Zogenix Completes Enrollment in First ZX008 Phase 3 Clinical Trial in Dravet Syndrome

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Study 1 Top-Line Data on Track for 3Q 2017

EMERYVILLE, Calif., April 27, 2017 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ:ZGNX), a pharmaceutical company developing therapies for the treatment of orphan and central nervous system (CNS) disorders, today announced that the last patient has been randomized into the treatment period of Study 1, its first Phase 3 clinical trial evaluating ZX008 (low-dose fenfluramine) as an adjunctive treatment for seizures in children and young adults with Dravet syndrome.

“The completion of patient randomization in Study 1 is an important milestone for our ZX008 Phase 3 development program in Dravet syndrome,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We look forward to the availability of top-line data from this study, which we expect in the third quarter of this year. We are grateful for the participation of the patients, their families and the investigators involved in our ongoing clinical program.”

Study 1 is a three-arm, fixed-dose, placebo-controlled trial with 40 subjects per treatment group being conducted in the U.S., Canada, Europe, and Australia. Randomized subjects are titrated to their target dose (0.2 or 0.8 mg/kg/day ZX008, maximum of 30 mg/day, or placebo) over two weeks and then held at that fixed dose for 12 weeks of maintenance treatment. Subjects who complete Study 1 are eligible to enter a long-term, open-label extension study.

In addition to Study 1, Zogenix is conducting a second double-blind, randomized, two-arm pivotal Phase 3 trial, Study 1504, in which all patients will be taking stiripentol, valproate and clobazam as part of their baseline standard care. In February 2017, the Company announced the initiation of the safety and efficacy portion of Study 1504, which compares a single dose of ZX008 versus placebo across the titration and 12-week maintenance periods. Study 1504 will enroll 40 subjects per treatment group.

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 ZX008’s potential as a treatment for seizures associated with Dravet syndrome; the timing of top-line results for Study 1; and the enrollment of patients in Study 1504. 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 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; 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; 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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