# Zogenix Announces Receipt of FDA Breakthrough Therapy Designation for ZX008 in Dravet Syndrome

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**Designation Based on Positive Results from Study 1, the First Pivotal Phase 3 Trial of ZX008**

EMERYVILLE, Calif., Feb. 06, 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 U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for its investigational product, ZX008 (low-dose fenfluramine), for the treatment of seizures associated with Dravet syndrome.

FDA Breakthrough Therapy Designation is intended to expedite the development and review of medicines aimed at treating a serious or life-threatening disease where there is preliminary clinical evidence that the investigational therapy may offer substantial improvement over existing therapies on at least one clinically significant endpoint. FDA Breakthrough Therapy Designation for ZX008 is based on the results from Study 1, Zogenix's first global Phase 3 trial of ZX008, which met the primary efficacy endpoint, as well as all prespecified key secondary efficacy endpoints.

"We are very pleased that the FDA has granted Breakthrough Therapy Designation based on the efficacy and safety results from Study 1 reported in fall of 2017," said Gail M. Farfel, Ph.D., Chief Development Officer of Zogenix. "We look forward to working closely with the FDA as we conclude our Phase 3 clinical program in Dravet syndrome, a rare and catastrophic form of childhood epilepsy."

ZX008 is designated as an orphan drug in both the U.S. and Europe for Dravet syndrome and Lennox-Gastaut syndrome, and has received Fast Track designation in the U.S. for the treatment of Dravet syndrome.

**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, the potential for expedited development based on the FDA's decision to designate ZX008 as a Breakthrough Therapy, and the timing of completing the Phase 3 clinical program in Dravet syndrome. 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: Breakthrough Therapy Designation does not guarantee that the FDA will approve ZX008 or expedite its review of ZX008; 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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