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

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Study 1504 Top-Line Data on Track for 2Q 2018

EMERYVILLE, Calif., Jan. 31, 2018 (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 last patient has been randomized into the treatment period of Study 1504, its second Phase 3 clinical trial evaluating ZX008 (low-dose fenfluramine) as an adjunctive treatment for seizures in children and young adults with Dravet syndrome. Previously, in the third quarter of 2017, the Company announced positive top-line data from its first global Phase 3 trial of ZX008, Study 1, that met the primary efficacy endpoint, as well as all prespecified key secondary efficacy endpoints.

“The completion of patient randomization in Study 1504 represents another significant achievement in our ZX008 Phase 3 development program in Dravet syndrome,” said Stephen J. Farr, Ph.D., President and CEO of Zogenix. “We expect to announce top-line data from this study in the second quarter of this year. The data generated to date from the Phase 3 clinical program have further strengthened our confidence in the potential of ZX008 to become an important treatment option for the control of seizures in patients suffering from Dravet syndrome, a rare and catastrophic form of epilepsy.”

Study 1504 is a double-blind, randomized, two arm Phase 3 trial with approximately 40 subjects per treatment group being conducted in the U.S., France, Spain, the Netherlands, U.K., Canada, and Germany, in which all subjects are taking stiripentol as part of their baseline standard of care. Randomized subjects are titrated to an active dose of 0.5 mg/kg/day ZX008 (maximum of 20 mg/day) or placebo, over three weeks and then held at that fixed dose for 12 weeks of maintenance treatment. The study dose of ZX008 accounts for the established drug-drug interaction between stiripentol and ZX008 and provides the same systemic exposure of ZX008 as the dose of 0.8 mg/kg/day (maximum 30 mg/day) previously evaluated in Study 1, where concomitant use of stiripentol was excluded. As in Study 1, the primary efficacy measure in Study 1504 is a comparison of the change in monthly convulsive seizure frequency between ZX008 and placebo during the treatment period compared with the baseline observation period.

Study 1 results were announced in fall 2017. The trial met its primary objective of demonstrating that ZX008, at a dose of 0.8 mg/kg/day, is superior to placebo as adjunctive therapy in the treatment of Dravet syndrome in children and young adults based on change in the frequency of convulsive seizures between the 6-week baseline observation period and the 14-week treatment period ($p<0.001$). ZX008 0.8 mg/kg/day also achieved statistically significant improvements versus placebo in all key secondary measures, including the proportion of patients with clinically meaningful reductions in seizure frequency and longest seizure-free interval. The same analyses comparing a 0.2 mg/kg/day ZX008 dose versus placebo also demonstrated significant improvement compared with placebo. Both doses of ZX008 were safe and well-tolerated during the study, and most adverse events were mild or moderate in severity, and consistent with the known profile of the compound.

ZX008 is designated as an orphan drug in both the U.S. and Europe, and has received Fast Track designation in the U.S. for the treatment of Dravet syndrome. ZX008 is an investigational treatment and is not approved for use in any country.

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 or in the poster presentations 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 forward-looking statements include statements regarding: ZX008’s potential as a treatment for seizures associated with Dravet syndrome, and the timing of top-line results from Study 1504. These statements are based on Zogenix’s current beliefs and expectations. 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 FDA may not agree with Zogenix’s interpretation of the results of the Study 1 and other data; the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008; 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; 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 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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