.S. arm of the trial. "There is a significant need for new medicines that can substantially reduce seizure activity in LGS, and I am hopeful that this Phase 3 trial of ZX008 may offer hope to the children and adults living with this debilitating condition."

The Phase 3 multicenter, global LGS trial is divided in two parts. Part 1 is a double-blind, placebo-controlled investigation to assess the safety, tolerability and efficacy of ZX008, low-dose fenfluramine, when added to a patient's current anti-epileptic therapy. The trial will include two dose levels of ZX008 (0.2 mg/kg/day and 0.8 mg/kg/day, up to a maximum daily dose of 30 mg), as well as placebo. After establishing baseline seizure frequency for 4 weeks, randomized patients will be titrated to their dose over a 2-week titration period, followed by a 12-week fixed dose maintenance period. Zogenix is targeting a total of 225 patients (75 per treatment arm) in the trial. The primary endpoint of the clinical trial is change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.8 mg/kg/day dose. The key secondary endpoints include change in the number of seizures that result in drops between baseline and the combined titration and maintenance periods at the 0.2 mg/kg/day dose, and the proportion of patients achieving a 50 percent reduction in drop seizures. Part 2 of the clinical trial will be a 12-month open-label extension to evaluate the long-term safety, tolerability and effectiveness of ZX008.

The initiation of this Phase 3 program follows a Phase 2 open-label, dose-finding investigator-initiated clinical trial of ZX008 for the treatment of LGS that was conducted by Lieven Lagae, M.D., Ph.D., Professor at the University of Leuven, Belgium, Head of the Pediatric Neurology Department. The interim Phase 2 results were presented at the 70th Annual Meeting of the American Epilepsy Society in December 2016. Of the 13 subjects enrolled, seven (54 percent) achieved at least a 50 percent reduction in the number of major motor seizures, with a range of 50 percent to 90 percent improvement. In addition, there was an approximately 2-fold increase in the number of responders (with a reduction of 50 percent or greater) on a dose of 0.4 mg/kg/day vs. 0.2 mg/kg/day. Importantly, per protocol, dose escalation stopped when a patient's major motor seizure frequency was reduced by ≥50 percent of baseline.

"Following the recent positive top-line results from our first Phase 3 clinical trial for ZX008 in Dravet syndrome, the initiation of this Phase 3 program in LGS represents another important clinical milestone for our ZX008 development program in intractable childhood-onset epilepsy syndromes," said Gail M. Farfel, Ph.D., Chief Development Officer of Zogenix. "Based on these results, as well as those from the investigator-initiated study led by Professor Lagae, we are excited to evaluate the potential of ZX008 as a safe and effective treatment for children and adult patients with LGS."

ZX008 for the treatment of LGS has previously been designated as an orphan drug by both the U.S. Food and Drug Administration and the European Commission. The Phase 3 trial is planned for up to 85 sites in North America, Europe, Asia-Pacific, South America, South Africa and Australia. For additional information, including inclusion/exclusion criteria, please visit https://clinicaltrials.gov, using NCT Identifier # 03355209.

About Zogenix
Zogenix (Nasdaq:ZGNX) is focused on developing therapies for patients with rare central nervous system (CNS) conditions that have limited or no treatment options but face a critical need. 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 Phase 3 clinical trial in Lennox-Gastaut syndrome, including the number of patients to be enrolled. 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; 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 in LGS 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; 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

Media: David Polk
Senior Media Relations Strategist, INC Research/inVentivHealth
310-309-1029 | david.polk@inventivhealth.com

Primary Logo

Source: Zogenix, Inc.